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**NO-KNOCK AND NONSENSE, AN ALLEGED
CONSTITUTIONAL PROBLEM**

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NO-KNOCK AND NONSENSE, AN ALLEGED CONSTITUTIONAL PROBLEM†

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On July 16, 1969, the Nixon Administration sent to the Congress a major revision of the existing federal narcotic and dangerous drug laws entitled the Controlled Dangerous Substances Act.¹ Hearings have been held in the Senate and much debate has ensued. In addition to discussions concerning penalties, industry regulation and research, one item has attracted a great deal of attention, indeed, far more than anyone involved with the proposal originally thought. From the first, "no-knock" was the lead for newspaper articles concerning the bill.² It became immediately apparent that there existed a great deal of misinformation about this no-knock authority and its impact upon the average citizen. Visions of kicked-in doors, sinister police invading residences in the dark of night, and other manifestations of the "police state" sprang to mind. In addition to this popular misconception, the only formal disagreement to come out of the Senate Judiciary Committee, which reported favorably on the Controlled Dangerous Substances Act, concerned no-knock and questioned its constitutionality. Indeed, this controversy eventually led to a revision of the original no-knock provision before the proposed Act was passed by the Senate. The House has not yet acted on the bill.

This article has been written to place the issue in proper perspective. The historical origins of no-knock in the common law will be traced, and the relevant state statutes and decisions will be analyzed. The federal posture, legislation and case law, will also be examined. Finally, the article will refocus upon the proposed Controlled Dangerous Substances Act and its no-knock provision, section 702(b). It is the opinion of the authors that this section is, in fact, a realistic compromise between those who favor the common-law exception in its

† The views expressed herein are those of the authors and do not necessarily represent the views of the Bureau of Narcotics and Dangerous Drugs specifically, nor of the Department of Justice generally. The authors wish to acknowledge the invaluable assistance of Roy E. Kinsey and Robert G. Pinco.

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¹ S.3246, 91st Cong. 2d Sess. (1970).

² See, e.g., Stokes, *Nixon's Drug Bill*, THE NATION, Sept. 22, 1969, at 271.

totality and those who insist that such authority is an unconstitutional invasion of privacy.

I. HISTORICAL DEVELOPMENT OF "THE KNOCK" COMMON LAW

England

A man's home, mortgaged though it may be, has long been considered under Anglo-American tradition to be his castle. Indeed, this principle is embodied in the fourth amendment to the United States Constitution, which prohibits "unreasonable searches and seizures."³ Yet, long before the framers of that document set quill to ink, the English judiciary had consistently been compelled to consider the issue of the King's right of entry into private dwellings. The difficulties inherently involved in this question can be illustrated by the fact that the ancient principle which proclaims that "Every man's house is his castle" is matched in age by the maxim that "The King's keys unlock all doors."⁴ Actually, these principles relate to different processes, the former applying to civil actions, and the latter to those of a criminal nature. Thus, the fifteenth century statement of the rule indicated that invasion of the home was justified in cases involving a felony; the apprehension of the felon was in the interest of both the common weal and the King. On the other hand, in cases involving debt or trespass, the interest of a private party would not justify the invasion of a dwelling to apprehend the wrongdoer.⁵

The most familiar statement of the common-law rule is contained in *Semayne's Case*⁶:

In all cases when the King is [a] party, the sheriff (if the doors be not open) may break the party's house, either to arrest him, or to do other execution of the [King's] process, if otherwise he cannot enter. But before he breaks it, he ought to signify the cause of his coming, and to make request to open [the] doors . . .⁷

Since the opinion was actually concerned with a writ issued in a civil

³ The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

U.S. CONST. amend. IV.

⁴ See BROOM'S LEGAL MAXIMS 281, 432 (10th ed. 1929).

⁵ Y. B. Pasch., 13 Edw. 4, f.9a (1455).

⁶ 77 Eng. Rep. 194 (Ex. 1603). The use of the word "ought" in the last sentence of the dictum should be noted as it relates to a central issue within the framework of this article.

⁷ *Id.* at 195.

case, it was only by way of dicta that "the knock," or announcement of purpose, was enunciated as a specific obligation in connection with authorized entry into private dwellings.

During this period in English history, authorities differed as to the circumstances under which a breaking of doors would be permissible. For example, Coke expressed the view in his *Fourth Institutes* that a warrant to break open a house in search for a felon, issued upon suspicion, contravened both the Magna Carta and existing case law.⁸ However, the indictment of the suspected party would empower the sheriff, by virtue of the warrant, to forcibly enter the house.⁹ On the other hand, Hale apparently believed that, even in the absence of a warrant, a constable possessed sufficient power to break open a door whenever a felony had actually been committed. In addition, he indicated that when a suspected felon took flight and entered a house, a warrantless constable could break in if "the door will not be opened upon demand of the constable and notification of his business."¹⁰

While the debate continued and the common-law standards evolved,¹¹ it is apparent that houses were in fact being entered on a sufficiently indiscriminate basis to contribute to a general feeling of uncertainty and discontent.¹² Yet, it is clear that during this period, discussion of the governmental right to break and enter private dwellings centered not upon the necessity of prior warning or announcement of purpose, but rather, upon the *justification* for the breaking or, in other words, the "reasonableness" of the forced entry. Judges and legal scholars of that era were concerned with such relevant questions as: Was there a warrant? Was there hot pursuit? Was the commission of a felony observed? Was there an immediate threat of violence or danger to the law enforcement official? And finally, was there a previous notice of authority and purpose?¹³

Within the context of the above circumstances, the phraseology used in *Semayne's Case* becomes more significant as an expression of seventeenth century legal philosophy in England. The sheriff "ought" to signify why he is about to execute the King's process before he breaks and enters. But the broadest examination of English law and

8 E. COKE, *THE FOURTH PART OF THE INSTITUTES OF THE LAWS OF ENGLAND: CONCERNING JURISDICTIONS OF COURT* 177 (6th ed. 1681).

⁹ *Id.*

¹⁰ 2 M. HALE, *PLEAS OF THE CROWN* 90-92 (1st Am. ed. 1847).

¹¹ See W. HOLDSWORTH, *HISTORY OF ENGLISH LAW* 598 (3d ed. 1934).

¹² Similarly, it was the subsequent employment of the so-called "writs of assistance" during the colonial era which pointed to a parting of the ways between England and her colonies.

¹³ See *Accarino v. United States*, 179 F.2d 456, 460-62 (D.C. Cir. 1949).

precedent discloses no evidence that such a suggestion was ever, in fact, a requirement which would render the subsequent entry legal. For too long this case has been read out of context; to ignore the precatory wording is to further confuse the problem.

United States

In the United States, the common-law rule of *Semayne's Case* was generally followed in early decisions. Thus, in *Oystead v. Shed*,¹⁴ the Massachusetts Supreme Judicial Court emphasized the right of a citizen to be free from forcible entry into his home for civil arrest purposes, although there is some question as to whether this pronouncement was necessary to the decision. It was recognized, however, that force could be utilized when the entry was effected to seize specific goods (as under writs of attachment).¹⁵ Similarly, it was recognized as early as 1822 that, if notice was in fact a general requirement, under certain circumstances that requirement would be rendered unnecessary. One such instance was clearly enunciated by a Connecticut court in *Read v. Case*,¹⁶ which held that imminent danger to life eliminated the need to provide notice. Indeed, a later Kentucky case, *Hawkins v. Commonwealth*,¹⁷ attempted to extend this rule, indicating that no notice whatsoever was required in criminal cases, since the "offender" would then be presented with an opportunity to avoid the process of the law. The continuing uncertainty regarding the notice or announcement aspect in criminal cases was exemplified in *Commonwealth v. Reynolds*,¹⁸ which attempted to summarize the existing law by stating that an officer could *always* break and enter after announcement of purpose and refusal, but that some courts had refused to impose such an obligation upon law enforcement authorities where the crime constituted a misdemeanor.

STATUTES

At the turn of the century, the states began to enact statutes specifically dealing with the authority of an officer to break and enter in order to make an arrest.¹⁹ Although initially the vast majority of these statutes expressly required some form of notice prior to forcible entry,²⁰

¹⁴ 13 Mass. 520 (1816).

¹⁵ *Keith v. Johnson*, 31 Ky. 604 (1833).

¹⁶ 4 Conn. 166 (1822).

¹⁷ 53 Ky. 395 (1854).

¹⁸ 120 Mass. 190 (1876).

¹⁹ See notes 21-80 and accompanying text *infra* for a treatment of various state statutes dealing with the authority to execute search or arrest warrants via forced entry.

²⁰ See Blakey, *The Rule of Announcement and Unlawful Entry: Miller v. United States and Ker v. California*, 112 U. PA. L. REV. 499, 508 (1964).

a more recent trend has been toward the elimination of the notice requirement under specified conditions.

California

California has developed a fairly stringent approach to noncompliance with the "knock and notice" provisions of its penal code. The California statute closely resembles its federal counterpart, section 3109 of the Criminal Code,²¹ but the decisions of the California judiciary have developed a far more substantial basis for it than the federal courts. In addition, the large number of California decisions has placed that state in a position of leadership with respect to the numerous other states which have identical or very similar statutes.²² Thus, it is appropriate that our discussion of the relevant statutes should begin with an examination of the California experience.

Section 844 of the California Penal Code provides:

To make an arrest, a private person, if the offense be a felony, and in all cases a peace officer, may break open the door or window of the house in which the person to be arrested is, or in which they have reasonable grounds for believing him to be, after having demanded admittance and explained the purpose for which admittance is desired.²³

On its face, the statute is merely a codification of the common law and, as such, the very fact that the common-law exceptions were omitted would seem to preclude any form of no-knock arrest or search. Nevertheless, in 1956, compliance with the statute was interpreted by the California Supreme Court in *People v. Maddox*²⁴ to be excused under the common-law exceptions to the rule of announcement.²⁵ Thus, announcement before arrest was excused if the facts known to the officer

²¹ The officer may break open any outer or inner door or window of a house, or any part of a house, or anything therein, to execute a search warrant, if after notice of his authority and purpose, he is refused admittance or when necessary to liberate himself or a person aiding him in the execution of the warrant.

¹⁸ U.S.C. § 3109 (1964).

²² See notes 44-80 and accompanying text *infra*.

²³ CALIF. PENAL CODE § 844 (West Supp. 1968).

²⁴ 46 Cal. 2d 301, 294 P.2d 6, *cert. denied*, 352 U.S. 858 (1956). In *Maddox*, the police had defendant's premises under surveillance for approximately a month and had witnessed known narcotics addicts frequenting the place. In fact, on the day of the arrest and immediately prior thereto, the police arrested two addicts who stated that they had just left the premises. When the police knocked on defendant's door, they were told to "wait a minute," and then they heard the sound of retreating footsteps. They then broke the door and entered the house. See also *People v. Martin*, 45 Cal. 2d 755, 290 P.2d 855 (1955).

²⁵ See 6 C.J.S. *Arrest* § 14 n.21 (1955).

before his entry were sufficient to support his good faith that compliance would have increased his peril or frustrated the arrest.²⁶ Additionally, in *Maddox*, as well as in a series of similar cases which followed, destruction of evidence was recognized as another ground for noncompliance with section 844 or its warrant counterpart, section 1531.²⁷ The destruction exception was traditionally limited to narcotics and bookmaking paraphernalia, since it was based on the assumption that, by the very nature of these items, they were easily disposable. The California courts extended this standard in narcotic cases (which comprised the bulk of the cases in this area) by not requiring any showing whatever of particular exigency, as would generally be required to excuse compliance with the knock or notice provisions of its statutes.

During the decade following *Maddox*, the California courts failed to grant suppression motions on unlawful entry pleas.²⁸ Finally, in 1967, in an abrupt reversal, the California Supreme Court in *People v. Gastelo*²⁹ declared:

we have excused compliance with the statute in accordance with established common law exceptions to the notice and demand requirements on the basis of the specific facts involved. No such basis exists for nullifying the statute in all narcotics cases, and, by logical extension, in all other cases involving easily disposable evidence.³⁰

Thus, the Court clearly foreclosed noncompliance with the statutory requirements of knock and notice when such noncompliance was based solely on the police officer's "general experience relative to the disposability and the kind of evidence sought and the propensity of offenders to effect disposal."³¹

"Just as the police must have sufficiently particular reason to enter

²⁶ *Read v. Case*, 4 Conn. 166, 170 (1822).

²⁷ The officer may break open any outer door or inner door or window of a house, or any part of a house, or anything therein, to execute the warrant, if, after notice of his authority and purpose, he is refused admittance.

CALIF. PENAL CODE § 1531 (West 1956). See cases collected in *People v. DeSantiago*, 71 A.C. 18, 453 P.2d 353, 76 Cal. Rptr. 809 (1969).

²⁸ See *Blakey*, *supra* note 20, at 532 n.245.

²⁹ 67 Cal. 2d 586, 432 P.2d 706, 63 Cal. Rptr. 10 (1967). In *Gastelo*, the police, on the basis of a reliable informant's report that he had purchased narcotics from defendant at the apartment of defendant's girlfriend, obtained a warrant for the search of said apartment. Early one morning four officers went to the apartment, and without knocking, announcing their purpose or demanding admittance, they forced entry. The police served the warrant, searched the apartment and found a small packet of heroin. Defendant was arrested and later confessed to possession of the heroin. On appeal from his conviction, defendant contended that the trial court had committed prejudicial error in admitting the heroin into evidence over his objection that it was illegally seized.

³⁰ *Id.* at 588, 432 P.2d at 708, 63 Cal. Rptr. at 12.

³¹ *People v. DeSantiago*, 71 A.C. 18, 24, 453 P.2d 353, 359, 76 Cal. Rptr. 809, 815 (1969).

at all, so must they have some particular reason to enter in the manner chosen."³² The Court further stated that the particular reason for the mode of entry had to be based upon specific facts which would lead a police officer to reasonably conclude that the occupants of the place to be searched had resolved to effect disposal in the event of police intrusion.³³

A month and a half later, in *Meyer v. United States*,³⁴ the United States Court of Appeals for the Ninth Circuit, citing the *Gastelo* case, granted a motion to suppress evidence seized in a raid on a "bookie operation where officers had no reason for omitting a prior announcement of their identity and purpose except general knowledge that destruction of evidence [betting slips] was likely in this type of offense."³⁵ The court, quoting from *Gastelo*, stated:

Under the Fourth Amendment, a specific showing must always be made to justify any kind of police action attempting to disturb the security of people in their homes. Unannounced forcible entry is in itself a serious disturbance of that security and cannot be justified on a blanket basis. Otherwise the constitutional test of reasonableness would turn only on practical expediency, and the amendment's primary safeguard — the requirement of particularity — would be lost.³⁶

It at once became apparent that *Gastelo* (on the state level) and *Meyer* (on the federal level) were redefining the constitutional and practical limits of the knock and announce rule in a relatively exacting manner. Then, in *People v. Carillo*,³⁷ the California Court retreated slightly from the strict position it had assumed in *Gastelo*, by permitting noncompliance when, immediately prior to entry, the arresting officers were able to detect activity from within the residence which might lead them to reasonably conclude that the occupants within were then engaged in the destruction of the evidence sought.

In *People v. Rosales*,³⁸ and again in *Greven v. Superior Court*,³⁹ the Court attempted to clearly delineate the parameters of excusable noncompliance with the knock and notice requirements of sections 844 and 1531. Defining the constitutional basis of the announcement re-

³² 67 Cal. 2d 586, 588, 432 P.2d 706, 708, 63 Cal. Rptr. 10, 12 (1967).

³³ Cf. *People v. Barnett*, 156 Cal. App. 2d 803, 320 P.2d 128 (1958).

³⁴ 386 F.2d 715 (9th Cir. 1967).

³⁵ *Id.* at 718.

³⁶ *Id.*

³⁷ 64 Cal. 2d 387, 412 P.2d 377, 50 Cal. Rptr. 185 (1968), citing *Ker v. California*, 374 U.S. 23, 46 (1963) (dissenting opinion of Mr. Justice Brennan).

³⁸ 68 Cal. 2d 299, 437 P.2d 489, 66 Cal. Rptr. 1 (1968).

³⁹ 71 A.C. 303, 455 P.2d 432, 78 Cal. Rptr. 504 (1969).

quirement, the *Rosales* Court stated "that [this] requirement is . . . the essence . . . which safeguard[s] individual liberty."⁴⁰ The Court also emphasized that such rules reflect a concern not only for the rights of persons suspected of crimes but also for the security of innocent persons who may be on the premises. Similarly, the *Greven* Court noted that "the reverence of the laws for the individual's right of privacy in his house [is paramount],"⁴¹ and then expounded upon the public policy argument of discouraging, whenever possible, creation of situations conducive to violence.⁴² It went on to state that substantial compliance with the knock and notice rule required at least an identifying announcement by officers, even if the exigencies of the situation would have prevented a statement of purpose. This, the Court stated, was as far as the case would stretch the term "substantial compliance" for excusing law enforcement authorities from the mandates of sections 844 and 1531 of the penal code.

Thus, the California courts have placed the fourth amendment in a fairly prominent position, restricting to a great degree the latitude of discretion previously accorded law enforcement authorities. But the restrictions have been fairly realistic, leaving the court, rather than a formalistic rule, the arbiter of new situations arising out of searches and arrests. This approach, as will be seen, is far more flexible than the District of Columbia's approach which rejects most judicial exceptions to its knock and notice statute.⁴³

Florida

Florida has a statute similar to California, but has adopted a much stricter approach to its interpretation.⁴⁴ For example, in *Benefeld v.*

⁴⁰ 68 Cal. 2d at 304, 437 P.2d at 492, 66 Cal. Rptr. at 4, quoting *Ker v. California*, 374 U.S. 23, 49 (1963) (dissenting opinion of Mr. Justice Brennan). The Court also quoted from *Miller v. United States*, 357 U.S. 301 (1958), but did not apply the *virtually certain test*. Rather, the Court required a reasonable good faith belief as to the exceptions to the announcement requirement provided such belief was accompanied by more than general knowledge as to the comparative ease of disposing of narcotics. For a discussion of *Miller*, see notes 85-96 and accompanying text *infra*. *Rosales* held that the failure of the enforcement authorities to explain their purpose and demand entrance vitiated the arrest. The police, acting on information that defendant was selling narcotics, had observed him from the window and surrounded the house prior to forcing entry. Under these facts, noncompliance with section 844 could not be excused since there was "no suspicious activity," and "no evidence that would justify a belief that such compliance would have increased the officer's peril, frustrated the arrest, or resulted in the destruction of the evidence."

⁴¹ 71 A.C. at 306, 455 P.2d at 435, 78 Cal. Rptr. at 507, quoting *Miller v. United States*, 357 U.S. 301, 313 (1958).

⁴² *Id.* at 307, 455 P.2d at 436, 78 Cal. Rptr. at 508.

⁴³ See *Miller v. United States*, 357 U.S. 301, 309 (1958); *Hair v. United States*, 289 F.2d 894 (D.C. Cir. 1961).

⁴⁴ FLA. STAT. ANN. § 901.19 (1965).

State,⁴⁵ the Supreme Court of Florida noted that its statute, a mere codification of the common law, was not burdened by the exceptions to the knock and announce rule which had been engrafted by the California courts onto their statute.⁴⁶ Nonetheless, the Court then devised four exceptions to the Florida rule:

1. where the person within already knows the officer's authority and purpose;
2. where the officers are justified in the belief that the persons within are in imminent peril of bodily harm;
3. if the officer's peril would have been increased had he demanded entrance and stated the purpose or,
4. where those within made aware of the presence of someone outside are then engaged in activities which justify the officers in the belief that an escape or destruction of evidence is being attempted.⁴⁷

The following year, in *Koptyra v. State*,⁴⁸ the Florida District Court of Appeals was confronted with a no-notice entry situation in which no force was involved. An undercover agent, after attending a "pot party" for a short time, left and returned shortly thereafter with additional officers to arrest those present at the party. The agent, who was admitted to the house upon knocking, merely permitted his colleagues to follow him through the door. In concert, they then proceeded to arrest the occupants and to search the entire area immediately adjacent thereto.⁴⁹ The court affirmed the conviction, but sidestepped the constitutional issue by distinguishing *Benefield* on the ground that the case at bar did not involve a breaking. This interpretation, of course, was rendered inapplicable.

Thus, it appears that the present state of the exceptions in Florida, *i.e.*, those stated in *Benefield*, represent a stricter interpretation of the common-law exceptions to knock and notice than California has adopted.

⁴⁵ 160 So. 2d 706 (Fla. 1964). The facts in *Benefield* closely parallel *Miller v. United States*, 357 U.S. 301 (1958). For a discussion of *Miller*, see notes 85-96 and accompanying text *infra*. The *Benefield* court rejected the State's reliance upon *Ker* as justification for noncompliance with the statute.

⁴⁶ *Id.* at 710.

⁴⁷ *Id.* In *Benefield*, the police gained access to defendant's home by opening an unlocked door. Immediately prior to the entry, one Hollander had informed the officers that he had deposited money with defendant as a "payoff" to secure a liquor license. Under these facts, the unannounced entry was regarded as violative of the Florida statute.

⁴⁸ 172 So. 2d 628 (Fla. D. Ct. 1965).

⁴⁹ Under *Chimel v. California*, 395 U.S. 752 (1969), such a search incidental to an arrest would no longer be permitted. See notes 123-124 and accompanying text *infra*.

Utah

Utah, Idaho, Iowa and South Dakota,⁵⁰ like Florida and many other states which have adopted statutes resembling the knock and notice provisions of the California Penal Code, have used California's decisions as a basis for interpreting their own statutes. For example, in 1967, Utah amended its search warrant provision to read:

Officer may break door or window to execute warrant — Authority. The officer may break open any outer or inner door or window of a house, or any part of a house or anything therein, to execute the warrant:

(1) If, after notice of his authority and purpose, he is refused admittance; or

(2) Without notice of his authority and purpose, if the judge, justice or magistrate issuing the warrant has inserted a direction therein that the officer executing it shall not be required to give such notice. The judge, justice or magistrate may so direct only upon proof under oath, to his satisfaction that the property sought is a narcotic, illegal drug, or other similar substance which may be easily and quickly destroyed or disposed of, or that danger to the life or limb of the officer or any other may result, if such notice were to be given.⁵¹

Clearly, this provision merely codified California case law as it existed immediately prior to the *Gastelo*,⁵² *Rosales*,⁵³ and *Greven*⁵⁴ cases. Although the Utah Supreme Court has not yet interpreted the statute, it has, in essence (at least on its face), rejected the fourth amendment based argument. Instead, it has adopted an expanded common-law approach, requiring a mere affirmation by the arresting officer that the object sought was of an easily disposable nature without any requirement as to the exigencies of the situation. Yet, the Utah Supreme Court has been at least somewhat cognizant of the constitutional ramifications of the no-knock provision. In *State v. Loudon*,⁵⁵ the Court, addressing itself to a slightly different situation, noted that, while constitutional safeguards were not to be ignored, nevertheless they were to be weighed against the "practical exigencies of police work."⁵⁶ This case seems to

⁵⁰ UTAH CODE ANN. § 77-13-12 (1953); IDAHO CODE ANN. §§ 19-611, 19-4409 (1948); IOWA CODE ANN. § 751.9 (1950); S.D. CODE §§ 23-22-18, 23-15-14 (1967).

⁵¹ UTAH CODE ANN. § 77-54-9 (1953).

⁵² 67 Cal. 2d 586, 432 P.2d 706, 63 Cal. Rptr. 10 (1967).

⁵³ 68 Cal. 2d 299, 437 P.2d 489, 66 Cal. Rptr. 1 (1968).

⁵⁴ 71 A.C. 303, 455 P.2d 432, 78 Cal. Rptr. 504 (1969).

⁵⁵ 15 Utah 2d 64, 387 P.2d 240 (1963).

⁵⁶ *Id.* at 67, 387 P.2d at 243. The Court discussed in detail the constitutional safeguards espoused by the United States Supreme Court in *Ker v. California*, 374 U.S. 23 (1963). For a discussion of this case, see notes 100-07 and accompanying text *infra*.

have been the extent of Utah's consideration of no-knock, and represents, at best, an evasion of the constitutional issue — at least for the time being.

Washington

Washington, which also has a statute similar to California's section 844, has interpreted noncompliance with the knock and announce rule in a slightly different manner than California. Addressing itself to the constitutional issue in *State v. Young*,⁵⁷ the Supreme Court of Washington held that, "when officers come armed with a search warrant, forcible entry without announcement of identity and purpose may be justified when exigent and necessitous circumstances exist."⁵⁸ Since such circumstances may be deemed to exist when, "narcotics or other property subject to immediate destruction" are involved,⁵⁹ the Washington Court adopted a position which is roughly analogous to the post-*Maddox* attitude of the California courts.⁶⁰

New York, Nebraska, South Carolina and North Dakota

Several states have adopted a slightly different approach to the no-knock exceptions to the rule requiring notice of identity and purpose by the arresting officer. Nebraska, New York, North Dakota and South Carolina⁶¹ have included the requirement of judicial approval for a no-knock direction to any arrest or search warrant. Illustrative is section 799 of the New York Code of Criminal Procedure which specifies:

The officer may break open an outer or inner door or window of a building, or any part of the building, or anything therein, to execute the warrant, (a) if, after notice of his authority and purpose, he be refused admittance, or (b) without notice of his authority and purpose, if the judge, justice or magistrate issuing the warrant has inserted a direction therein that the officer executing it shall not be required to give such notice. The judge, justice or magistrate may so direct only upon proof under oath, to his satisfaction, that the property sought may be easily and quickly destroyed or disposed of, or that danger to the life or limb of the officer or another may result, if such notice were to be given.⁶²

⁵⁷ 76 Wash. 2d 212, 455 P.2d 595 (1969).

⁵⁸ *Id.* at 214, 455 P.2d at 598. The Court cited both *Ker v. California*, 374 U.S. 23 (1963) and *Miller v. United States*, 357 U.S. 301 (1958). *Id.* at 213-14, 455 P.2d at 597.

⁵⁹ The Washington Supreme Court specifically noted that its new rule was similar to the *Maddox* case. *Id.* at 214, 455 P.2d at 598.

⁶⁰ *Id.*

⁶¹ NEB. REV. STAT. § 29411 (1965); N.Y. CODE CRIM. PROC. §§ 175, 178, 799 (McKinney 1964); N.D. CODE § 29-29.1-01 (1967); S.C. CODE §§ 17-257, 53-198 (1962).

⁶² N.Y. CODE CRIM. PROC. § 799 (McKinney 1964).

There is presently a controversy as to whether the addition of this clause requiring judicial approval will satisfy the fourth amendment *reasonableness* requirement set out by the United States Supreme Court in *Ker v. California*.⁶³ One point of view can be found in *People v. DeLago*.⁶⁴ There, the New York Court of Appeals permitted police officers armed with a search warrant to make an unannounced entry at the apartment of the defendant where

it was represented to the court by affidavit that gambling materials were likely to be found at this location and in issuing the warrant, the court could take judicial notice that contraband of that nature is easily secreted or destroyed if persons unlawfully in possession thereof are notified in advance that the premises are about to be searched.⁶⁵

Citing and discussing *Ker* and *Maddox*, the Court found that the police tactics were inoffensive to constitutional standards, and that section 799, which authorizes the inclusion of the no-knock provision in the search warrant after judicial approval, was also in compliance with the mandates of the fourth amendment. The Court made this finding notwithstanding the fact that

there [was] nothing in the affidavit to show specifically how or where these gambling materials would be likely to be destroyed or removed, [because] the likelihood they would be was an inference of fact which the Judge signing the warrant might draw.⁶⁶

Thus *DeLago* indicates that the New York courts recognize that there is a question of constitutional dimension, but that exigent circumstances, which do not have to be supported by specific facts, remove the forcible entry from constitutional condemnation. It is also worth noting that the lower New York courts have held that an unannounced entry could be made without a warrant if there existed probable cause to arrest and exigent circumstances justified noncompliance with the statute.⁶⁷

⁶³ 374 U.S. 23 (1963). For a discussion of this case, see notes 100-07 and accompanying text *infra*.

⁶⁴ 16 N.Y.2d 289, 213 N.E.2d 659, 266 N.Y.S.2d 353 (1965), *cert. denied*, 383 U.S. 963 (1966).

⁶⁵ *Id.* at 292, 213 N.E.2d at 661, 266 N.Y.S.2d at 356.

⁶⁶ *Id.*

⁶⁷ *People v. McIlwain*, 28 App. Div. 2d 711, 281 N.Y.S.2d 218 (2d Dep't 1967); *People v. Montanaro*, 24 Misc. 2d 624, 229 N.Y.S.2d 677 (Kings County Ct. 1962); *People v. Cocchiara*, 31 Misc. 2d 495, 221 N.Y.S.2d 856 (Ct. Gen. Sess. N.Y. County 1961).

District of Columbia

Basically, three statutes concern search warrant entries in the District of Columbia, and all three have very similar language;⁶⁸ two are local statutes applicable only to the District,⁶⁹ while the third, section 3109 of the Criminal Code,⁷⁰ is of general application. For many years the latter has been held applicable to the District of Columbia, and the case law for any of the three has been considered almost interchangeable.⁷¹ Each of the statutes bears a marked resemblance to the California statute, yet they have been interpreted in an entirely different manner by the Supreme Court and the lower federal courts in the District. While the California courts have engrafted a series of exceptions onto their statute, decisions in the District of Columbia relating to section 3109 have continued to interpret any possible exceptions to the "knock and wait" rule in a highly restrictive manner.

One of the major cases in the District of Columbia was *Accarino v. United States*,⁷² which involved a warrantless arrest and search, and a subsequent gambling conviction. The Court of Appeals for the District of Columbia Circuit discussed at length the common-law background of the rule requiring notice and announcement of purpose.⁷³ Emphasizing "a man's right of privacy in his home," the *Accarino* court rejected the Government's repeated attempts to excuse its failure to obtain a warrant for the forcible arrest and search. (*Accarino* was subsequently utilized by the District of Columbia courts as a basis for their interpretation of the District of Columbia and federal warrant statutes.)

In 1958 the landmark case of *Miller v. United States*⁷⁴ was handed down by the Supreme Court. It would serve no purpose to discuss *Miller* extensively at this point, since the case will be treated in considerable depth in a subsequent section.⁷⁵ Suffice it to say that Mr.

⁶⁸ The officer may break open any outer or inner door or window of a house, or any part of a house, or anything therein, to execute a search warrant, if, after notice of his authority and purpose, he is refused admittance or when necessary to liberate himself or a person aiding him in the execution of the warrant.

⁶⁹ 18 U.S.C. § 3109 (1964).

⁶⁹ D.C. CODE ANN. § 25-129(g) (1967) (liquor); D.C. CODE ANN. § 33-414(g) (1967) (narcotics).

⁷⁰ 18 U.S.C. § 3109 (1964).

⁷¹ See, e.g., *United States v. Miller*, 357 U.S. 301, 306 (1958); See Blakey, *supra* note 20, at 513 for a more complete explanation of the application of section 3109 to the District of Columbia.

⁷² 179 F.2d 456 (D.C. Cir. 1949).

⁷³ *Id.* at 460; see Blakey, *supra* note 20, at 510-14.

⁷⁴ 357 U.S. 301 (1958).

⁷⁵ See notes 85-96 and accompanying text *infra*. See generally Blakey, *supra* note 20, at 516-31.

Justice Brennan, who delivered the opinion for the Supreme Court, evaded the issue of whether section 3109, as a codification of the common law, implicitly encompassed exceptions adopted in such states as California with the statement "whether the unqualified requirements of the rule admit an exception justifying noncompliance in exigent circumstances is not a question we are called upon to decide in this case."⁷⁶ However, other decisions by the District of Columbia Circuit interpreted possible exceptions to section 3109 in a fairly strict manner, requiring almost total compliance with the statute's mandates. For example, in *Masiello v. United States*,⁷⁷ there was a conflict in the testimony as to whether or not the police, who had announced only their presence before entering the premises, had notified the defendant that they had a search warrant. The court remanded the case to determine if the police had *in fact* totally complied with the statute's knock and notification requirements. Similarly, in *Keiningham v. United States*⁷⁸ and *Hair v. United States*,⁷⁹ the court stated that the *Miller* rule requires police officers "who seek to invade the privacy of an individual's home to announce their authority and their purpose in demanding entrance before 'barging in.'"⁸⁰ These decisions indicate a judicial reluctance to permit any expansion of no-knock in the District of Columbia.

II. ANNOUNCEMENT AND THE CONSTITUTION

The fourth amendment to the United States Constitution denounces only "unreasonable" searches and seizures. This is a word which, quite naturally, has confounded legal scholars for hundreds of years. Yet, the fourth amendment was approved only after the inclusion of the language banning "unreasonable seizures and searches."⁸¹ Undoubtedly, individual reaction against the so-called "general warrants" or "writs of assistance" was primarily responsible for its inclusion. However, as was previously indicated, neither this attitude nor the

⁷⁶ 357 U.S. at 309.

⁷⁷ 304 F.2d 399 (D.C. Cir. 1962).

⁷⁸ 287 F.2d 126 (D.C. Cir. 1960).

⁷⁹ 289 F.2d 894 (D.C. Cir. 1961).

⁸⁰ *Id.* at 896. It is worth noting that the *Hair* court excluded evidence of gambling paraphernalia; several state courts have held such material to be "easily disposable" contraband which would permit noncompliance with their knock and notice statutes. The *Hair* decision was merely a reaffirmation of a similar holding in an earlier case. See *Woods v. United States*, 240 F.2d 37 (D.C. Cir. 1956).

⁸¹ See B. MITCHELL & L. MITCHELL, *A BIOGRAPHY OF THE CONSTITUTION OF THE UNITED STATES* 199 (1964).

standard was novel. The common law was fairly well settled against unreasonable searches in general, although no rules of reason had been clearly defined. Use of the term "unreasonable" was, of course, practical and, at the same time, the most farsighted way of satisfying current feeling in 1789, while providing flexibility for the future. Nevertheless, the term must have had some definite connotations to the founding fathers and their contemporaries during the consideration and approval of the Bill of Rights. The growth of the law in this area would tend to obscure this fact, although modern courts often pay lip service (and sometimes more) to common-law trends and traditions.⁸² It might be well to bear in mind the words of Mr. Chief Justice Taft on this subject:

The Fourth Amendment is to be construed in the light of what was deemed an unreasonable search and seizure when it was adopted, and in a manner which will conserve public interests as well as the interests and rights of individual citizens.⁸³

The language of the fourth amendment suggests that the search and seizure itself was of primary concern to the drafters. The protection of the amendment extends to "persons, houses, papers, and effects," each of which can involve different factual circumstances. Whether an announcement of purpose is required for any or all of these protected entities is beyond the scope of the present discussion, for the Supreme Court in recent years has evidently concluded that a statement of identity and purpose is a basic prerequisite to entry into a home without the occupant's acquiescence — a prerequisite that has constitutional dimensions.⁸⁴ However, the road to this conclusion is sinuous at best, being paved with inconsistencies as well as exceptions. Furthermore, the end of the road is not necessarily in sight.

In deciding the case of *Miller v. United States*,⁸⁵ Mr. Justice Brennan and his colleagues were, in effect, confronting the rule of an-

⁸² See, e.g., *Miller v. United States*, 357 U.S. 301 (1958); *Accarino v. United States*, 179 F.2d 456 (D.C. Cir. 1949).

⁸³ *Carroll v. United States*, 267 U.S. 132, 149 (1924).

⁸⁴ *Ker v. California*, 374 U.S. 23 (1963).

⁸⁵ 357 U.S. 301 (1958). In *Miller* the officers involved had neither a search nor an arrest warrant. After arriving at the apartment in question, one of the officers knocked on the door, and in response to an inquiry as to who was there, replied in a low voice, "police." The defendant opened the door slightly, leaving the safety chain intact. Upon seeing the officer, he immediately started to close it. However, one officer grabbed the door and was able to force entry by breaking the chain. Miller and his girlfriend were arrested, and a search of the apartment uncovered marked informant money. The defendants' pretrial motion to suppress the evidence as illegally seized was denied, and when the trial judge subsequently refused to consider the question of suppression, the defendants were found guilty of violating the District of Columbia's narcotics laws. This conviction had been affirmed on appeal and the Supreme Court granted certiorari.

nouncement for the first time. In rendering its decision, the Supreme Court quite naturally turned to *Accarino*, which was considered something of a landmark at the time due to its extensive discussion of the common-law rule on forcible entry. *Accarino*, like *Miller*, involved a case arising in the District of Columbia, but there are several factors which make Mr. Justice Brennan's deference to "the rule of *Accarino*" somewhat unfortunate. To begin with, *Accarino* was based, to a great extent, upon the absence of an arrest warrant. Judge Prettyman had concluded:

Unless the necessities of the moment require that the officer break down a door, he cannot do so without a warrant; and if in reasonable contemplation there is opportunity to get a warrant, or the arrest could as well be made by some other method, the outer door to a dwelling cannot be broken to make an arrest without a warrant.⁸⁶

It was primarily on this basis that the *Accarino* court had determined that the evidence, which was seized following the forced entry and subsequent arrest of the defendant by law enforcement officers, should have been excluded. Unfortunately, however, Judge Prettyman chose to add the following comment:

Upon one topic there appears to be no dispute in the authorities. Before an officer can break open a door to a home, he must make known the cause of his demand for entry.⁸⁷

If indeed there had been no dispute prior to *Accarino*, it was because the issue had never been squarely presented in a modern criminal case. Furthermore, as previously mentioned, the common law was by no means fixed on this point (except in the general agreement that there were reasonable exceptions to any announcement rule which might exist).

Miller, like *Accarino*, was decided on non-constitutional grounds. Language to the contrary notwithstanding, a close reading reveals that *Miller* stands as a determination of District of Columbia law, the fourth amendment being only indirectly involved. As in *Accarino*, the officers who arrested Miller after the forced entry had no warrant. Both cases speak in terms of a common-law right of privacy in the home.⁸⁸ Similarly, both cite *Semayne's Case*⁸⁹ as well, but while *Accarino* recognized that this venerable decision concerned a writ issued

⁸⁶ 179 F.2d at 464.

⁸⁷ *Id.* at 465.

⁸⁸ 357 U.S. at 313; 179 F.2d at 464.

⁸⁹ 77 Eng. Rep. 194 (Ex. 1603).

in a civil case,⁹⁰ *Miller* recited the oft-quoted pronouncement as if it related to breaking in order to arrest for a felony.⁹¹ Such a misconception with regard to *Semayne's Case*, and to the entire body of Anglo-American law on this subject, is regrettably not uncommon. More serious is the fact that Mr. Justice Brennan failed to reach any conclusions with respect to common-law exceptions (such as the immediate threat of violence). Additionally, the rationale underlying the notice rule, *i.e.*, that a knock of notice was, in most cases, the better way to avoid violence which might breach the King's peace, was completely ignored. The concept of privacy, as relied upon by *Miller*,⁹² is a somewhat later and more amorphous development. Prior to the adoption of the Constitution, the statement that "the King's keys unlock all doors"⁹³ was probably closer to the truth.

Although *Miller* may be based upon "the rule of *Accarino*" or District of Columbia law, its implications are broader because of the majority's insistence on relating its holding to section 3109 of the Criminal Code.⁹⁴ In Mr. Justice Brennan's view, this section reflected a congressional desire to codify the traditional rules of forced entry.⁹⁵ He construed it as a restatement of *Semayne's Case*, and therefore applicable, in effect, to all forcible entries, although by its language section 3109 is limited to the execution of search warrants. The ambiguity thus developed is evidenced by the decisions which followed *Miller*.⁹⁶

In *Wong Sun v. United States*,⁹⁷ the Supreme Court's next major opportunity to consider its holding in *Miller*, Mr. Justice Brennan again articulated for the majority. Here, agents had forcibly entered a dwelling without a prior notice of authority and purpose, although one of the agents apparently identified himself to the defendant before forcing open the door to effectuate the arrest.⁹⁸ Mr. Justice Brennan repeated the "virtual certainty" test he formulated in *Miller*, but could find no facts justifying the conclusion that the officers were virtually

⁹⁰ 179 F.2d at 460. See note 7 and accompanying text *supra*.

⁹¹ 357 U.S. at 308.

⁹² *Id.* at 307.

⁹³ BROOM'S LEGAL MAXIMS, *supra* note 4, at 432.

⁹⁴ 18 U.S.C. § 3109 (1964).

⁹⁵ 357 U.S. at 313.

⁹⁶ See, *e.g.*, *United States v. Barrow*, 212 F. Supp. 837 (E.D. Pa. 1962), where Judge Lord relied upon *Miller* as interpreting section 3109 to apply to the broad range of search and seizure situations. As he put it, "[p]lainly stated, the Court had to decide not the application of a local rule as such, but whether or not the criteria of section 3109 has been met . . ." *Id.* at 845.

⁹⁷ 371 U.S. 471 (1963).

⁹⁸ *Id.* at 474.

certain that the defendant already knew their purpose. However, the door to other exceptions recognized at common law was opened somewhat wider in *Wong Sun*, when Mr. Justice Brennan specifically mentioned the exceptions of "the imminent destruction of vital evidence, or the need to rescue a victim in peril"⁹⁹ while reiterating the fact that the Government claimed no such circumstances in the case.

Up to this point, "the knock" itself had not yet assumed constitutional proportions; prior holdings were based on common law, state law, section 3109, and various combinations of these authorities. Consequently, the stage was not particularly well set for *Ker v. California*.¹⁰⁰ Mr. Justice Clark, who had dissented in both *Miller* and *Wong Sun*, wrote for the *Ker* majority. Mr. Justice Brennan, on the other hand, authored the dissent, which expressed the views of the Chief Justice and two other Justices as well.¹⁰¹ Although the decision was extremely close, there was virtual unanimity on one point: the rule of announcement is a constitutional requirement implicit in the fourth amendment proscription against unreasonable searches and seizures. But, while the minority felt that the circumstances in *Ker* did not satisfy any exceptions to the "knock" requirement which they were willing to recognize, the majority was of the view that

in the particular circumstances of this case the officers' method of entry, sanctioned by the law of California, was not unreasonable under the standards of the Fourth Amendment as applied to the States through the Fourteenth Amendment.¹⁰²

George and Diane Ker were undoubtedly surprised when law enforcement officers quietly utilized a pass key to enter their apartment. In fact, they neglected to conceal a two pound brick of marihuana which was resting ostentatiously in their kitchen. More marihuana was subsequently discovered in both the kitchen and bedroom after the Kers were arrested. There was no warrant obtained, nor was there any announcement of identity and purpose, prior to the officers' surreptitious entry. The omission of notice was ostensibly to prevent the destruction of evidence,¹⁰³ and was sanctioned by a judicial exception to the California statute which ordinarily required announcement.¹⁰⁴

Although no force was used to effect the entry in *Ker*, the majority

⁹⁹ *Id.* at 484.

¹⁰⁰ 374 U.S. 23 (1963).

¹⁰¹ *Id.* at 46.

¹⁰² *Id.* at 40-41.

¹⁰³ *Id.* at 28.

¹⁰⁴ See, e.g., *People v. Maddox*, 46 Cal. 2d 301, 294 P.2d 6, cert. denied, 352 U.S. 858 (1956) discussed at note 24 and accompanying text *supra*.

recognized that the use of a pass key under these circumstances was the legal equivalent of a breaking. However, the Court refused to consider the question of entry by ruse or trickery,¹⁰⁵ thereby fostering future uncertainty on this issue. Additionally, despite the fact that this area is pervaded with unresolved questions, the Court chose to overlook the opportunity to clarify the relevant standards. In relying upon "the particular circumstances of this case,"¹⁰⁶ Mr. Justice Clark evidently recognized a "destruction of evidence" exception, but refused to discuss other "exigent circumstances" — although Mr. Justice Brennan listed his three somewhat restrictive exceptions.¹⁰⁷ Similarly, the majority opinion did not clarify whether the same result would obtain in this case if federal rather than state officers had been involved, or if a search or arrest warrant had been issued. But one thing must be said for *Ker*: although the rules for its application were left uncertain, with Mr. Justice Clark and Mr. Justice Brennan polarized, an exception to the announcement rule was incorporated into the fourth amendment for situations where there is a reasonable possibility that evidence might otherwise be destroyed.

At least one jurisdiction felt that the destruction exception set forth in *Ker* should be clarified to a much greater degree. In *Meyer v. United States*,¹⁰⁸ the Court of Appeals for the Ninth Circuit was faced with a situation in which the police had, by their own admission, failed to comply with the state statute. The omission of the required knock and notice was based solely upon the general knowledge of the arresting officers regarding the disposability of paraphernalia used in bookmaking operations. The Government conceded that a violation of the knock and announce provisions of the statute would render the arrest and subsequent search invalid and the evidence obtained inadmissible. It argued, however, that because of the general nature of bookmaking paraphernalia, the *Ker* destruction exception excused noncompliance with the statute. The Ninth Circuit, in a per curiam decision, flatly rejected this position. Citing the *Gastelo* case¹⁰⁹ as controlling, the

¹⁰⁵ See *Jones v. United States*, 304 F.2d 381 (D.C. Cir. 1962), *cert. denied*, 371 U.S. 851 (1963); *Leahy v. United States*, 272 F.2d 487 (9th Cir. 1959), *cert. granted*, 363 U.S. 810 (1960), *appeal dismissed per stipulation*, 364 U.S. 945 (1961).

¹⁰⁶ 374 U.S. at 40-41.

¹⁰⁷ (1) where the persons within already know of the officers' authority and purpose, or (2) where the officers are justified in the belief that persons within are in imminent peril of bodily harm, or (3) where those within, made aware of the presence of someone outside (because, for example, there has been a knock at the door), are then engaged in activity which justifies the officers in the belief that an escape or the destruction of evidence is being attempted.

Id. at 47 (dissenting opinion).

¹⁰⁸ 386 F.2d 715 (9th Cir. 1967).

¹⁰⁹ 67 Cal. 2d 586, 432 P.2d 706, 63 Cal. Rptr. 10 (1967).

court stated that neither it nor the Supreme Court had ever held that mere disposability of the evidence sought would render a no-knock, forcible entry constitutionally reasonable. The court noted that the Supreme Court in *Ker* had divided four-to-four on the question of whether the evidence offered to excuse compliance with the notice and demand requirements was in fact constitutionally sufficient. It construed *Ker* as excusing compliance with the statute, in accordance with the established common-law exceptions, *only* on the basis of the *specific facts* presented in that case; "[o]therwise, the constitutional test of reasonableness would turn only on practical expediency and the [fourth] amendment's primary safeguard — the requirement of particularity — would be lost."¹¹⁰

Meyer thus attempted to clarify the destruction exception set forth in *Ker*. Clearly, in the Ninth Circuit's view, that case stood for the proposition that no-knock is permissible in the destruction of evidence situation. However, it is equally clear that the *Meyer* court would require a more stringent form of judicial review based upon the particularity of the facts in the case at hand.

In reliance upon *Ker*,¹¹¹ some states have codified the destruction of evidence exception, and have authorized the issuance of no-knock warrants;¹¹² predictably, state courts appear to be upholding such legislation.¹¹³ *Sabbath v. United States*,¹¹⁴ the most recent Supreme Court decision in this area, indicates that these courts are on relatively safe ground. Although the decision in *Sabbath* turned upon an application of section 3109, rather than the fourth amendment, Mr. Justice Marshall's opinion helped to purify a few of *Ker's* muddy waters. It verified that all entries into dwellings by federal officers are to be tested in terms of section 3109; *any* unannounced entry constitutes a "breaking," regardless of actual force employed. This should not be surprising, especially in view of *Ker*. However, entry by ruse was once again set

¹¹⁰ 386 F.2d at 718.

¹¹¹ The Supreme Court has refused thus far to reconsider its position in *Ker*. See *La Peluso v. California*, 239 Cal. App. 2d 715, 49 Cal. Rptr. 85, cert. denied, 385 U.S. 829 (1966).

¹¹² See, e.g., NEB. REV. STAT. § 29-411 (1964); N.Y. CODE CRIM. PROC. § 799 (McKinney Supp. 1964); UTAH CODE ANN. § 77-54-9 (1967).

¹¹³ See, e.g., *People v. DeLago*, 16 N.Y.2d 289, 213 N.E.2d 659, 266 N.Y.S.2d 353 (1965), cert. denied, 383 U.S. 963 (1966). For a discussion of this, see notes 64-67 and accompanying text *supra*.

¹¹⁴ 391 U.S. 585 (1968). In *Sabbath*, customs agents had apprehended one Jones crossing the border from Mexico to California with cocaine allegedly given him by the defendant. The cocaine was also to be delivered to the defendant and the officers arranged for Jones to make the delivery. They waited five or ten minutes outside the defendant's apartment after Jones had entered to make delivery. Then the agents, without a warrant, knocked, waited a few seconds, and then opened the unlocked door.

apart, which in itself provides some clarification.¹¹⁵ Most importantly, the Court reinforced the concept of implicit exceptions to the constitutional rule of announcement. It did so in a somewhat curious way, however, utilizing a footnote which speaks in terms of "[e]xceptions to any possible constitutional rule."¹¹⁶ And in referring to the "recognized" exceptions, the note cites Mr. Justice Brennan's dissent in *Ker* without reference to the majority opinion in that case. One can only conclude that this reference was due to Mr. Justice Brennan's neat exposition of what he viewed to be the exceptions — something Mr. Justice Clark and the majority failed to do. In other words, the citation should not be construed as favoring the minority view of the destruction of evidence exception over the majority view, thereby impliedly circumscribing, if not overruling, the holding in *Ker*. However, one cannot help but wish, once again, for greater certainty.

Where, then, are we at this point? For one thing, we seem to have a federal statute¹¹⁷ which is duplicative of both the common law and the Constitution. In the alternative, it appears that entries by state officers will be judged by state law and reviewed by fourth amendment standards in appropriate cases. On the other hand, entries by federal officers will be scrutinized in terms of section 3109, which codifies the common law. Both section 3109 and the fourth amendment contemplate exceptions in exigent circumstances, but whether section 3109 is more stringent in application cannot yet be determined. Certainly, there is a constitutionally recognized exception to the announcement rule, and a properly drafted amendment to section 3109 reflecting the exception for potential destruction of evidence should pass constitutional muster. Other exceptions might survive judicial scrutiny as well.¹¹⁸ One thing is certain: the constant growth in drug traffic is resulting in increased pressure from law enforcement agencies which will, in turn, encourage a corresponding growth in the law — or, if not growth, at the very least a clarification or refinement of existing standards.

Proponents of a strict announcement requirement have created a constitutional certainty from a common-law uncertainty. A structure resting upon such dubious foundation cannot long avoid some shifting. Undoubtedly, our founding fathers themselves would have disagreed if

¹¹⁵ *Id.* at 590 n.7, which indicates that the Court is not willing to go out of its way to undermine the established view of entry by ruse as being outside the scope of "breaking." Raised as a constitutional issue, the result might be different.

¹¹⁶ *Id.* at 591 n.8.

¹¹⁷ 18 U.S.C. § 3109 (1964).

¹¹⁸ *E.g.*, to avoid loss of life or when there is virtual certainty that the officers' purpose is known.

asked specifically in 1789 whether they considered unannounced entries into dwellings "unreasonable." In fact, the exclusionary rule itself was not clearly formulated until almost one hundred years had elapsed.¹¹⁹ Nor could they have foreseen the growth in organized crime and the impact of present day gambling and drug traffic. To elevate the announcement rule to a constitutional requirement in 1963 was probably historically unsound. To premise it upon a vague right of privacy, rather than on the avoidance of potential violence was a further departure from precedent. Still, the rule exists and, as long as the right to individual privacy is, in fact, balanced with the public interest in suppressing illegal gambling and drug peddling, who will complain?

It is difficult to see, however, what actual protection is given to any right of privacy by the announcement rule. Once identity and purpose are stated, entry must always be permitted; if permission is denied, or even delayed for an inordinate amount of time, entry may be forced, provided the officer has a valid purpose in gaining admission. Since no discretion is vested in the occupant, in what manner does notice protect his privacy? If he has something to hide, perhaps the knock will provide him with more time to conceal or destroy it. If he plans to resist or flee, he will be alerted. On the other hand, if he plans none of these and is otherwise lawfully engaged, how will the knock benefit him? If the door is locked, he may be able to avoid a broken door by responding to the demand for entry. If he is engaged in very private activities, perhaps of a carnal nature, or is otherwise indisposed, he may have time to avoid embarrassment — but not interruption. Or if he is asleep, he will be spared the possible shock of awakening to the sight of a stranger in his home (entry by stealth), or of awakening to the sound of a breaking door.

Thus balanced, the protections to privacy seem to be somewhat tenuous when compared to the potential for public harm. This is particularly true with respect to potential destruction of evidence, especially when one considers that the probable cause requirement would have to be met in any event. And where a statute provides for the issuance of no-knock warrants, the judicial review factor must be added to the scales. In jurisdictions where such warrants are available, courts should of course look with a jaundiced eye upon officers who fail to obtain warrants without good cause. This is not to say that privacy should not be protected — constitutionally, if necessary. Many, if not most, searches would be "unreasonable" under the fourth amendment if preceded by an unannounced entry. But there is an extreme

¹¹⁹ *Boyd v. United States*, 116 U.S. 616 (1886).

need for reasonable exceptions to be identified and clarified. Exclusionary rules will not deter if they are not understood by the policeman on the beat.¹²⁰

Perhaps our view of privacy should be reconsidered. Would it not be inconsistent to permit electronic eavesdropping under the fourth amendment with appropriate judicial supervision,¹²¹ while denying no-knock entry under limited circumstances with similar supervision? Which is the greater invasion of privacy? It bears repeating that, if we are to continue to judge the announcement rule and its exceptions by fourth amendment standards, the somewhat vague and recent concept of privacy should not be given undue priority over traditional and more comprehensible concepts of reasonableness. Language from Mr. Justice Frankfurter's opinion in *United States v. Rabinowitz*,¹²² which was cited with approval by Mr. Justice Stewart in a more recent opinion overruling *Rabinowitz*,¹²³ helps to place the matter in perspective:

To say that the search must be reasonable is to require some criteria of reason. It is no guide at all either for a jury or for district judges or the police to say that an "unreasonable search" is forbidden — that the search must be reasonable. What is the test of reason which makes a search reasonable? The test is the reason underlying and expressed by the Fourth Amendment: the history and the experience which it embodies and the safeguards afforded by it against the evils to which it was a response.¹²⁴

III. NEW APPROACHES TO NO-KNOCK

The proposed Controlled Dangerous Substances Act contains a no-knock warrant provision similar to many of those mentioned earlier in this article.¹²⁵ Subsection (b) authorizes unannounced entries in cir-

¹²⁰ See Blakey, *supra* note 20, at 533.

¹²¹ See *Berger v. New York*, 388 U.S. 41 (1967).

¹²² 339 U.S. 56, 68 (1950) (dissenting opinion).

¹²³ *Chimel v. California*, 395 U.S. 752, 760 (1969). In *Chimel*, police officers, after serving the defendant with an arrest warrant at his home, proceeded to search the entire house for items taken in an alleged burglary. The Court invalidated the search as being unreasonable since, even though it was incidental to a valid arrest, there was no probable cause. The Court limited a search incidental to an arrest to the arrestee's person and the area "within his immediate control" — within which he might gain possession of a weapon or destructible evidence.

¹²⁴ 395 U.S. at 765, quoting *United States v. Rabinowitz*, 339 U.S. at 83 (dissenting opinion).

¹²⁵ Any officer authorized to execute a search warrant relating to offenses involving controlled dangerous substances the penalty for which is imprisonment for more than one year may, without notice of his authority and purpose, break open an outer or inner door or window of a building, or any part of the building or anything therein, if the judge or United States Magistrate issuing the warrant is satisfied that there is probable cause to believe that (A) the property sought may and if such notice is given, *will be easily and quickly destroyed or disposed of*, or (B) the giving of such notice *will immediately endanger the life or safety of*

cumstances where the judge or magistrate issuing the warrant is satisfied that there is probable cause to believe that, if the officers knocked and announced their authority and purpose, either the evidence sought will be quickly destroyed or the officers placed in danger of physical harm. These warrants may only be issued for offenses relating to controlled dangerous substances, and the warrant must state on its face that the officers executing it are authorized to dispense with knocking or announcing their authority and purpose. In addition, there is a requirement that the officers identify themselves and their purpose as soon as possible after gaining entry.¹²⁶

Strong opposition has been voiced against the proposed no-knock provision on both constitutional and policy grounds. Critics contended that the initial language of section 702(b), which authorized the issuance of a no-knock warrant if "there is probable cause to believe that if such notice were to be given the property at issuance in the case may be easily and quickly disposed of . . .,"¹²⁷ was too ambiguous and that it was susceptible to a wide variety of interpretations.¹²⁸ Additionally, they argued that the language did not make clear whether it was the nature of the property that was intended to be a ground for issuance of the warrant, or whether specific facts demonstrating that the occupants of the premises to be searched were ready, willing, and able to destroy the evidence at the first sign of police intrusion were required.¹²⁹

The original intent of section 702(b) was to require a two-step process for obtaining a no-knock warrant. The first was compliance

the executing officer or another person, and has included in the warrant a direction that the officer executing it shall not be required to give such notice: Provided, that any officer acting under such warrant, shall, as soon as practicable after entering the premises, identify himself and give the reasons and authority for his entrance upon the premises.

S.3246, 91st Cong., 2d Sess. § 702 (1970) (emphasis added).

¹²⁶ This proviso was included in the Senate Judiciary Committee to insure reasonably prompt notice to the occupants and thereby minimize the possibility of mistake of intent and potential violence.

¹²⁷ Before its amendment in the Senate, section 702(b) read: Any officer authorized to execute a search warrant relating to offenses involving controlled dangerous substances the penalty for which is imprisonment for more than one year may, without notice of his authority and purpose, break open an outer or inner door or window of a building, or any part of the building, or anything therein, if the judge or United States Magistrate issuing the warrant is satisfied that there is probable cause to believe that if such notice were to be given the property sought in the case *may be easily and quickly destroyed or disposed of, or that danger to the life or limb of the officer or another may result*, and has included in the warrant a direction that the officer executing it shall not be required to give such notice: Provided, that any officer acting under such warrant, shall, as soon as practicable after entering the premises, identify himself and give the reasons and authority for his entrance upon the premises. (Emphasis added.)

¹²⁸ S. REP. NO. 613, 91st Cong., 1st Sess. 159 (1969).

¹²⁹ *Id.*

with the requirements necessary for obtaining a conventional search warrant: that there is probable cause to believe that a crime has been committed and that evidence or fruits of such crime are located on the premises to be searched. The next step was that the applicants also show that there is probably cause to believe that contraband drugs are located on the premises and that, by their nature, they are capable of quick destruction, and might in fact be so destroyed should the occupants be made aware of an imminent police intrusion. In effect, a number of elements was required: probable cause to believe that contraband drugs were located on the premises, that such drugs by their nature could be easily destroyed or disposed of, and that the occupants of the premises would be likely to destroy such drugs upon notice by the police of their intent to execute a search warrant. These requirements clearly satisfied the criteria established in existing law.¹³⁰ Nevertheless, the extensive criticism which the original section 702(b) was subjected to resulted in its amendment on the Senate floor;¹³¹ the present language — “will be easily and quickly destroyed or disposed of” and “will immediately endanger the life or safety of the executing officer”¹³² — reflects this amendment.

An alternative approach would be to require positivity rather than probable cause in any application for a no-knock authorization. This would comport with the general standard for the issuance of nighttime search warrants under rule 41(e) of the Federal Rules of Criminal Procedure.¹³³ Simply stated, a positivity standard requires a greater quantum of factual information than does the probable cause standard. Under normal probable cause standards, the judge or magistrate does not have to be positive that the evidence sought is located on the premises to be searched in order to grant the warrant. Rather, the applicant need only disclose sufficient facts to warrant an averment that the evidence sought is likely to be on the premises. However, such facts would be insufficient to meet the positivity test.¹³⁴

¹³⁰ See notes 21-80 and accompanying text *supra*.

¹³¹ Section 702 was amended pursuant to a provision offered by Senator Robert Griffin and strongly supported by Senator Joseph Tydings. Senator Tydings had successfully inserted similar “will result” language into the proposed District of Columbia Court Reform and Reorganization Act. In the House version of the latter, H.R. 16196, the “no-knock” provision merely requires that destruction or disposal be likely to result. Presumably, this conflict will eventually be resolved.

¹³² See note 125 *supra* for the entire text of the proposed subsection.

¹³³ FED. R. CRIM. P. 41(e).

¹³⁴ Rule 41(e), which governs the issuance of nighttime search warrants, requires that the affidavit disclose sufficient facts to warrant the affiant in asserting a positive belief that the evidence is located on the premises to be searched. *United States v. Raidl*, 250 F. Supp. 278 (N.D. Ohio 1965). An exception is made to rule 41(e) for issuance of search warrants involving narcotic drugs. By virtue of 18 U.S.C. § 1405 (1964), the execu-

Adoption of a positivity test for the issuance of no-knock warrants would mean that the applicant would have to disclose facts evidencing a positive belief that contraband drugs are on the premises to be searched, and that they are of such a nature that they can be easily disposed of or destroyed. While this test would clearly remedy many of the ambiguities which the critics have found inherent in the provision, it would impose a much heavier burden upon officers seeking no-knock authority. Additionally, it would compel the judiciary to determine just what standards apply to "positivity" versus "probable cause," — a question which has been consistently avoided in nighttime warrant cases.¹³⁵ While a compromise, this alternate approach is neither necessary nor recommended in the light of existing law.¹³⁶

Critics also assert that the proposed no-knock provision was of doubtful constitutional validity. Such contentions are based upon the fourth amendment's prohibition against unreasonable searches and seizures and the implied right of individual privacy.¹³⁷

Taken in a broad context, the right of privacy is the right of an individual to be left alone, shielded from unwarranted governmental intrusions.¹³⁸ However, in the words of Mr. Justice Stewart,

the Fourth Amendment cannot be translated into a general constitutional "right to privacy." That amendment protects individual privacy against certain kinds of governmental intrusion, but its protection goes further, and often has nothing to do with privacy at all.¹³⁹

Some critics of the no-knock provision would find implicit in the right of privacy the requirement of advanced notice prior to any lawful governmental intrusion, such as the execution of a valid search warrant. However, the dimensions of an individual's right to privacy severely contract when one is dealing with the execution of a search warrant. For purposes of conducting a search, the officers authorized to execute the warrant are legally entitled to entry into the designated premises, with or without the consent of the occupant. Should an occupant refuse ad-

tion of search warrants relating to offenses involving narcotic drugs at any time of the day or night is permitted provided there is probable cause to believe that grounds for the warrant exist. This same exception has been incorporated into section 702(a) of the proposed Controlled Dangerous Substances Act.

¹³⁵ *Distefano v. United States*, 58 F.2d 963 (5th Cir. 1932); *United States v. Castle*, 213 F. Supp. 52 (D.D.C. 1962).

¹³⁶ This is especially true in view of the "will be easily and quickly destroyed" language now engrafted upon section 702(b). The question of evidence required by the language closely approaches the standard applied under the positivity approach.

¹³⁷ S. REP. No. 613, 91st Cong., 1st Sess. 159 (1969).

¹³⁸ *United States v. Katz*, 389 U.S. 347 (1968).

¹³⁹ *Id.* at 349.

mission to the premises, the officers are also empowered to use the necessary force to gain entry.¹⁴⁰

When the framers of the Constitution made provisions for the issuance and execution of search warrants, they recognized that there would be instances in which an individual would have to be deprived of his substantive right to privacy. In order to protect the individual when this event should arise, the framers required the element of reasonableness in the conducting of any search. Hence, what is really meant by referring to the general rule requiring notice of authority and purpose prior to execution of a search warrant is a standard of reasonableness — a balancing of probable cause, need and the individual's right to privacy. Reasonableness is not an equivalent for "right to privacy," the latter being a part of the former and weighed, with other factors, to determine proper legal equilibrium.

The no-knock provision, requiring court authorization to dispense with an announcement, reasserts the general principle that reasonableness of a search demands notice of authority and purpose. It is also a codification of some exceptions to the general rule.¹⁴¹ In effect, it is a congressional declaration that under certain, specified circumstances, notice of authority and purpose can be dispensed with and the search will still remain within the bounds of reasonableness.

Relying upon past experience with narcotic and dangerous drug law enforcement, Congress could rationally justify these two exceptions as being necessary for effective law enforcement. It is merely asserting that under circumstances where prior notice would lead to destruction of evidence or would endanger the lives of the officers executing the warrant, an unannounced or forcible entry will not invalidate the search as unreasonable.

It should be emphasized that the provision does not compel Congress to impose a loose standard. Rather, while Congress will make a general finding that notice of authority and purpose can lead to destruction of evidence or injury to the officers, the provision requires, in addition, that a neutral judge or magistrate render a specific finding of either in each individual case. Before notice of authority and purpose can be dispensed with, the judge or magistrate issuing the warrant must be satisfied that there is probable cause to believe that such grounds exist. He must specifically find probable cause to believe

¹⁴⁰ *Butler v. United States*, 275 F.2d 889 (D.C. Cir. 1960).

¹⁴¹ Under the proposed no-knock provisions, the only times unannounced entries will be permitted are when knocking and announcing authority and purpose would either lead to the quick destruction of the evidence sought or where the officers executing the warrant are placed in danger of physical harm.

either destruction of the evidence or injury to the agents will result if notice of authority and purpose are given. Probable cause requires more than mere generalities; rather, it requires specific facts. A no-knock warrant under the proposed provision cannot be issued solely on the basis that most drug traffickers keep their supply of drugs in a place where they can be easily disposed of. More specificity is required by the definition of probable cause. Information relating to the actual location of the drugs or the propensity of the suspect to be violent will have to be known by the agents and made available to the judge when application for the warrant is made.

CONCLUSION

Having traced the historical background, state and federal legislation and case law regarding the requirement of announcing authority and purpose prior to entering a person's dwelling, the question settles down to a moral, rather than legalistic, judgment as to whether no-knock should be permitted. Weighing values of privacy, potential for violence and the need to preserve evidence in drug cases, it would seem that no-knock authority is not only necessary but desirable within the framework of the federal drug proposal. Since the proposed Act sets out the statutory requirements rather than placing reliance on common-law doctrines,¹⁴² it would provide law enforcement agencies a source on which to rely in this area. Furthermore, the bill requires the interposition of a judge or magistrate before no-knock authority can be obtained in executing a warrant. This judicial supervision has been repeatedly favored by the Supreme Court and should be required in this instant situation.¹⁴³

What is needed is meaningful reaction, not rationalization. Only then will the fourth amendment be upheld and the populace protected.

¹⁴² Note that in many states, federal officers are also considered state peace officers and can execute state laws under state procedures, *e.g.*, California.

¹⁴³ *Sibron v. United States*, 392 U.S. 40 (1968); *United States v. Katz*, 389 U.S. 347 (1968); *McDonald v. United States*, 335 U.S. 451 (1948).

APPENDIX†

STATES REQUIRING ANNOUNCEMENT OF AUTHORITY AND PURPOSE BEFORE FORCED ENTRY
TO EXECUTE SEARCH WARRANTS OR ARRESTS (WITH OR WITHOUT A WARRANT)

State	Search Warrant	Arrests (with or without warrant)
Alabama	Notice Required ALA. CODE tit. 15, § 108 (1958).	Notice Required ALA. CODE tit. 15, §§ 153, 155 (1958).
Alaska	No-Knock Permitted ALASKA STAT. § 12.35.040 (1962).	Notice Required ALASKA STAT. § 12.25.100 (1962).
Arizona	Notice Required* ARIZ. REV. STAT. ANN. § 13-1446(B) (1956).	Notice Required ARIZ. REV. STAT. ANN. § 13-1411 (1956).
	* State v. Mendoza, 454 P.2d 140 (1968) (allowing "No-Knock" for destruction exception).	
Arkansas	No Statute—Common Law Applies	Notice Required ARK. STAT. ANN. § 43-414 (1964).
California	Notice Required* CAL. PENAL CODE § 1531 (West Supp. 1969).	Notice Required* CAL. PENAL CODE § 844 (West Supp. 1969).
	* People v. Maddox, 46 Cal. 2d 301, 204 P.2d 6 (1956); People v. Gastelo, 67 Cal. 2d 586, 432 P.2d 706 (1967); People v. Rosales, 68 Cal. 2d 299, 437 P.2d 489 (1968) (allows No-Knock for destruction exception).	
Colorado	No Statute—Common Law Applies	No Statute—Common Law Applies
Connecticut	No Statute—Common Law Applies*	No Statute—Common Law Applies
	* State v. Marino, 152 Conn. 85, 203 A.2d 305 (1964) (allows No-Knock for destruction exception to common-law announcement rule).	
Delaware	No Statute—Common Law Applies*	No Statute—Common Law Applies
	* Dyton v. State, 250 A.2d 383 (1969) (allows No-Knock for destruction exception to common-law announcement rule).	
District of Columbia	Notice Required D.C. CODE ANN. § 25-129(g) (1967) (liquor). D.C. CODE ANN. § 33-414(g) (1967) (narcotics). 18 U.S.C. § 3109 (Supp. IV, 1969).	No Provision—Common Law Applies
	But an annotation to D.C. CODE ANN. § 23-301(6) (1967) states that for search or arrest that the police can break in after an announcement of identity and purpose. There are no exceptions. "Breaking and entering premises without an announcement is clearly illegal and an improper entry renders a subsequent search invalid."	

† The citations listed in the following appendix are illustrative only and in no way are to be considered all-inclusive.

APPENDIX (Continued)

State	Search Warrant	Arrests (with or without warrant)
Florida	Notice Required* FLA. STAT. § 933.09 (1967). * <i>Benefield v. State</i> , 160 So. 2d 706 (1964) (allows No-Knock for destruction exception).	Notice Required FLA. STAT. § 901.19 (1967).
Georgia	Notice Required GA. CODE ANN. § 27-308 (1969). The arrest provision states that the police may use force to break into a building and does not require any announcements prior to the breaking. The new search statute does require an announcement before breaking.	No-Knock Permitted only with warrant GA. CODE ANN. § 27-205 (1969).
Hawaii	No-Knock Permitted if door to house is open. Notice required if door is closed. HAWAII REV. LAWS tit. 37, § 708.37 (1968).	Notice Required HAWAII REV. LAWS tit. 37, § 708.11 (1968).
Idaho	Notice Required IDAHO CODE ANN. § 19-4409 (1948).	Notice Required IDAHO CODE ANN. § 19-611 (1948).
Illinois	No-Knock Permitted ILL. ANN. STAT. ch. 38, § 108-8 (Smith-Hurd 1964). The arrest statute states that no notice or announcement required for arrest but <i>People v. Barbee</i> , 35 Ill. 2d 407, 220 N.E.2d 401 (1966) requires announcement before arrest. The search warrant section concludes that notice is not necessary if constitutional standards (of reasonableness) are met. <i>See also</i> <i>People v. Macias</i> , 39 Ill. 2d 208, 234 N.E.2d 783 (1968); <i>People v. Hartfield</i> , 94 Ill. App. 2d 421, 237 N.E.2d 193 (1968) (allowing No-Knock for destruction exception).	No-Knock Permitted ILL. ANN. STAT. ch. 38, § 107-5(d) (Smith-Hurd 1964).
Indiana	No Statute—Common Law applies* * <i>Hadley v. State</i> , 238 N.E.2d 888, 906 (1968) (allows No-Knock for destruction exception to the common-law rule of announcement).	Notice Required IND. ANN. STAT. § 9-1009 (1956).
Iowa	Notice Required IOWA CODE ANN. § 755.9 (1966).	Notice Required IOWA CODE ANN. § 751.9 (1966).
Kansas	No Statute—Common Law applies	Notice Required KAN. STAT. ANN. § 62-1819 (1964).
Kentucky	No Statute—Common Law applies	Notice Required KY. REV. STAT. §§ 70.077, 70.078 (1969).
Louisiana	No-Knock Permitted LA. CRIM. PRO. CODE ANN. art. 164 (West 1967). The new statute on arrests without warrants is broader now and not limited only to felonies.	Notice Required LA. CRIM. PRO. CODE ANN. art. 224 (West 1967).

APPENDIX (Continued)

State	Search Warrant	Arrests (with or without warrant)
Maine	No Statute—Common Law applies* * <i>State v. Martelle</i> , 252 A.2d 316 (1969) (allows No-Knock as an exception to the common-law rule of announcement. "An officer . . . is bound, on demand to make known his authority, but his omission to do so can do no more than deprive <i>him</i> of the protection which the law throws around its ministers, when in the rightful discharge of their duty.").	No Statute—Common Law applies* No Statute—Common Law applies* (allows No-Knock as an exception to the common-law rule of announcement. "An officer . . . is bound, on demand to make known his authority, but his omission to do so can do no more than deprive <i>him</i> of the protection which the law throws around its ministers, when in the rightful discharge of their duty.").
Maryland	No Statute—Common Law applies* * <i>Henson v. State</i> , 236 Md. 518, 204 A.2d 516 (1969); <i>Waugh v. State</i> , 3 Md. App. 379, 239 A.2d 596 (1968) (allowing destruction exception to the common-law rule of announcement).	No Statute—Common Law applies* No Statute—Common Law applies* (allows No-Knock as an exception to the common-law rule of announcement. "An officer . . . is bound, on demand to make known his authority, but his omission to do so can do no more than deprive <i>him</i> of the protection which the law throws around its ministers, when in the rightful discharge of their duty.").
Massachusetts	No Statute—Common Law applies* * <i>Commonwealth v. Rossetti</i> , 211 N.E.2d 658, 665 (1965) (Court referred to No-Knock for destruction exception to the common-law rule of announcement in dictum.)	No Statute—Common Law applies* No Statute—Common Law applies* (allows No-Knock as an exception to the common-law rule of announcement. "An officer . . . is bound, on demand to make known his authority, but his omission to do so can do no more than deprive <i>him</i> of the protection which the law throws around its ministers, when in the rightful discharge of their duty.").
Michigan	Notice Required MICH. STAT. ANN. § 28.1259(6) (Cum. Supp. 1970). The search provision had not been included previously.	Notice Required MICH. STAT. ANN. § 28.880 (Cum. Supp. 1970). The search provision had not been included previously.
Minnesota	No Statute—Common Law applies* * <i>State v. Parker</i> , 283 Minn. 127, 166 N.W.2d 347 (1969).	Notice Required MINN. STAT. ANN. §§ 639.33, 639.34 (1965). No Statute—Common Law applies* (allows No-Knock as an exception to the common-law rule of announcement. "An officer . . . is bound, on demand to make known his authority, but his omission to do so can do no more than deprive <i>him</i> of the protection which the law throws around its ministers, when in the rightful discharge of their duty.").
Mississippi	No Statute—Common Law applies	Notice Required MISS. CODE ANN. § 2472 (1957).
Missouri	No-Knock Permitted MO. REV. STAT. § 542.390 (1959).	Notice Required MO. REV. STAT. § 544.200 (1959).
Montana	No-Knock Permitted* MONT. REV. CODES ANN. § 95-709 (1969).	Notice Required* MONT. REV. CODES ANN. § 95-901 (1969). * The general arrest statute and the search statute give the right to break in without the requirement of notice. The arrest with or without warrant statutes require notice unless notice would jeopardize the arrest.
Nebraska	No-Knock Permitted* NEB. REV. STAT. § 29-411 (1965).	No-Knock Permitted* NEB. REV. STAT. § 29-411 (1965). * "Warrants: execution; powers of officer; direction for executing. In executing a warrant for the arrest of a person charged with an offense, or a search warrant, or when authorized to make an arrest for a felony without a warrant, the officer may break open any outer or inner door or window of a dwelling house or other building, if, after notice of his office and purpose, he is refused admittance; or without giving notice of his authority and purpose, if the judge or magistrate issuing search warrant has inserted a direction therein that the officer executing

APPENDIX (Continued)

State	Search Warrant	Arrests (with or without warrant)
	<i>it shall not be required to give such notice, but the political subdivision from which such officer is elected or appointed shall be liable for all damages to the property in gaining admission. The judge or magistrate may so direct only upon proof under oath, to his satisfaction that the property sought may be easily or quickly destroyed or disposed of, or that danger to the life or limb of the officer or another may result, if such notice be given; but this section is not intended to authorize any officer executing a search warrant to enter any house or building not described in the warrant."</i>	
Nevada	Notice Required NEV. REV. STAT. § 179.090 (1967).	Notice Required NEV. REV. STAT. § 171.138 (1967).
New Hampshire	No Statute—Common Law applies	No Statute—Common Law applies
New Jersey	No Statute—Common Law applies*	No Statute—Common Law applies*
	* State v. Juliano, 97 N.J. Super. 25, 234 A.2d 236 (1967) (allows No-Knock for destruction exception to common-law rule of announcement).	
New Mexico	No Statute—Common Law applies	No Statute—Common Law applies
New York	No-Knock Permitted* N.Y. CODE CRIM. PROC. § 799 (McKinney Supp. 1969).	Notice Required N.Y. CODE CRIM. PROC. §§ 175 (arrest with warrant), 178 (arrest without warrant) (McKinney Supp. 1969).
	* "The officer may break open an outer or inner door or window of a building, or any part of the building, or anything therein, to execute the warrant, (a) if, after notice of his authority and purpose, he be refused admittance, or (b) without notice of his authority and purpose, if the judge, justice, or magistrate issuing the warrant has inserted a direction therein that the officer executing it shall not be required to give such notice. The judge, justice, or magistrate may so direct only upon proof under oath, to his satisfaction, that the property sought may be easily and quickly destroyed or disposed of, or that danger to the life or limb of the officer or another may result, if such notice were to be given."	
North Carolina	No Statute—Common Law applies	Notice Required N.C. GEN. STAT. § 15.44 (Cum. Supp. 1969).
North Dakota	No-Knock Permitted if judge so provides N.D. CENT. CODE § 29-29.1-01 (Supp. 1969).	Notice Required N.D. CENT. CODE § 29-06-14 (1960).
Ohio	Notice Required* OHIO REV. CODE § 2935.12 (Anderson 1967).	Notice Required OHIO REV. CODE § 2935.12 (Anderson 1967).
	* United States v. Blank, 251 F. Supp. 166 (N.D. Ohio 1966) and State v. Johnson, 16 Ohio Misc. 278, 240 N.E.2d 574 (1968) (allowing No-Knock for destruction exception).	

APPENDIX (Continued)

State	Search Warrant	Arrests (with or without warrant)
Oklahoma	Notice Required OKLA. STAT. ANN. tit. 22, § 1228 (Supp. 1969).	Notice Required OKLA. STAT. ANN. tit. 22, §§ 194 (arrest with warrant), 197 (arrest without warrant) (Supp. 1969).
Oregon	Notice Required* ORE. REV. STAT. § 141.110 (Supp. 1969).	Notice Required ORE. REV. STAT. §§ 133.290 (arrest with warrant), 133.320 (arrest without warrant) (Supp. 1969).
	* State v. Cortman, 466 P.2d 681, 683 (1968) (allows No-Knock for destruction exception).	
Pennsylvania	No Statute—Common Law applies*	No Statute—Common Law applies.
	* United States <i>ex rel.</i> Manduchi v. Tracy, 350 F.2d 658 (3d Cir.), <i>cert. denied</i> , 382 U.S. 943 (1965) (allowed No-Knock for destruction exception to common-law rule of announcement).	
Rhode Island	No Statute—Common Law applies*	No Statute—Common Law applies.
	* State v. Johnson, 230 A.2d 831 (1967) (allows No-Knock for de- struction exception to common-law rule of announcement).	
South Carolina	No-Knock Permitted S.C. CODE ANN. § 17-257 (1962).	Notice Required S.C. CODE ANN. § 53-198 (1962).
South Dakota	No-Knock Permitted S.D. COMP. LAWS ANN. § 11C2 (1970).	Notice Required S.D. COMP. LAWS ANN. § 23-22-19 (1967).
Tennessee	Notice Required TENN. CODE ANN. § 40.509 (1955).	Notice Required TENN. CODE ANN. § 40.807 (1955).
Texas	No-Knock Permitted TEX. CODE CRIM. PROC. art. 18.18 (1966).	Notice Required TEX. CODE CRIM. PROC. art. 15.25 (1966).
Utah	No-Knock Permitted* UTAH CODE ANN. § 77-54-9 (Supp. 1969).	Notice Required UTAH CODE ANN. 1953, § 77-13-12 (Supp. 1969).

* 1967 Amendment to search warrant provisions reads:
"Officer may break door or window to execute warrant—Authority. The
officer may break open any outer or inner door or window of a house,
or any part of a house or anything therein to execute the warrant:

(1) If, after notice of his authority and purpose, he is refused
admittance; or

(2) Without notice of his authority and purpose, if the judge,
justice, or magistrate issuing the warrant has inserted a direction
therein that the officer executing it shall not be required to give such
notice. The judge, justice, or magistrate may so direct only upon proof
under oath, to his satisfaction, that the property sought is a narcotic,
illegal drug, or other similar substance which may be easily and
quickly destroyed or disposed of, or that danger to the life or limb of
the officer or any other may result, if such notice were to be given."

See also State v. Loudon, 15 Utah 2d 64, 387 P.2d 240 (1963).

APPENDIX (*Continued*)

State	Search Warrant	Arrests (with or without warrant)
Vermont	No-Knock Permitted VT. STAT. ANN. tit. 24, § 302 (1967).	No-Knock Permitted VT. STAT. ANN. tit. 24, § 302 (1967).
Virginia	No Statute—Common Law applies	No Statute—Common Law applies
Washington	No Statute—Common Law applies*	Notice Required* WASH. REV. CODE ANN. § 10.31.040 (Supp. 1969).
	* State v. Young, 76 Wash. 2d 212, 455 P.2d 595 (1969) (allows No-Knock for destruction exception).	
West Virginia	No-Knock Permitted for structures other than a "dwelling" W. VA. CODE ANN. § 62.1A-5 (1966).	No Statute—Common Law applies
Wisconsin	No Statute—Common Law applies	No Statute—Common Law applies
Wyoming	Notice Required	Notice Required for arrest with warrant WYO. STAT. ANN. § 7-165 (1959). No statute for arrest without warrant—Common Law applies

DEPARTMENT OF JUSTICE

ROUTING SLIP

TO:	NAME	DIVISION	BUILDING	ROOM
1.	Mr. John Dean			
2.				
3.				
4.				

☐ SIGNATURE	☐ COMMENT	☐ PER CONVERSATION
☐ APPROVAL	☐ NECESSARY ACTION	☐ AS REQUESTED
☐ SEE ME	☐ NOTE AND RETURN	☐ NOTE AND FILE
☐ RECOMMENDATION	☐ CALL ME	☐ YOUR INFORMATION
☐ ANSWER OR ACKNOWLEDGE ON OR BEFORE _____		
☐ PREPARE REPLY FOR THE SIGNATURE OF _____		

REMARKS

I just sent this up to Congressman Corman, at his request.

FROM:	NAME	BUILDING & ROOM	EXT.	DATE
M. R.	Sonnenreich	1405 I St	128-4644	8/18/70
Reproduced at the Richard Nixon Presidential Library				

The Comprehensive Drug Abuse
Prevention and Control Act of 1970

The Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. 18583, represents a consolidation and modernization of the various Federal enforcement and regulatory laws relating to the control of narcotics, marihuana, and stimulant and depressant drugs. Existing Federal law in this area has been inadequate to cope with the mounting problem of drug abuse in recent years, and in this sense, H.R. 18583 will represent remedial legislation.

The bill establishes a coordinated system of drug classification which places drugs in any one of five schedules, depending on their degree of abuse potential and medical use. Provisions are also made to streamline the procedures which enable the Attorney General to bring new drugs under control or move drugs within the various schedules.

A closed regulatory system, which requires annual registration, record keeping, and inventories of controlled substance stocks, is established for the legitimate manufacture, distribution, and dispensing of controlled substances. Production quotas are imposed on the manufacture of certain substances, and the flexibility of the drug scheduling scheme will permit these quotas to be imposed on the manufacture of other drugs should the need arise.

H.R. 18583 further provides a new penalty scheme for offenses relating to narcotics, marihuana, and stimulant and

and depressant drugs. With but one exception, no minimum mandatory sentences are provided for. Drug users are distinguished from drug traffickers in terms of the severity of the sentences imposed. Simple possession is treated as a misdemeanor with special provisions for first offender treatment in the event it is the defendant's first conviction for an offense relating to controlled substances. Special provisions are also made for imposing severe minimum mandatory sentences on those persons who traffic in these drugs for profit as part of a continuing criminal enterprise.

The bill also provides new tools for special agents of the Bureau of Narcotics and Dangerous Drugs to aid them in the effective enforcement of the Act. Authorization to execute search warrants without notice of authority and purpose, upon approval of a judge or magistrate, will permit the seizure of evidence which heretofore has been destroyed or disposed of. New provisions relating to administrative inspection warrants will permit inspections of premises where drugs are manufactured or distributed if the person in charge refuses to consent or there is not imminent danger to the public health or safety. New forfeiture provisions will permit the seizure of the vehicles used by drug traffickers to transport and sell illicit drugs.

The bill further imposes new restrictions on the importation and exportation of controlled substances in order to

insure that the drugs will be used for legitimate purposes and not diverted into illicit channels. Such new controls are needed to help in shutting down the flow of these drugs from abroad, while at the same time allowing the Federal Government to better monitor the traffic in general.

August 18, 1970

MEMORANDUM FOR STAN EBNER

Re: No-Knock

In preparing floor speeches for the forthcoming House debate on the drug bill, the attached document might serve some purpose. Jeff Donfeld brought it to my attention. I don't know anything about the Hudson Institute, but if they are a "big time" group, the position might be helpful. I pass this along for any use you can make of it.

John Dean

U. S. Aids France in Drug Push

By MILT FREUDENHEIM

PARIS (CDN)—American and French narcotics agents have seized heroin worth \$3.6 million since late June in their drive to shut off French sources that supply 80 per cent of the heroin reaching the U. S.

Amid opposition needling alleging politically motivated delays and coverups, French authorities increased their drug law enforcement manpower in southern France in July from 9 agents to 25.

Interior Minister Raymond Marcellin has promised 25 more agents for October to scour the French Riviera for the elusive heroin laboratories.

In 19 years of looking, French police managed to uncover only 13 secret laboratories, including 2 last year and none so far this year.

But with the new French agents, John T. Cusack, chief U. S. narcotics agent for Europe, says enforcement prospects "couldn't be better."

U. S. Pressure

He denied as "invention" the charges in two Paris news weeklies that Marcellin began to move only under pressure from U. S. Attorney General Mitchell.

The charges published in the satirical but well-informed *Le Canard Enchaîné* and the influential leftist *Nouvelle Observateur* said Marcellin's quick visit to Mitchell in Washington three weeks ago was made under duress.

Canard said that U. S. Ambassador Arthur K. Watson had sent Washington reports on the Marseilles heroin racket that the paper charged Marcellin's ministry had been sitting on.

Insinuating that the reports told of "high political protection coming from personalities of the government (Gaullist) party," Canard alleged that Watson's predecessor, R. Sargent Shriver, had "discreetly stifled" them to avoid embarrassing French leaders.

U. S. embassy officials deny that any reports alleging French government protection of the heroin racket were received by Shriver or Watson.

The embassy denial left open whether local corruption in the Marseilles area had hampered narcotics enforcement.

Nouvelle Observateur said Marcellin's ministry had received reports from Marseilles police officials more than a year ago detailing the big-time heroin mobsters and sites of clandestine laboratories where the morphine base smuggled from Turkey is refined into heroin.

"In order to act," *Observateur* charged, "the Marseilles police awaited the orders of the Interior Ministry. Although some arrests were made recently — in order to prove otherwise — it seems in fact that they are still waiting."

PRESERVATION COPY

Mr. Ingersoll, distinguished guests, and members of Special Agent Class #10.

I have had the opportunity and occasion to graduate no less than five times. Accordingly, I have had some experience at sitting where you are sitting. If I have any one conclusion to draw from that experience it is that I cannot tell you who addressed the graduation class nor can I tell you what he said.

I have asked others if they can remember what was said at their graduation and with few exceptions I find that my own experience is not an uncommon one. So today you are not going to hear great rhetoric, grand platitudes or a locker room type pep talk to charge you up before you go into the field. You are not going to hear it because it is a waste of your time and mine. Instead, I would like to take just a few minutes to share some of my own observations about the work you have commenced and the mission you have undertaken.

First I would like to share a few observations about BNDD.

-- BNDD is the newest of the Federal law enforcement agencies. What does this mean? Well, it means that you have an unusual opportunity to grow as BNDD grows. It also means that you have a responsibility to assist in building a strong foundation that has already been started for the Bureau -- a foundation that will support an agency charged with a vital mission.

-- BNDD is the lead agency within the Federal establishment for enforcing drug laws. Because of the dimensions of your mission and because of the critical nature of the problem you are dealing with, you must be the best law enforcement officers in the business. Remember that your effort will not be ^{only} important for the effectiveness of the Federal effort, but also your effort and effectiveness will also serve as a model for state and local efforts.

-- BNDD is also fortunate to have Jack Ingersoll as its Director. Back in 1968 when the prior Administration sent the reorganization plan to Congress to create BNDD, I worked with a number of Republican Congressmen who were strongly opposed to the reorganization. There was a sincere concern that placing drug enforcement in the Department of Justice would result in a weakening of the Federal effort. Many Republicans were sure that a Democratic appointee would view the drug problem as purely ^a social and medical problem. Well, Director Ingersoll was appointed by the Democrats -- and obviously he has been reappointed by the Republicans. This is a tribute to his professionalism in building BNDD and his ~~straight~~ strength in enforcing the Federal drug laws.

I need not tell you of the innovation and programs he has developed -- you should be well aware of them, having just completed your training school.

I might also note for those of you who haven't made this observation yourself -- BNDD has some of the most attractive secretaries in Washington. However, I'm not sure whether the Director can claim credit for this fact or not.

I have enjoyed working with the Director the last few years and have witnessed his tremendous ability to lead the Bureau. We have worked most closely on the proposed new revisions in the Federal drug laws. Hopefully this important legislation will be enacted by Congress in the coming weeks. Its adoption will provide you with many new and necessary legal tools for carrying on your law enforcement and regulatory activities. Its adoption will also be a tribute to the Director and this Bureau which has been responsible for its development, presentation to the Congress through repeated public and private appearances. It will, of course, be your responsibility to implement it.

Gentlemen, the job before you is enormous. The spread of drug abuse throughout our culture has created a law enforcement problem that transcends what is routinely considered to be law enforcement. In a large measure, the problem you are dealing with is both psychological and sociological. Aside from your most important function of halting the illicit traffic in these drugs, you will also be cast into the limelight surrounding all the social issues confronting our nation today. The drug culture we are experiencing is in many ways symptomatic of the disenchantment and rejection of our established values by the youth of this country. The profession you have chosen will require you to answer some difficult questions. For example,

~~3200~~
As graduates of the ~~Executive Protective Service~~
~~Recruit Training Course~~, you stand at the threshold
of achievement.

You have been selected because of your honesty,
your integrity and your desire to ~~suppress crime~~.
And you have been trained to do this to the best of
your ability.

Yours is not a small responsibility. Rather it is a
great responsibility not only to the people of our
country, but also to people around the world.

It is a tribute that the law enforcement officer is
not asked if he can do the job. It is presumed that
he can. I am confident that you can do the job and
do it well.

James J. Rowley

James J. Rowley, Director
U.S. Secret Service

good luck & congratulations.

Not with to deny prob-

I had dinner while in San Clark with a Dr. and his wife. ~~The~~ During the conversation he told me his 21 year old daughter had become a ~~hippy~~ hippie; that she had fallen in love with a man who used drugs and had recently started dealing in drugs. She had come to her father a few days earlier and ask him for \$500.00. He ~~is~~ knew what she wanted the money for - for her boy friend to make a buy from a Mexican contact so that he could make some money on the resale. He did give her the money, ~~but~~ he asked me - what should he do. Should he turn his daughter in to the police - how ~~can~~ could he divorce her from this activity - ~~is~~ How could he - as a Dr. who knew the medical effect of drugs - explain this to her -

Further, you are going to be asked such questions - and even tougher questions. Your answer must be good answers, but many of the questions ~~is~~ just can't be answered. Indeed, your job is impossible.

The Bureau of Narcotics and Dangerous Drugs most significantly represents the Federal Government's crucial responsibility in providing leadership and direction towards the removal of drug addiction and drug abuse from our society. Gentlemen, you must be aware that these substances threaten, in a most profound way, the very fabric of American society. History will record the results of the effort upon which each of you is about to embark. To fail is unthinkable. To succeed, you will be severely tested. But I am confident you will meet that test; I am confident you will succeed. For, in the longrun we have no alternative -- not if America is to survive as a great nation, not if we are to survive as a great people. Not, in fact, if Western civilization, as we know it is to survive at all.

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April 20, 1970

The Honorable John W. Dean, III
Associate Deputy Attorney General
Department of Justice
Washington, D.C.

Dear John,

Enclosed is a copy of the article from the Congressional Record which carried the poem, Psychedelirium Tremens. In its own way, it is quite effective, and I hope you can make good use of it.

I enjoyed being on the Program with you and Mike and will look forward to seeing you again.

Very truly yours,

John H. Wood
General Attorney

JHW:la
Enclosure

GEORGE J. GOTTWALD, JR., WHO DIED IN THE SERVICE OF HIS COUNTRY

A Soldier who falls in the line of duty, deserves our humble respect and profound gratitude.

George J. Gottwald, Junior, was such a soldier.

His Spirit and Courage, His Dedication to duty, place him among the hallowed ranks of Patriotic Americans whose unflinching Love of Country and Loyalty to their Comrades in Arms; have since the birth of our Country, secured the blessings of Liberty for All Americans.

Specialist Fourth Class George Gottwald never planned great battles nor did he lead an Army in the field. He did more than that: He gave his life for his Country.

There is no greater Sacrifice.

There can be no honor paid to his Memory that can fully express how much we revere it. Yet, the Cecil W. Fogg Post of the American Legion, of Hyde Park, Massachusetts, and their Affiliates; is doing what it can by Dedicating the George J. Gottwald, Jr., Square, to the memory of this brave boy.

The Legions National Commander William C. Doyle has said of the Patriotism exemplified by George J. Gottwald, Jr.:

"It is a Respect for the Rights of our Fellow Man. It is a Concern for Freedom of Man, as our God given Rights; but a recognition also that every Right carries with it an accompanying Responsibility."

George Gottwald did not shirk that Responsibility.

By his heroic act he has upheld the Honor and Tradition of the Military Services of the United States of America.

May every Bostonian, as he passes through the George J. Gottwald, Jr., Square, remember the Man for whom it is named and Soldiers like him who have Sacrificed in order that others can enjoy the blessings of Democracy and Freedom.

My heart goes out to Family and Friends assembled at this Dedication.

I salute the Cecil W. Fogg Post and their Affiliates the V.F.W. All Boston Post of Roslindale, the William Doyle and Irving K. Adams Post of the Legion and the Boston Fire Department Band for their participation at this worthy, patriotic ceremony.

It is my prayer that this fine American will not have died in vain—that through his heroism we have been brought a little closer to a just and lasting peace.

JOHN W. MCCORMACK,

Speaker, U.S. House of Representatives.

(By cable.)

Read by Master of Ceremonies Peter L. Caparelli at the opening of the Dedication Ceremonies at the George J. Gottwald, Jr., Square, Sunday, March 23rd at 2:15 p.m.

Born: Boston, Mass.

Educated: Boston Public Schools.

Parish: St. John Chrysostom.

Enlisted: U.S. Army, October 1966.

Parents: George J. and Caroline Gottwald, 6 Metropolitan Avenue, Roslindale.

Specialist Fourth Class George J. Gottwald, Jr., volunteered to lead his Platoon on a hazardous mission in Viet Nam and was intercepted, intermittently, by enemy machine gun fire, while crawling to the aid of a wounded Medic.

Wounded three times by enemy machine gun fire, he remained undaunted—and fell mortally wounded under heavy concentrated enemy fire in his fourth attempt to reach the side of his Comrade.

Posthumously awarded the Silver Star by direction of the President of the United States, March 8, 1968.

This Memorial Tribute published by his Brothers and Sisters, Frederick, William, Richard, Thomas, Edward, Caroline, Jean and Denise Gottwald and distributed in commemoration of the George J. Gottwald, Jr., Square.

Dedication: Sunday, March 23, 1969, 2 p.m.

at the intersection of Washington Street and Metropolitan Avenue, by the Cecil W. Fogg American Legion Post and Affiliates.

PSYCHEDELIRIUM TREMENS: POEM BY JANE GOODSSELL

HON. LEE METCALF

OF MONTANA

IN THE SENATE OF THE UNITED STATES

Friday, April 18, 1969

Mr. METCALF. Mr. President, the Senators Neuberger, first Dick, then his gracious widow, Maurine, demonstrated their ability with words. The ability to write is a Neuberger family trait. Dick's sister, Jane Goodsell, is at home with poetry or prose. Recently I read her "Psychedelirium Tremens," a light treatment of a serious subject.

I ask unanimous consent that her poem be printed in the RECORD.

There being no objection the poem was ordered to be printed in the RECORD, as follows:

PSYCHEDELIRIUM TREMENS

Remember when hippie meant big in the hips,
And a trip involved travel in cars, planes, and ships?
When pot was a vessel for cooking things in,
And hooked was what Grandmother's rug might have been?
When fix was a verb that meant mend or repair,
And be-in meant simply existing somewhere?
When neat meant well organized, tidy and clean,
And grass was a ground-cover, normally green?
When lights and not people were switched on and off,
And the pill might have been what you took for a cough?
When camp meant to quarter outdoors in a tent,
And pop was what the weasel went?
When groovy meant furrowed with channels and hollows,
And birds were winged creatures, like robins and swallows?
When fuzz was a substance that's fluffy like lint,
And bread came from bakeries, not from the mint?
When square meant a 90-degree angled form,
And cool was a temperature not quite warm?
When roll meant a bun, and rock was a stone,
And hang-up was something you did to a phone?
When chicken meant poultry, and bag meant a sack,
And junk, trashy cast-offs and old bric-a-brac?
When jam was preserves that you spread on your bread,
And crazy meant balmy, not right in the head?
When cat was a feline, a kitten grown up,
And tea was a liquid you drank from a cup?
When swinger was someone who swings in a swing,
And pad was a soft sort of cushiony thing?
When way out meant distant and far, far away,
And a man couldn't sue you for calling him gay?
When dig meant to shovel and spade in the dirt,
And put-on was what you would do with a shirt?
When tough described meat too unyielding to chew,

And making a scene was a rude thing to do? Words once so sensible, sober, and serious, Are making the freak scene like psychedelirious.

It's groovy, man, groovy, but English it's not, Methinks that the language has gone straight to pot.

JANE GOODSSELL.

TRIBUTE TO COUNCILMAN JULIUS LENHART, OF MCKEESPORT, PA.

HON. JOSEPH M. GAYDOS

OF PENNSYLVANIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, April 17, 1969

Mr. GAYDOS. Mr. Speaker, during these times of civil unrest, turmoil, and in some instances, outright revolt against law and order and the fundamental precepts on which this great country was founded, it is most important that significant activities and affairs receive due recognition in order that all Americans will not be misunderstood and unjustly criticized. Fortunately, there are still individuals and associations who maintain high principles, social obligation, and dedication to what is good in America. One of these citizens is Councilman Julius Lenhart, of McKeesport, Pa., who recently received the first Man of the Year Award from the McKeesport Hungarian Social Club, a nationality fraternal organization that has affected the lives of many McKeesporters and numbers among those associations that love America.

On Saturday, April 12, 1969, the McKeesport Hungarian Social Club honored an outstanding public servant and community leader as the recipient of the club's first Man of the Year Award. A special banquet provided the setting for the presentation of a distinguished service plaque to Councilman Lenhart, which honored his social, political, cultural and charitable activities and accomplishments in and among the citizenry of McKeesport and the surrounding area.

Outstanding dignitaries attended this auspicious occasion to honor Councilman Lenhart. Mayor Albert Elko of the city of McKeesport delivered the official greetings and the president of the Hungarian Social Club, Steve Breda, presented an address of welcome. The well known and very popular bishop of the Free Hungarian Reform Church, Bishop Lewis J. Nagy, served as toastmaster and the Hungarian Social Club vice president, Alec S. Meszar, was also present. The national secretary of the William Penn Fraternal Association, Albert J. Stelkovich, was present and participated in the presentation program. Invocation was delivered by Basil Shereghy and convocation by Rev. Dr. Laszlo Brezoviczy.

Councilman Lenhart has distinguished himself in the city of McKeesport and the metropolitan area as a dedicated public official who has been responsible for innovating the entire McKeesport recreation program. The youth of McKeesport now enjoy unprecedented athletic facilities which have stimulated a rededication to athletic activities of all kinds including baseball, football, soccer,

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The Honorable John W. Dean, III
Associate Deputy Attorney General
Department of Justice
Washington, D.C.

CHAPTER II—BUREAU OF NARCOTICS AND DANGEROUS DRUGS, DEPARTMENT OF JUSTICE

- Part*
- 301 Cooperation with States.
 - 302 Importation and exportation of narcotic drugs.
 - 303 Opium poppies.
 - 304 [Reserved]
 - 305 Opiates.
 - 306 Surrender of heroin.
 - 307 Manufacturing of narcotic drugs.
 - 308 [Reserved]
 - 315 Enforcement of the Drug Abuse Control Amendments of 1965 of the Federal Food, Drug, and Cosmetic Act.
 - 316 Administrative functions, practices, and procedures.
 - 319 Habit-forming drugs.
 - 320 Depressant and stimulant drugs; definitions, procedural and interpretative regulations.
 - 330 Seizure, forfeiture, and disposition of vessels, vehicles, and aircraft for domestic narcotic and marihuana violations.

CROSS REFERENCES: Application and enforcement of the Harrison Narcotic Act: See Panama Canal, 35 CFR Part 65.

Bureau of Customs, Department of the Treasury: See Customs Duties, 19 CFR Chapter I.
Manufacture of opium for smoking purposes under the act of January 17, 1914: See Internal Revenue, 26 CFR Part 150.

Regulations under the Harrison Narcotic Law, as amended: See Internal Revenue, 26 CFR Part 151.

Regulations under the Marihuana Tax Act of 1937: See Internal Revenue, 26 CFR Part 152.

Regulations of the Public Health Service, Department of Health, Education, and Welfare, applying to narcotic addicts: See Public Health, 42 CFR Part 33.

NOTE: Other regulations issued by the Department of Justice appear in Title 4, Title 8, Title 28.

PART 301—COOPERATION WITH STATES

- Sec.
301.1 State or municipal prosecutions.
301.2 Attendance of officers.
301.3 Hearings before licensing boards or other State agencies having power to suspend or revoke licenses.
301.4 General.

AUTHORITY: The provisions of this Part 301 issued under sec. 8, 46 Stat. 587; 21 U.S.C. 198.

SOURCE: The provisions of this Part 301 appear at 33 F.R. 14818, Oct. 3, 1968, unless otherwise noted.

§ 301.1 State or municipal prosecutions.

The Director of the Bureau of Narcotics and Dangerous Drugs, hereinafter referred to as "Director," may furnish to State or municipal prosecuting officers a report or statement of such information, obtained from time to time by the Bureau of Narcotics and Dangerous Drugs concerning a violation or suspected violation of narcotic laws, as the Director may deem cognizable by the said prosecuting officers for further investigation or prosecution in their respective jurisdictions.

§ 301.2 Attendance of officers.

The Director may direct the attendance of any officer, agent, or employee of the Bureau of Narcotics and Dangerous Drugs who may be in possession of pertinent information, to testify as a witness in any inquiry or proceeding instituted by authority of law by or before a grand jury, municipal magistrate, or State court, where the direct object of such inquiry or proceeding is to determine whether there has been, in a particular case, a violation of the State law or municipal ordinance relating to drugs. The Director may also direct any such officer, agent, or employee to produce for examination at said inquiry or proceeding such record of the Bureau of Narcotics and Dangerous Drugs or copy of any part thereof as the Director may deem pertinent to the particular case. The officer, agent, or employee so producing any permanent record of said Bureau for examination shall not relinquish custody or control thereof but, immediately upon conclusion of the inquiry or proceeding, shall promptly return the record to its appropriate official repository.

§ 301.3 Hearings before licensing boards or other State agencies having power to suspend or revoke licenses.

The Director may furnish to State licensing boards or other State agencies authorized by law to revoke or suspend licenses to practice a profession, or engage in a trade, in the course of which narcotic drugs are possessed, controlled, or dispensed; or to any State board, officer, or agency authorized by law to grant, suspend, or revoke any license or permit when, in the exercise of said authority, the narcotic drug addiction of the applicant, licensee, or permittee, or his conviction of a violation of any law relating to narcotic drugs, may have a material bearing upon the granting, withholding, suspension, or revocation of said license or permit, such information in the possession of the Bureau of Narcotics and Dangerous Drugs as the Director may deem appropriate to the enforcement of any State law or regulation or municipal ordinance relating to the granting, withholding, suspension, or revocation of State licenses or permits: *Provided*, That no information shall be furnished with respect to any case in which an offer in compromise has been accepted under authority of section 7122—Internal Revenue Code (26 U.S.C. 7122), unless such case involves the reported narcotic drug addiction of a person who is registered or qualified for registration under 26 U.S.C. 4701-4707, 4731-4735, 4771, 4774, 4721-4726, 4731-4736, or unless the information is requested in a particular case by such State licensing board or State agency or duly qualified representative thereof, for use in the enforcement of any State law or regulation or municipal ordinance relating to the granting, withholding, suspension, or revocation of State licenses. The Director may also direct the attendance, as a witness, in hearings held by such boards or agencies, of any officer, agent, or employee of the Bureau of Narcotics and Dangerous Drugs, and the production of records or copies thereof, subject to the same limitations, so far as applicable, as provided in § 301.2 with respect to an inquiry or proceeding instituted by or before a grand jury, municipal magistrate, or State court.

§ 301.4 General.

(a) Nothing contained in this part shall be construed to authorize the Director to furnish information, or to di-

rect the attendance of any officer, agent, or employee to testify, relative to the possession of or traffic in drugs in any case where the litigants are private parties or where the object of the prospective inquiry, proceeding, or hearing is other than that indicated in §§ 301.1-301.3.

(b) The Director shall exercise sound discretion in executing the authority granted in this part to the end that no investigation being conducted at any time under his direct or indirect supervision shall be prejudiced by the premature disclosure of facts developed by the investigation. The Director shall solicit the cooperation of appropriate State and municipal officers in arranging to execute the authority granted in this part in any given case, so that there shall be a minimum of interference with or interruption to the investigative duties of any officer or agent of the Bureau of Narcotics and Dangerous Drugs or with the duty of such officer or agent to present properly and promptly to Federal prosecuting attorneys, grand juries, and courts such cases as the Director may direct.

PART 302—IMPORTATION AND EXPORTATION OF NARCOTIC DRUGS

Subpart A—Imports

- Sec.
302.1 Importation.
302.2 Who may import.
302.3 Application for permission to import.
302.4 Alternative foreign ports.
302.5 Import permit.
302.6 Preparation of import permit.
302.7 Effect of permit.
302.8 Shipments in greater or less amount than that authorized.
302.9 Cancellation of permit.
302.10 Disposition of copies of permit.
302.12 Examination of shipment by customs officer.
302.13 Duties of appraiser.
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302.15 Foreign trade zones.
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Subpart B—Exports

- 302.17 Exportation.
302.18 Application for export permit.
302.19 Foreign import license or permit to be submitted.
302.20 Additional information.
302.21 Disposition of copies of export permit.
302.22 Shipment from interior port.
302.23 Special conditions relative to export permits.
302.24 Expiration date.
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- Sec.
302.26 Exportation to countries which have exceeded estimate.
302.27 Records required of exporter.
Subpart C—In-Transit Shipments
302.28 In-transit shipments.
Subpart D—Special Coca Leaves
302.29 Importation of special coca leaves.
302.30 Information required of prospective importer.
302.31 Matters to be considered in granting permit.
302.32 Approval or disapproval of application.
302.33 Application for permit to import.
302.34 Registration of importer.
302.35 Allotment for calendar year not importable in succeeding year.
302.36 Issuance of permits.
302.37 Withdrawal from customs custody.
302.38 Manufacturing operation.
302.39 Residue.
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302.41 Director's representative to have access to factory.
302.42 Reports to Director.
302.43 Discontinuance of business.
302.44 Cancellation of permit.
302.45 Compliance with act of December 17, 1914, as amended.
302.46 Returns required.
302.47 Report of importations.
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302.49 Reports of manufacture.
302.50 Report of residues destroyed.
302.51 Summary.

Subpart E—General

- 302.52 Importation or exportation by mail prohibited.
302.53 Medical stores on vessels.
302.54 Drugs seized to be delivered to collector of customs.
302.55 Forwarding drugs to Drugs Disposal Committee.
302.56 Disposition of forfeited drugs.
302.57 [Reserved]
302.58 Permits issued prior to effective date of regulations.
302.59 Regulations subject to provisions of other pertinent laws and regulations.

SOURCE: The provisions of this Part 302 appear at 33 F.R. 14819, Oct. 3, 1968, unless otherwise noted.

Subpart A—Imports

AUTHORITY: The provisions of this Subpart A issued under sec. 2, 35 Stat. 614, as amended; 21 U.S.C. 173.

§ 302.1 Importation.

Crude opium and coca leaves may only be imported under formal permit issued by the Director, Bureau of Narcotics and Dangerous Drugs (referred to in this

part as the Director) pursuant to a duly executed application therefor, and after a determination by said Director that the quantity of crude opium or coca leaves requested in the application is necessary to provide for, and will be applied to, medical and legitimate uses only. An exception to so much of this rule as requires a formal permit may be made in the case of an emergency which, in the judgment of the Director, so affects the welfare of all or a large proportion of the population as to justify such extraordinary action. No permit shall be granted for the importation of opium to be manufactured into heroin, its salts, derivatives, or preparations. No permit shall be granted for the importation of opium unless such opium has been produced in a country permitted such production by, and which has become a Party to, the 1953 Opium Protocol.

CROSS REFERENCE: For importation of narcotic drugs for scientific purposes only see § 307.151 of this chapter.

§ 302.2 Who may import.

In exercising the powers and discharging the duties conferred and imposed upon him by the act with respect to the importation of crude opium and coca leaves, the Director shall take such action as in his opinion will effectuate the intent and purpose of the act; and pursuant to this policy, in determining whether any applicant shall be permitted to import such crude opium and coca leaves, the Director shall consider the character and standing of the applicant, his production facilities and trade connections, whether there is reasonable probability that he will apply all crude opium and coca leaves imported and narcotic drugs manufactured by him to medical and legitimate purposes, whether he may serve the public interests by lowering costs or improving quality of narcotic drugs by the use of improved methods, or any other factors which the Director deems appropriate to consider in carrying out the policy mentioned. In the case of new applicants the Director shall also consider whether the allotments to them of shares in the amount of crude opium and coca leaves determined by him to be necessary for medical and legitimate uses would probably have the effect of so reducing or rendering uncertain the supply of crude opium and coca leaves available from year to year to manufacturers already engaged in the manufacture of narcotic

drugs as to endanger the efficient administration of the Narcotic Drugs Import and Export Act.

§ 302.3 Application for permission to import.

Application for permission to import crude opium or coca leaves shall be made under oath on a form provided by the Department of Justice and forwarded to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. The application shall show, in the spaces provided thereon, the name of the crude material desired to be imported (i. e., crude opium or coca leaves), the number of bales or cases of such crude material, the maximum total pounds of such material, the total tentative allotment to the importer of such crude material for the current calendar year, the total number of pounds of said allotment for which permits have previously been issued, and the total quantity of crude material actually imported during the current year to date. Information under the three subheads last mentioned need only be shown with respect to the particular crude drug for which application for permission to import is being made. The application shall also show the following: The name and address of the consignor, if known at the time application is submitted, but if unknown at that time, the fact should be indicated and the name and address afterwards furnished to the Director as soon as ascertained by the importer; the foreign port of exportation (i. e., the place where the article will begin its journey of exportation to the United States); the port of entry into the United States; the latest date said shipment will leave said foreign port; and the stock on hand of the kind of crude drug desired to be imported under the respective subheads provided. If the application is executed and forwarded before the 15th day of a given month the stock on hand may be shown as of the last day of the penultimate preceding month, but if the application is executed and forwarded on or after the 15th day of a given month the stock on hand must be shown as of the last day of the month immediately preceding.

§ 302.4 Alternative foreign ports.

If desired, alternative foreign ports of exportation within the same country may be indicated upon the application, thus, (a) Calcutta, (b) Bombay. If a formal

permit is issued pursuant to such application it will bear the names of the two ports in the order given in the application and will authorize shipment from either port. Alternate ports in different countries will not be authorized in the same permit.

§ 302.5 Import permit.

The import permit shall be prepared in quintuplicate upon a form which has been approved by the Director, but such permit shall not be valid unless signed by the Director.

§ 302.6 Preparation of import permit.

Import permits shall be serially numbered, the five copies of a given permit all to bear the serial number of that permit. Each copy of the permit shall have printed or stamped thereon the disposition to be made thereof. Each permit shall bear a notation to the effect that the Director is satisfied that the consignment proposed to be imported is required for legitimate purposes. Each permit shall also be dated and shall certify that the importer named thereon is thereby permitted under the provisions of the Narcotic Drugs Import and Export Act as amended, to import, through the port named, one shipment of not to exceed the specified quantity of crude opium or coca leaves, as the case may be, shipment to be made from a stated port before a specified date. All copies of import permits shall bear the signature of the Director or his delegate, and facsimiles of signatures shall not be used. All permits issued shall be entered in a register kept by the Director for that purpose. No permit shall be altered or changed by any person after being signed by the Director, and any change or alteration upon the face of any permit, after it shall have been signed by the Director, shall render it void and of no effect. Permits are not transferable.

§ 302.7 Effect of permit.

A permit duly signed and issued shall be authority to import, by the importer named thereon, one shipment only of not to exceed the maximum quantity of crude opium or coca leaves, as the case may be, specified on the permit, from a specified foreign port of export (see §§ 302.3, 302.4), said shipment to be made on or before the date indicated for that purpose upon the permit. This date may, in the discretion of the Director correspond with the date given on the application on the line labeled "Latest date

shipment will leave above foreign port," but such date shall not be later than 4 months from the date permit is issued unless, for good cause shown, the Director allows a longer period within which to make the shipment and so specifies on the permit. The maximum quantity of crude opium or coca leaves shall be stated on the permit in terms of pounds.

§ 302.8 Shipments in greater or less amount than that authorized.

(a) If the shipment made under the permit is greater than the maximum amount authorized to be imported under the permit as determined at the weighing by the customs officer, such difference shall be seized and forfeited to the Government.

(b) If the shipment made under the permit is less than the maximum amount authorized to be imported under the permit as determined at the weighing by the customs officer, such difference, when ascertained by the Director shall be recredited to the tentative allotment against which the quantity covered by the permit was charged, and the balance of any such tentative allotment with any such recredits will remain available to the importer to whom made (unless previously revoked in whole or in part) for importations pursuant to such permit or permits as are requested and issued during the remainder of the calendar year to which the allotment is applicable. No permit shall be issued for importation of a quantity of crude opium or coca leaves as a charge against the tentative allotment for a given calendar year, after the close of such calendar year, unless for good cause shown, the Director decides to make an exception in a proper case.

§ 302.9 Cancellation of permit.

A permit may be canceled after being issued, at the request of the importer, provided no shipment has been made thereunder. In the event that a permit is lost, the Director may upon the production by the importer of satisfactory proof, by affidavit or otherwise, issue a duplicate permit. Nothing in this subpart shall affect the right, hereby reserved by the Director, to cancel a permit at any time for proper cause.

§ 302.10 Disposition of copies of permit.

If it is decided to approve an application for permission to import crude opium or coca leaves, an import permit

shall be prepared in quintuplicate, each copy of which shall be signed by the Director. The five copies of each permit are designated respectively as original, duplicate, triplicate, quadruplicate, quintuplicate. After being signed these copies shall be distributed and shall serve purposes as follows:

(a) The original copy, together with the quintuplicate copy, shall be transmitted to the importer, who will retain the quintuplicate copy on file as his record of authority for the importation, and he shall transmit the original copy of the permit to the foreign exporter. The foreign exporter will submit the original copy of the permit to the proper governmental authority in the exporting country, if required as a prerequisite to the issuance of an export authorization. This copy of the permit will accompany the shipment. Upon arrival of the imported merchandise the collector of customs at the port of entry will forward the original copy of the permit with the bill of lading to the appraiser for the port, who, after appraising the merchandise, will return the original copy of the permit to the Director with a report on the reverse side of such original copy, showing the name of the port of importation, date prepared, net quantity and kind, and report of analysis of the merchandise entered.

(b) The duplicate copy shall be forwarded to the proper governmental authorities of the exporting country.

(c) An additional copy shall be forwarded to the collector of customs at the United States port of entry, which shall be the customs port of destination in the case of shipments transported under immediate transportation entries, in order that said collector may compare it with the original copy and the bill of lading upon arrival of the merchandise.

(d) The other copy of the permit shall be retained on file in the office of the Director.

If a discrepancy is noted between corresponding items upon different copies of a permit bearing the same serial number when compared by the United States collector of customs, the officer shall refuse to permit entry of the importation until the facts are communicated to the Director and further instructions are received.

§ 302.12 Examination of shipment by customs officer.

Immediately upon the unloading of crude opium from the importing vessel, the customs officer shall carefully examine the cases or packages, note their condition, seal the packages, and if the port of importation as shown on the permit covering the shipment is the same as the port of first arrival, shall cause the cases or packages to be transported under customs guard and by bonded cartman to the appraiser's stores, where they shall be placed in a separate and specially protected inclosure. If the shipment is destined to a port of entry other than the port of first arrival, it shall be entered for immediate transportation without appraisal, by bonded carrier, to the port of entry to which destined after examination, notation of condition and sealing by the customs officer at the port of first arrival. Upon arrival of the shipment at the port of entry to which destined the customs officer shall observe the same procedure as to examination, notation of condition, and sealing as required at the port of first arrival, shall compare the original copy of the permit accompanying the shipping documents with the copy theretofore furnished to the collector of the port in the manner hereinbefore provided, and shall cause the shipment to be transported under customs guard and by bonded cartman to the appraiser's stores, where it shall be placed in a separate and specially protected inclosure.

CROSS REFERENCES: For transportation in bond and merchandise in transit, see 19 CFR Part 18. For cartage and lighterage regulations, see 19 CFR Part 21.

§ 302.13 Duties of appraiser.

(a) The original copy of the permit, with the bill of lading for the shipment shall be forwarded to the appropriate appraiser, who shall take action thereon as provided in § 302.10.

(b) The appraiser shall cause such arrangements to be made as will insure the safe-keeping of the crude opium while in the appraiser's stores.

(c) No delivery of crude opium to the importer from the appraiser's stores shall be permitted until the collector or his representative and the appraiser or his representative shall be satisfied and so note on the delivery permit, after personal examination, that the importer has taken all proper precautions for the

safe transportation of the crude opium from the appraiser's stores to the importer's premises or to the premises of the common carrier if shipment is to be made.

(d) Except as specially provided in the regulations in this part, the procedure in the case of coca leaves shall be the same as in the case of other dutiable merchandise.

CROSS REFERENCE: For Bureau of Customs regulations relating to appraisements, see 19 CFR Part 14.

§ 302.14 Purposes for which crude opium and coca leaves may be entered.

(a) Except as otherwise specifically authorized by the Attorney General and arranged by the Director, crude opium may be entered only for consumption or for transportation in bond between the port of first arrival and the port of entry specified upon the import permit. No entry of either crude opium or coca leaves shall be permitted except upon an import permit duly issued by the Director, and any quantity of crude opium or coca leaves imported or attempted to be imported not in accordance with such permit and the regulations in this part shall be subject to forfeiture under the act.

(b) Coca leaves may be entered either for consumption or warehouse or for transportation in bond between the port of first arrival and the port of entry specified on the permit covering the shipment.

CROSS REFERENCES: For Bureau of Customs regulations covering transportation in bond and merchandise in transit, see 19 CFR Part 18. For Bureau of Customs regulations covering entry for consumption, see 19 CFR 8.27-8.29. For Bureau of Customs regulations covering entry for warehouse, see 19 CFR 8.30-8.32.

§ 302.15 Foreign trade zones.

No narcotic drug as defined in the act of May 26, 1922 (42 Stat. 596; 21 U.S.C. Ch. 6), as amended, shall be permitted to be introduced into a foreign trade zone, established under the act approved June 18, 1934 (48 Stat. 998; 19 U.S.C. 81a-81u), except that such quantities of narcotic drugs as are required for direct emergency medical needs within a zone may be admitted into said zone from customs territory of the United States subject to the requirements of the act of December 17, 1914 (68A Stat. 549; 26 U.S.C. 4701-4707, 4731-4735, 4771-4774,

4721-4726, 4731-4736), as amended, and regulations thereunder. Any narcotic drugs not admissible into a zone as provided in this section, found within a zone shall be seized and disposed of according to law.

CROSS REFERENCE: For regulations under the act of December 17, 1914, as amended, see 26 CFR Part 151.

§ 302.16 Statements rendered by importers.

Whenever required by the Director, importers shall render to him not later than 30 days after receipt of the request therefor a statement under oath of the stocks of narcotic drugs on hand as of the date specified by the Director in his request, and, if desired by the Director, an estimate of the probable requirements for medical and legitimate uses of the importer for any subsequent period that may be designated by the Director. In lieu of any special statement that may be considered necessary, the Director may accept the figures given upon the monthly return or returns submitted by said importer under the act of December 17, 1914, as amended, and regulations thereunder.

Subpart B—Exports

AUTHORITY: The provisions of this Subpart B issued under 38 Stat. 275, as amended; 21 U.S.C. 182.

§ 302.17 Exportation.

(a) Except as otherwise provided in paragraph (b) of this section, no person shall in any manner export from or take out of the United States, or cause to be exported or taken out of the United States any narcotic drug, nor shall any carrier receive for exportation, or export, or carry out of the United States any narcotic drug, unless and until a permit, in due form to export the narcotic drug in each instance shall have been issued by the Director.

(b) A pharmaceutical preparation, containing a narcotic drug, conforming to the standards set forth in 26 CFR 151.422 as a Class "M" product may be exported or taken out of the United States without compliance with requirements set forth in §§ 302.17-302.27.

§ 302.18 Application for export permit.

A separate permit must be obtained for each consignment of narcotic drugs to be exported. Application for permission to export narcotic drugs shall be made

under oath on an approved form provided by the Department of Justice for the purpose, and such application shall be transmitted to the Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C. 20537. Each application shall show the date of execution, the exporter's internal-revenue registry number, and shall show in the space provided the name and detailed description of the narcotic drug or preparation desired to be exported, the net quantity thereof, the number and size of packages or containers, the name and quantity of the narcotic drug contained in any preparation being stated and the quantity of any solids being given in grams. The application shall contain a printed statement to the effect that the application is made for permission to export the narcotics listed therein, pursuant to the provisions of the Narcotic Drugs Import and Export Act, as amended, and the regulations thereunder. The application shall include the name, address, and business of the consignee, the foreign port of entry, the port of exportation, the approximate date of exportation, the name of the exporting carrier or vessel (if known, or if unknown it should be stated whether shipment will be made by express, freight, or otherwise, exports of narcotic drugs by mail being prohibited), the date and number, if any, of the supporting foreign import license or permit accompanying the application, and the authority by whom such foreign license or permit was issued. The application shall also contain an averment that the packages are marked according to the regulations, and to the best of affiant's knowledge and belief the narcotics therein are to be applied exclusively to medical and legitimate uses within the country to which exported, will not be reexported therefrom, and are needed thereon because there is an actual shortage hereof and a demand therefor for medical and legitimate uses within such country. The application shall be signed by the exporter, or by his duly appointed agent whose title shall be given in the space provided therefor, and shall contain the address from which the drugs will be shipped for exportation.

302.19 Foreign import license or permit to be submitted.

There shall also be submitted with the application any import license or permit (and a translation thereof if in a

foreign language) or a certified copy of any such license or permit issued by competent authorities in the country of destination, or other documentary evidence deemed adequate by the Director, showing that the merchandise is consigned to an authorized permittee, that it is to be applied exclusively to medical and scientific uses within the country of destination, that it will not be reexported from such country, and that there is an actual shortage of and a demand for the merchandise for medical and scientific uses within such country. Verification by an American consular officer of signatures on foreign import licenses will be necessary if such licenses do not bear the seal of the officer signing them.

§ 302.20 Additional information.

If after careful consideration of the application it is found that approval cannot be given, such fact and the reasons therefor will be communicated to the applicant by the Director. If additional information is required, or other action is necessary to correct any mistake or irregularity in the application or accompanying documents, opportunity will be afforded the prospective exporter by the Director to furnish such additional information or to correct such mistake or irregularity before the application is finally disapproved.

§ 302.21 Disposition of copies of export permit.

If, from the facts presented in the application, the Director finds it is proper to permit the requested exportation, an export permit shall be prepared in sextuple in the office of the Director. Each of the six copies of the export permit shall be marked as to disposition and shall be distributed and serve purposes as follows:

(a) The original copy, together with the duplicate and triplicate copies, shall be transmitted to the exporter who will retain the triplicate copy on file as his record of authority for the exportation. The exporter shall present to the customs authorities, at the port of export, except when the shipment is to proceed from an interior port, and then at such interior port, at the time of shipment, the original and duplicate copies. The shipper's export declaration shall be presented to the customs authorities at the port of exportation from the United States. After customs endorsement of

export in the space provided on the reverse side of the export permit, the collector of customs shall forward the endorsed original copy of the export permit with the shipment, and return the endorsed duplicate copy to the office of the Director.

(b) The quadruplicate copy of the export permit shall be forwarded to the collector of customs at the port of export for comparison with the original and to be retained for the customs record.

(c) The quintuplicate copy of the export permit shall be sent to the officer in the country of destination who issued the import certificate, or other documentary evidence upon which the export permit is founded.

(d) The sextuple copy of the export permit shall be retained on file in the office of the Director.

§ 302.22 Shipment from interior port.

In the event the consignment shall proceed from an interior port, the collector of customs at the interior port, after endorsing the original and duplicate copies of the export permit, shall forward the original copy with the shipment and shall transmit the duplicate copy of the export permit to the collector of customs at the port of lading on the export vessel or conveyance, and the latter collector of customs, after endorsing the duplicate copy, shall transmit it to the office of the Director.

§ 302.23 Special conditions relative to export permits.

Each export permit shall be serially numbered, and shall be predicated upon a separate import certificate or other documentary evidence, and not more than one shipment shall be made thereon. All export permits shall be entered in a register kept for that purpose in the office of the Director. Export permits are not transferable.

§ 302.24 Expiration date.

An export permit shall not be valid after the date specified therein, which date shall conform to the expiration date specified in the supporting import certificate or other documentary evidence upon which the export permit is founded, but in no event shall the date be subsequent to three months after the date the permit is issued. Any unused export permit shall be returned by the permit-

tee to the office of the Director for cancellation.

§ 302.25 Who may export.

No export permit will be issued unless and until the applicant shall be duly registered or qualified as an exempt official in accordance with the act of December 17, 1914, as amended, and the regulations thereunder.

CROSS REFERENCE: For regulations under the act of December 17, 1914, as amended, see 26 CFR Part 151.

§ 302.26 Exportation to countries which have exceeded estimate.

No export permit shall be issued for the exportation of any narcotic drug to any country when the Director has information to show that the estimates submitted with respect to that country for the current period, under the Narcotics Limitation Convention of 1931 have been, or, considering the quantity proposed to be imported, will be exceeded. If it shall appear, through subsequent advice received from the International Narcotic Control Board that the estimates of the country of destination have been adjusted to permit further importation of the narcotic drug, an export permit may then be issued if otherwise permissible.

§ 302.27 Records required of exporter.

The exporter shall keep a record of any serial numbers that might appear on packages of narcotic drugs in quantities of one ounce or more in such a manner as will identify the foreign consignee.

Subpart C—In-Transit Shipments

§ 302.28 In-transit shipments.

(a) Each in-transit shipment under section 2 of the act (42 Stat. 597; 21 U.S.C. 180) will be considered by the Director on its individual merits, but in general the regulations governing exports (§§ 302.17–302.27) will be applied so far as practicable.

(b) Articles in transit manifested merely as drugs, medicines, or chemicals, without evidence to satisfy the collector of customs that they are nonnarcotic, shall be detained and subjected at the carrier's risk and expense to such examination as may be necessary to satisfy the collector whether they are of a narcotic character. With a view to avoiding such inconvenience, the carrier should not accept in-transit shipments of such articles unless accompanied by properly verified certificates of the shippers,

specifying the items in the shipment and stating whether narcotic or not.

(38 Stat. 275, as amended; 21 U. S. C. 182)

Subpart D—Special Coca Leaves

AUTHORITY: The provisions of this Subpart D issued under sec. 6, 46 Stat. 587; 21 U.S.C. 173a.

§ 302.29 Importation of special coca leaves.

Additional amounts of coca leaves (hereinafter designated as special coca leaves) may be imported only under formal permit issued pursuant to § 302.33, by persons authorized to import in accordance with the regulations in this part. Applications for such authority shall be made in writing to the Director and shall include an estimate of the quantity of leaves required by the applicant for the calendar year to which the application relates.

§ 302.30 Information required of prospective importer.

The Director shall take such action on any application as in his opinion will effectuate the intent and purpose of section 6 of the act of June 14, 1930 (46 Stat. 587; 21 U.S.C. 173a), and of the regulations in this part. No authority to import will be granted unless and until the applicant shall have furnished proof satisfactory to the Director.

(a) That, if an individual, he, or if a partnership, each member thereof, or if an association or corporation, the manager, each officer and director, and each member of any board of control, is of good character and standing;

(b) That the applicant is able, by means of a definite process and formula demonstrated to the satisfaction of the Director, to manufacture an extract of coca leaves containing no cocaine, ecgonine, or any salt, derivative, or preparation from which cocaine or ecgonine may be synthesized or made;

(c) That the applicant has the financial standing and responsibility to undertake such manufacturing operation with reasonable likelihood of successful compliance with the intent and purpose of section 6 of the act of June 14, 1930, and of the regulations in this part; and

(d) Of any other matter or thing which the Director deems appropriate to consider.

§ 302.31 Matters to be considered in granting permit.

(a) The applicant shall also furnish proof satisfactory to the Director that

the estimated quantity of special coca leaves required by the applicant for the calendar year to which the application relates is reasonable under all the circumstances, taking into consideration, among other things, the applicant's trade connections, production facilities, and financial capacity to perform the indicated manufacturing operation with such estimated quantity of leaves.

(b) The applicant shall agree to comply with the provisions of section 6 of the act of June 14, 1930, and of the regulations in this part, and the provisions of the act of December 17, 1914, as amended, and to destroy, as hereinafter provided, under the supervision of an authorized representative of the Director, all cocaine, ecgonine, and all salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made, contained in and/or produced directly or indirectly from special coca leaves.

(c) The Director, in the determination of his action with respect to any application, may accept the proof furnished in connection with an application relating to a prior year, and may take into consideration any other matter or thing known to him or discovered by investigation which he may deem appropriate to consider in effectuating the intent and purpose of the act of June 14, 1930, and of the regulations in Part 301 of this chapter. In no event will authority to import be granted unless the Director is satisfied that the application is made in good faith and not for the purpose of evading the law.

§ 302.32 Approval or disapproval of application.

The Director shall advise the applicant of his approval or disapproval of the application, and, in the event of approval, of the tentative maximum quantity of special coca leaves allowed the applicant for importation covering the requirements (as determined by the Director) of the applicant for the calendar year to which the application relates. Such tentative maximum allowances may be increased or decreased in the discretion of the Director, either on his own motion or on application supported by proof satisfactory to the Director of the necessity therefor. No permit or permits will be issued allowing the applicant, in supplying such requirements, to import, as a charge against such tentative maximum allowance, a total quantity of special coca leaves in excess of such al-

lowance, except as such allowance shall be increased or decreased in accordance with this section.

§ 302.33 Application for permit to import.

A separate permit must be obtained for each shipment of special coca leaves imported by the applicant. Application for such permit or permits shall be made by the applicant on an approved form under oath. Such application shall show, in spaces provided thereon, the quantity in pounds of special coca leaves desired to be imported in the shipment and the number of bales or containers thereof; the tentative maximum quantity of special coca leaves allowed the applicant for the calendar year to which the application for permit relates, the total number of pounds of such tentative maximum quantity for which permits have previously been issued, and the total quantity of leaves actually imported thereunder; and the stock on hand of special coca leaves as such and the quantity of special coca leaves represented by finished stock or extract of coca leaves. The figures for stock on hand shall be given as of a date ascertained in the manner provided for in § 302.3. The application shall also show the name and address of the consignor, if known at the time the application is submitted; if unknown, the application shall so state, and the name and address shall be furnished to the Director as soon as ascertained by the importer; the foreign port of exportation (i. e., the place where the article will begin its journey of exportation to the United States); the port of entry into the United States; and the latest date the shipment will leave the foreign port. The provisions of § 302.4 are hereby made applicable to importations of special coca leaves.

§ 302.34 Registration of importer.

No permit or permits will be issued unless and until the applicant shall be duly registered in accordance with the act of December 17, 1914, as amended, and regulations thereunder, and shall have paid the special tax, have rendered the returns and reports, and have kept the records now or hereafter required by such act and regulations.

CROSS REFERENCE: For regulations under the act of December 17, 1914, as amended, see 26 CFR Part 151.

§ 302.35 Allotment for calendar year not importable in succeeding year.

No application for a permit or permits to import received by the Director after the expiration of the calendar year to which any authorized maximum allowance relates will be approved as a charge against such allowance.

§ 302.36 Issuance of permits.

Permits to import shall be issued in the form, and importations thereunder shall be made in the manner provided by the regulations in this part. Section 302.8 shall govern the procedure in the case of any shipment of a less or greater quantity of special coca leaves than the quantity authorized by the permit covering such shipment, and § 302.9 shall govern the procedure with respect to the cancellation, at the request of the importer, of permits to import special coca leaves.

§ 302.37 Withdrawal from customs custody.

Special coca leaves, upon withdrawal from customs custody, shall be removed to the place of manufacture and safely stored in a storeroom adequately protected against theft and against entry by any persons other than the importing manufacturer and his duly authorized agents and employees, or the Director and his duly authorized representative (herein referred to as the Director's representative). No special coca leaves shall be withdrawn or removed from said place of storage except in the presence of the Director's representative. The importer shall identify each bale or other unit package of special coca leaves after its importation by attaching thereto a label or tag bearing the number of the permit authorizing the importation, the date withdrawn from customs custody, the inscription "Special Coca Leaves," and an individual serial number. Such bales or packages shall be kept apart from any bales or packages not containing special coca leaves. No special coca leaves shall be used for any purpose other than the purpose authorized by the act of June 14, 1930, and the regulations in Part 301 of this chapter.

§ 302.38 Manufacturing operation.

(a) The manufacturer shall notify the Director, at least 10 days in advance, of the commencement of the manufacturing operation with respect to special coca leaves, which operation shall thereafter be conducted to completion

entirely separately and independently of any operation not involving special coca leaves. Nothing contained in this part, however, shall be construed to prohibit the manufacture from coca leaves, other than special coca leaves, of any extract permitted by law. The manufacturing operation involving special coca leaves shall be as continuous, and completed as expeditiously, as possible, and shall be under the observation of the Director's representative.

(b) Immediately prior to the introduction into the manufacturing process of any given quantity of special coca leaves, the manufacturer or his agent duly authorized for the purpose shall, when requested by the Director or his representative, furnish therefrom to the Director's representative such a sample (selected in the presence of the representative) as the latter may require, together with a memorandum dated and signed by the manufacturer or his said agent showing the quantity of special coca leaves from which such sample was taken and the number, and identifying marks (see § 302.37) of the original bales or unit packages of such leaves. The Director's representative shall forward the sample and the memorandum to the Director, or to such chemical laboratory as the Director may designate. A similar sample shall be taken at the same time by the manufacturer or his agent for the purpose of analysis.

§ 302.39 Residue.

At that point in the manufacturing process where the initial extract of special coca leaves undergoes a primary separation into two products, one containing principally flavoring extract and the other principally cocaine, ecgonine, and their salts and derivatives, the manufacturer or his duly authorized agent shall, in the presence of the Director's representative, segregate the latter product, remove its content of recoverable alcohol, and ascertain the weight of the residue, and shall sign and deliver to the representative a dated memorandum showing such weight, the quantity of special coca leaves represented by such residue, and the number, and identifying marks, of the original bales or unit packages of such leaves. The Director's representative shall forward such memorandum to the Director or to such chemical laboratory as the Director may designate, together with a sample of such residue, and the

manufacturer shall take a similar sample for the purpose of analysis. The residue, after the taking of such samples, shall be immediately destroyed by the manufacturer, by incineration, in the presence of the Director's representative. The same procedure shall be followed, in so far as the weighing, taking of samples, and forwarding of memoranda are concerned, with respect to the other product of the aforementioned primary separation; the residue, however, after the taking of samples, shall be continued in process. The representative may also take and forward samples of recovered alcohol.

§ 302.40 Samples.

(a) At any other stage in the process where substances containing cocaine, ecgonine, or salts, derivatives, or preparations from which cocaine or ecgonine may be synthesized or made, are separated from other substances, the procedure hereinabove set forth shall be followed, including the forwarding of samples and memoranda, relative thereto, the taking of similar samples for the purpose of analysis by the manufacturer, and the destruction, after the taking of such samples, of substances required to be destroyed. The manufacturer or his agent shall also furnish the Director's representative a sample of finished extract as it is withdrawn from process supposedly free from cocaine, ecgonine, and salts, derivatives, and preparations from which cocaine or ecgonine may be synthesized or made, together with a memorandum dated and signed by the manufacturer or such agent showing the quantity of finished extract, the quantity of special coca leaves represented by such finished extract, and the number, and identifying marks, of the original bales or unit packages of such leaves. The memorandum relative to each quantity of finished extract withdrawn from process shall include a certificate by the manufacturer that the quantity of finished extract of special coca leaves so withdrawn does not contain any cocaine, ecgonine, or any salt, derivative, or preparation from which cocaine or ecgonine may be synthesized or made. The manufacturer or his agent shall also furnish the Director's representative a sample of the spent or used special coca leaves from each factory run, and a memorandum dated and signed by the manufacturer or his agent showing the quantity of special

coca leaves represented by such spent leaves, and the number, and identifying marks of the original bales or unit packages of such special coca leaves. The Director's representative shall forward such samples and memoranda to the Director or to such chemical laboratory as the Director may designate. Similar samples of finished extract and of spent or used special coca leaves shall be taken by the manufacturer for the purpose of analysis. The spent leaves, after taking of such samples, shall be immediately destroyed by the manufacturer by incineration, in the presence of the Director's representative.

(b) The Director's representative shall have authority under the direction of the Director, to select and forward to the Director such other samples of special coca leaves and the products thereof as are deemed appropriate, whether or not such samples are otherwise required by the regulations in this part.

§ 302.41 Director's representative to have access to factory.

(a) The Director's representative shall have access at all times to the factory, storage rooms, and laboratories where any operation, process, or analysis involving special coca leaves, their salts, derivatives, preparations, products, or extracts is taking place, or where any such special coca leaves, their salts, derivatives, preparations, products, or extracts are situated or found.

(b) The Director's representative shall be afforded a full measure of cooperation in the performance of his duties in order that the intent and purpose of the act of June 14, 1930, may be accomplished. Failure on the part of any importing manufacturer or his agent or employee to afford such cooperation to the Director's representative, or to permit the access authorized by the preceding paragraph to the factories, storage rooms, or laboratories of such manufacturer, shall be grounds for canceling, pursuant to § 302.44, both the authority to import under the regulations in this part and the permits granted thereunder.

§ 302.42 Reports to Director.

The manufacturer shall make such additional reports to the Director, and shall furnish to him by written statement such analytical data relative to the alkaloidal content, at any stage in the process, of special coca leaves or any product

therefrom and such further information regarding analytical methods, as the Director may deem necessary.

§ 302.43 Discontinuance of business.

In the event that any person by reason of bankruptcy, insolvency, receivership, or voluntary or involuntary abandonment or discontinuance (other than mere suspension) of the business of manufacturing an authorized extract of coca leaves, or by reason of any other cause or condition (for example, see § 302.44 and § 302.41(b)), is unable in accordance with the act of June 14, 1930, and of the regulations in this part, to make use of any special coca leaves or of any of the products thereof the destruction of which is not otherwise provided for by the regulations in this part, such special coca leaves and such products shall be seized by the Director and destroyed by incineration; *Provided, however*, That after seizure and before destruction the manufacturer shall be given notice of the proposed destruction and the reasons therefor, and a reasonable opportunity to appear and show cause why such destruction should not be accomplished.

§ 302.44 Cancellation of permit.

The Director may withdraw any authorization and may cancel any permit previously granted to any manufacturer, if such manufacturer, by reason of bad faith, carelessness, incompetency, the causes for seizures specified in § 302.43 or any other cause, fails to comply with the regulations in this part, or by any act or omission fails to observe the intent or purpose of the act of June 14, 1930, *Provided, however*, That the manufacturer shall be given notice of the Director's proposed action in that regard and the reasons therefor, and a reasonable opportunity to appear and show cause why such action should not be taken.

§ 302.45 Compliance with act of December 17, 1914, as amended.

Nothing contained in the regulations in this part shall be construed to exempt any manufacturer from compliance with the act of December 17, 1914, as amended, and regulations thereunder.

CROSS REFERENCE: For regulations under the act of December 17, 1914, as amended, see 26 CFR Part 151.

§ 302.46 Returns required.

Every manufacturer using special coca leaves imported into the United States

pursuant to the act of June 14, 1930, shall render a quarterly return on Form 169 and its supplements, and shall thereon account for all transactions involving such leaves or substances derived therefrom which contain cocaine or ecgonine, or any salts, derivatives, or preparations from which cocaine or ecgonine may be synthesized or made. This return shall be signed and sworn to by the manufacturer or his authorized agent, and rendered direct to the Director, Bureau of Narcotics and Dangerous Drugs on or before the 12th day of the month following the period for which the return is made. Such return shall include a report of all importations of special coca leaves on Form 169a, a report of all materials entered into the processes of manufacture on Form 169b, a report of the various substances produced therefrom on Forms 169c, 169d, and 169e, a report of all such substances destroyed on Form 169f, and a summary of operations on Form 169g.

§ 302.47 Report of importations.

The report of importations on Form 169a shall show in appropriate columns the following data as to each importation:

- (a) The date of the import permit.
- (b) The serial number of the import permit.
- (c) The name of the foreign consignor.
- (d) The address of the foreign consignor.
- (e) The foreign port of export.
- (f) The number of bales imported.
- (g) The serial numbers of the bales imported.
- (h) The quantity imported in avoirdupois pounds.

§ 302.48 Report of materials used.

The report of materials entered into the processes of manufacture on Form 169b shall show in appropriate columns the following information as to each lot of leaves dumped:

- (a) The lot number or specification, a specification to be assigned to each dump for identification purposes in order to avoid repeating the serial numbers of the bales when the lot is subsequently referred to.
- (b) The date the leaves were put in process of manufacture.
- (c) The number of bales dumped.
- (d) The serial numbers of the bales.

(e) The quantity of leaves put in process, stated in avoirdupois pounds.

(f) The quantity of alcohol used for each extraction or wash of the leaves, by alcohol.

(g) The quantity of water used for each water extraction or dilution.

(h) The quantity of any other or additional substance introduced at any stage into the process of manufacture.

(i) The dry weight of any filter cloth or other absorbent material to be later removed from process after saturation.

§ 302.49 Reports of manufacture.

The reports of substances produced from special coca leaves, Forms 169c, 169d, and 169e, shall show, in appropriate columns the following information as to each production lot or dump:

- (a) The lot number.
- (b) The quantity of ground leaves entered into process, in terms of avoirdupois ounces and the quantity, in ounces and grains, of alkaloid contained therein as determined by analysis.
- (c) The quantity of substance in process after each distinct step in the manufacturing process and the total alkaloid contained in each, stated in ounces and grains.
- (d) The quantity of exhausted or spent leaves and the quantity of each residue removed from process, and the total alkaloid contained in each, stated in ounces and grains.
- (e) The weight of the used filter cloth or other absorbent material removed, after saturation.
- (f) The quantity, in gallons, of finished extract produced.

§ 302.50 Report of residues destroyed.

The report of residues destroyed, Form 169f, shall show for each lot destroyed, in appropriate columns the following data:

- (a) The lot number.
- (b) The quantity of spent leaves, residues, and saturated materials destroyed, stated separately for each.
- (c) The name of the Government officer witnessing the destruction.

§ 302.51 Summary.

(a) The summary, Form 169g, shall include a complete accounting for all transactions in raw leaves, leaves in process, and residues removed from production processes. The summary of raw coca leaves shall show:

- (1) The quantity of special coca leaves on hand at the beginning of the quarter.

(2) The quantity of special coca leaves imported during the quarter.

(3) The quantity of special coca leaves put into process of manufacture during the quarter.

(4) The quantity of special coca leaves on hand at the end of the quarter.

(5) Any other transaction during the quarter which increased or decreased the quantity of raw coca leaves on hand.

(b) The summary of coca leaves in process shall show:

(1) The quantity of special coca leaves in process at the beginning of the quarter.

(2) The quantity of such leaves placed in process during the quarter.

(3) The quantity of such leaves represented by lots completed during the quarter.

(4) The quantity of such leaves represented by lots in process at the end of the quarter.

(5) Any other transaction during the quarter which increased or decreased the quantity of leaves in process.

(c) The summary of residues removed from production in processes shall show, in appropriate columns, separately as to spent leaves, each residue and saturated material, the following information:

- (1) The quantity of each, on hand at the beginning of the quarter, awaiting destruction.
- (2) The quantity of each removed from process during the quarter.
- (3) The quantity of each destroyed during the quarter.
- (4) The quantity of each on hand at the end of the quarter.
- (5) Any other transaction during the quarter affecting the quantity of such residues on hand.

Subpart E—General

AUTHORITY: The provisions of this Subpart E issued under 38 Stat. 275, as amended; 21 U.S.C. 182.

§ 302.52 Importation or exportation by mail prohibited.

Neither importation nor exportation of narcotic drugs shall be made by means of the regular mails or by parcel post.

§ 302.53 Medical stores on vessels.

Collectors of customs may permit narcotic drugs in reasonable quantities and properly listed as medical stores of vessels to remain on such vessels if satisfied that such drugs are adequately safeguarded and used only for medical purposes. Smoking opium or opium pre-

pared for smoking shall be seized, however, whenever and wherever found within the jurisdiction of the United States.

CROSS REFERENCE: For allowance of narcotic drugs in medical stores, see 19 CFR 4.39 (e), 23.9 (h).

§ 302.54 Drugs seized to be delivered to collector of customs.

All narcotic drugs seized under the Narcotic Drugs Import and Export Act, as amended, by any Federal officer, other than a customs officer, shall be immediately delivered into the custody of the collector of customs in whose district the seizure was made, with a full report of the circumstances of the seizure, provided that where the seizure is made by a special agent of the Bureau of Narcotics and Dangerous Drugs in connection with an investigation which such agent considers may result in criminal prosecution under any Federal narcotic law, the drugs so seized shall not be delivered into the custody of the collector of customs, but custody of such drugs shall be retained by the appropriate officer of the Bureau of Narcotics and Dangerous Drugs until it is determined that same will not, or will no longer, be required as evidence, whereupon disposition thereof shall be made as provided by law.

CROSS REFERENCE: For customs regulations concerning seizure of narcotic drugs, see 19 CFR 18.21 (b), 23.9.

§ 302.55 Forwarding drugs to Drugs Disposal Committee.

All narcotic drugs which have been forfeited to the Government, and are no longer required for purposes of evidence, shall immediately be forwarded to the Director, Bureau of Narcotics and Dangerous Drugs (Drugs Disposal Committee), for proper disposition.

§ 302.56 Disposition of forfeited drugs.

Narcotic drugs forfeited to the United States under the provisions of law may be delivered to any department, bureau, or other agency of the U.S. Government upon proper application addressed to the Director, Bureau of Narcotics and Dangerous Drugs. The application shall show the name, address, and official title, bureau, or agency, and department, of the person to whom the narcotic drugs are to be delivered, the kind and quantity of narcotics desired, and the purpose for which intended. The delivery of such narcotic drugs shall be ordered by the

Director, Bureau of Narcotics and Dangerous Drugs, if in his opinion, there exists a medical or scientific need therefor. The order will be filled by the Drugs Disposal Committee which will obtain a receipt for narcotic drugs delivered.

§ 302.57 [Reserved]

§ 302.58 Permits issued prior to effective date of regulations.

Permits to import or export narcotic drugs which shall have been issued by the Director prior to the effective date of the regulations in this part shall continue in force and effect under the laws and regulations in effect when such authorizations were issued, unless specifically revoked by the Director.

§ 302.59 Regulations subject to provisions of other pertinent laws and regulations.

The regulations in this part shall be subject to the provisions of the customs, internal-revenue, and other pertinent laws of the United States and regulations promulgated thereunder.

CROSS REFERENCES: For regulations of the Bureau of Customs, see 19 CFR Chapter I. For regulations of the Bureau of Internal Revenue, see 26 CFR Chapter I.

PART 303—OPIUM POPPIES

- Sec.
- 303.1 Definitions.
- 303.2 Policy.
- 303.3 Production.
- 303.4 Application for license to produce.
- 303.5 Issuance of license to produce.
- 303.6 Limitations.
- 303.7 Production in excess of quantities named in licenses.
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- 303.10 Change of address or other facts shown in application.
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- 303.12 Hearing.
- 303.13 Director not required to issue or renew license.
- 303.14 Returns required of producers.
- 303.15 Returns required of manufacturers.
- 303.16 Disposition of forfeited opium poppies.
- 303.17 Penalties.

AUTHORITY: The provisions of this Part 303 issued under sec. 11, 56 Stat. 1048; 21 U.S.C. 188j.

SOURCE: The provisions of this Part 303 appear at 33 F.R. 14826, Oct. 3, 1968, unless otherwise noted.

§ 303.1 Definitions.

As used in the regulations in this part:

(a) The term "person" includes a part-

nership, company, association, or corporation, as well as a natural person or persons.

(b) The terms "produce" or "production" include the planting, cultivation, growth, harvesting, and any other activity which facilitates the growth of the opium poppy.

(c) The term "opium poppy" includes the plant *Papaver somniferum*, any other plant which is the source of opium or opium products, and any part of any such plant.

(d) The term "opium" includes the inspissated juice of the opium poppy, in crude or refined form.

(e) The term "opium products" includes opium and all substances obtainable from opium or the opium poppy, except the seed thereof.

(f) The term "license" means a license to produce the opium poppy or to manufacture opium or opium products, duly issued by the Director.

(g) The term "Director" means the Director, Bureau of Narcotics and Dangerous Drugs.

(h) The term "act" means the Opium Poppy Control Act of 1942.

§ 303.2 Policy.

It shall be the policy of the Director to administer and enforce the provisions of the act in such manner as will carry out the obligations of the United States under the treaties and conventions mentioned therein. The Director shall not issue licenses to produce the opium poppy unless such production is essential to supply narcotic drugs for the medical and scientific needs of the United States. If such production becomes necessary, the Director shall exercise sound discretion in the issuance of licenses to the end that there shall be no opportunity for the spread of drug addiction.

§ 303.3 Production.

No person who is not the holder of a license shall produce the opium poppy. Licenses shall be issued only for the production of the opium poppy to supply the medical and scientific needs of the United States for narcotic drugs. No licenses shall be issued for the production of the opium poppy solely for poppy seed.

§ 303.4 Application for license to produce.

Any person who desires to produce the opium poppy to supply medical and scientific needs of the United States for

narcotics drugs shall file an application, in duplicate, for a license with the Director at Washington, D.C. The application shall show the name and address of the applicant, the quantity, in pounds, of opium poppies desired to be produced, the acreage and exact location of the land desired to be devoted to opium poppy production, the type of soil desired to be devoted to opium poppy production, whether such applicant owns, rents, or leases such land and the type of equipment owned by the applicant to be used in cultivating and harvesting opium poppies. The applicant shall also submit proof that he is of good moral character, that his financial standing and farming experience are such as will reasonably insure that he can produce the acreage of opium poppies called for in the application, that there is or will be, at the time of harvesting, a market for the opium poppies desired to be produced and that the land to be devoted to opium poppy production is readily accessible to law enforcement officers at all times.

§ 303.5 Issuance of license to produce.

(a) The Director shall issue a license to produce the opium poppy only when, in his opinion, the medical and scientific needs of the United States for narcotic drugs cannot be met by the importation of crude opium. A license to produce the opium poppy shall be issued only to a person whom the Director finds (1) to be of good moral character; (2) to be of suitable financial standing and farming experience to render reasonably probable that such person will produce the quantity of opium poppies specified in the license; (3) to be the owner of or to control suitable farm land to be used as a production area, in such locality, as will, in the judgment of the Director, render reasonably probable efficient and diligent performance of the operations of producing the opium poppy in the quantity specified; (4) to have facilities for safeguarding the opium poppy crop which will reasonably insure that the opium poppies will not be diverted to illicit channels.

(b) Each such license shall be non-transferable and shall be valid only to the extent of the production area and maximum weight of opium poppy yield specified in the license, shall state the locality of the production area, and shall be effective for a period of one year from

the date of issue, and may be renewed, at the discretion of the Director, for a like period.

§ 303.6 Limitations.

All licenses to produce opium poppies, issued by the Director, shall be limited to such number, localities, and areas as the Director shall determine to be appropriate to supply the medical and scientific needs of the United States for opium or opium products, with due regard to provision for reasonable reserves. It shall be the policy of the Director so far as practicable, to confine the production of opium poppies to such areas as will permit efficient and economical enforcement of the narcotic laws and regulations.

§ 303.7 Production in excess of quantities named in licenses.

If a licensee produces opium poppies in excess of the quantity called for in his license, such excess quantity may be seized and forfeited to the United States, or, the Director may, if he deems it appropriate and finds that such excess opium poppies were produced in good faith, amend the license so as to cover all or part of such excess quantity, and allow them to be disposed of under the act.

§ 303.8 License to manufacture.

Any person who desires to manufacture opium or opium products from opium poppies shall first obtain the required license and quota for the manufacture of a basic class of narcotic drug and be subject to all of the provisions and requirements of the Narcotics Manufacturing Act of 1960 (Pub. Law 86-429, 74 Stat. 55), and the regulations issued pursuant thereto (Part 307 of this chapter). No further manufacturing license shall be required. However, no license to manufacture opium or opium products from opium poppies shall be issued by the Director unless he finds that the medical and scientific needs of the United States for narcotic drugs are not being or cannot be supplied from crude opium obtained by importation.

§ 303.10 Change of address or other facts shown in application.

Any person to whom a license has been issued shall immediately notify the Director of any change of the address or any other fact shown in his application, and of any subsequent change of address or other fact.

§ 303.11 Revocation or renewal of licenses.

(a) The Director may revoke or refuse to renew any license issued under the act if after due notice to a licensee and an opportunity for hearing he finds that the licensee has failed to comply with any of the qualifications found to exist at the time of the issuance of such license, if he finds that such licensee has failed to comply with the Federal or State narcotic laws and regulations, or laws supplementary thereto, or if he finds that the revocation or refusal to renew any license shall be in the public interest.

(b) If it is the intention of the Director to revoke or refuse to renew any license, he shall immediately notify the licensee thereof and his reasons therefor by registered letter addressed to his last address reported by him to the Director. The licensee shall be advised by the Director in such registered letter that he has 30 days from the date of the letter in which to submit his reasons showing cause why the Director should not revoke or refuse to renew the license. The licensee shall be further advised in such registered letter that upon his request, filed with the Director within the same 30 days, a hearing will be granted. If, within such 30 days, the licensee fails to submit reasons showing cause why the Director should not revoke or refuse to renew the license, the Director may revoke or refuse to renew his license without further proceedings. If, within such 30 days, the licensee fails to request a hearing, but submits reasons purporting to show cause, the Director shall consider the reasons and decide the matter and communicate his decision to the licensee within 15 days from the receipt of the reasons purporting to show cause.

§ 303.12 Hearing.

(a) If a hearing is requested, the Director shall notify the licensee of the time and place where such hearing will be conducted and held. The hearing shall be conducted and held at a place deemed by the Director to be reasonably convenient to the licensee. The hearing may be conducted by the Director or his duly authorized representative. The Bureau of Narcotics and Dangerous Drugs shall introduce at the hearing the evidence on which reliance is to be had for revocation of or refusal to renew the license. The licensee shall have an opportunity at the hearing to examine the evidence

submitted and to confront and cross-examine any witnesses for the Bureau of Narcotics and Dangerous Drugs.

(b) The licensee shall be afforded an opportunity to present all his evidence and argument on the matter and shall have the privilege of being represented by counsel of his own choice. The licensee shall be permitted 15 days from the date of the conclusion of the hearing to submit a written brief to the Director or his duly authorized representative.

(c) If the hearing is conducted by a representative of the Director, such representative shall file with the Director a stenographic report of the evidence and the arguments presented and any briefs submitted, together with his findings and recommendation. The Director, after considering this report and the briefs shall render his decision and communicate the same to the licensee within 45 days from the date of the conclusion of the hearing.

§ 303.13 Director not required to issue or renew license.

The Director shall not be required to issue or renew any license or licenses under the provisions of the act: *Provided, however*, That the Attorney General, on appeal, may require the Director to issue or renew a license.

§ 303.14 Returns required of producers.

Every person licensed as a producer of opium poppies shall render an annual return to the Director on or before the 15th day of January, for the annual period ending December 31 of the preceding year, reporting all transfers and dispositions of opium poppies and fully accounting for all opium poppies produced or otherwise obtained. Such returns shall be prepared on forms furnished by the Director, and shall include, for each such period, (a) a complete accounting for all poppy seeds received, planted, produced, harvested, or otherwise acquired or disposed of, and the seed on hand at the beginning and end of the period; (b) a complete reporting of the areas planted and harvested and the areas under cultivation at the beginning and end of the period; and (c) a full and complete accounting for all quantities of opium poppies produced, harvested, received, sold, or otherwise acquired or disposed of, and those on hand at the beginning and end of the period.

PART 305—OPIATES

Sec.

305.1 Opiate.

305.2 Chronological list of findings.

AUTHORITY: The provisions of this Part 305 issued under sec. 4731, 68A Stat. 557, as amended, sec. 17, 74 Stat. 67; 21 U.S.C. 514, 26 U.S.C. 4731.

SOURCE: The provisions of this Part 305 appear at 33 F.R. 14827, Oct. 3, 1968, unless otherwise noted.

§ 305.1 Opiate.

(a) **Definition.** The word "opiate" shall mean any drug (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g))), and substance proclaimed by the President, and substance declared by administrative regulation, or other substance found by the Director, Bureau of Narcotics and Dangerous Drugs (after considering the technical advice of the Secretary of Health, Education, and Welfare, or his delegate, on the subject) to have (1) an addiction-forming or addiction-sustaining liability similar to morphine or cocaine; or (2) to be capable of conversion into a drug having such addiction-forming or addiction-sustaining liability with relative technical simplicity and degree of yield as to create a risk of improper use.

(b) **Finding.** Prior to making any finding that a drug or other substance is an "opiate" (as defined in paragraph (a) of this section), the Director, Bureau of Narcotics and Dangerous Drugs shall give due notice of his intention to consider the desirability of making such a finding and afford an opportunity for a public hearing to all interested parties. Not less than twenty days prior to the date set for a hearing, the Director shall cause to be published in the FEDERAL REGISTER a notice setting forth the date, time and place of the proposed hearing. Any person desiring to be heard shall furnish written notice to the Director not later than twenty days from the date notice of hearing is published in the FEDERAL REGISTER. If no written notice of a desire to be heard shall be received by the Director within such period of twenty days, no hearing shall be held, but the Director shall proceed to make a finding based on all available evidence including pharmacological and clinical tests of the drug. If written notice of a desire to be heard is received by the Director within the prescribed period of twenty days, the hearing will be held in accordance with the original notice. When the Director

§ 303.15 Returns required of manufacturers.

Every person licensed as a manufacturer of opium or opium products from opium poppies shall render quarterly returns on forms furnished by the Director, reporting and accounting for all such manufacturing operations in the same manner as is required of persons producing such substances from opium imported into the United States (see 26 CFR 151.123-151.132): *Provided, however*, That the Director may, in any instance, specify such changes and modifications in such forms as the variations in manufacturing procedures and other circumstances may require.

§ 303.16 Disposition of forfeited opium poppies.

Opium poppies forfeited to the United States under the provisions of the act shall be destroyed by the Director or his authorized representative or, may be delivered to any department, bureau, or other agency of the U.S. Government upon proper application addressed to the Director. Such application shall show the name, address, and official title and department, bureau, or agency of the person to whom the narcotics are to be delivered, the quantity of opium poppies desired and the purpose for which they are intended. The delivery of such opium poppies may be ordered by the Director if in his opinion the purpose for which they are intended is medical or scientific.

§ 303.17 Penalties.

(a) Persons who violate the act shall be guilty of a felony and upon conviction thereof, be fined not more than \$2,000, or imprisoned not more than 5 years, or both, in the discretion of the court.

(b) Any person who willfully makes, aids, or assists in the making of, or procures, counsels, or advises in the preparation or presentation of, a false or fraudulent statement in any application for a license under the provisions of the act shall (whether or not such false or fraudulent statement is made by or with the knowledge or consent of the person authorized to present the application) be guilty of a misdemeanor, and, upon conviction thereof, be fined not more than \$2,000 or imprisoned for not more than 1 year, or both.

PART 304—[Reserved]

finds that a drug is an "opiate", he shall proclaim such finding in the FEDERAL REGISTER after which all of the provisions of the Federal narcotic laws shall apply to such drug.

(c) *Termination.* The Director may withdraw any previous finding that a drug or other substance is an "opiate" whenever he determines that such previous finding was erroneous. Such determination shall take effect immediately upon publication in the FEDERAL REGISTER and the particular drug or other substance shall thereupon cease to be an "opiate". The Director may, although he is not bound to, consider any action taken by the World Health Organization pursuant to Article 3 of the 1948 Protocol in withdrawing a drug or other substance previously declared an "opiate".

§ 305.2 Chronological list of findings.

(a) The following is a chronological list of the drugs or other substances proclaimed to be opiates by administrative declaration. Drugs or other substances listed include any salts thereof.

August 8, 1961

Betamethadol (B-4,4-diphenyl-6-dimethyl-amino-3-heptanol or B-6-dimethylamino-4,4-diphenyl-3-heptanol).

Etixeridine (1 - [2 - (2 - hydroxyethoxy) - ethyl] - 4 - phenylpiperidine-4-carboxylic acid ethyl ester) (Atenorax, Atenos, Carbettidine).

Levomoramide (1-3-methyl-2,2-diphenyl-4-morpholino-butyryl-pyrrolidine).

Racemoramide (d,1-3-methyl-2,2-diphenyl-4-morpholino-butyryl-pyrrolidine).

Trimeperidine (1,2,5-trimethyl-4-phenyl-4-propionoxypiperidine) (Promedol).

Phenoperidine (1-(3-hydroxy-3-phenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester).

October 5, 1961

Noracymethadol (α -di-3-acetoxy-6-methylamino-4,4-diphenyl heptane).

December 21, 1961

Norpethidine (ethyl 4-phenyl-4-piperidine-carboxylate).

(b) The following is a chronological list of drugs or other substances found by the World Health Organization as being capable of producing addiction or of conversion into a drug or other substance capable of producing addiction and designated as opiates by the Director of the Bureau of Narcotics and Dangerous Drugs pursuant to the provisions of

§ 307.61(b) of this chapter. Drugs and other substances listed include any salts thereof.

JUNE 20, 1962

(Methadone-intermediate) 4-cyano-2-dimethylamino-4,4 diphenylbutane.

(Pethidine - intermediate - A) 4-cyano-1-methyl-4-phenylpiperidine.

(Moramide - intermediate) 2 - methyl-3-morpholino - 1,1 - diphenylpropanecarboxylic acid.

APRIL 2, 1963

(Pethidine-intermediate-C) 1-methyl-4-phenylpiperidine-4-carboxylic acid.

APRIL 7, 1964

(Norpipanone) 4,4-diphenyl-6-piperidino-3-hexanone.

(Fentanyl) 1-phenethyl-4-N-propionylanilino-piperidine.

MARCH 1966

(Piritramide) 1 - (3 - cyano-3,3-diphenylpropyl) - 4 - (1-piperidino) piperidine-4-carboxylic acid amide.

JANUARY 14, 1969

(Bezitramide) 1-(3-cyano-3,3-diphenylpropyl)-4-(2-oxo-3-propionyl-1-benzimidazolyl)-piperidine.

[33 F.R. 14827, Oct. 3, 1968, as amended at 34 F.R. 496, Jan. 14, 1969]

PART 306—SURRENDER OF HEROIN

Sec.

306.1 Forfeiture of heroin.

306.2 Disposition of surrendered and forfeited heroin.

306.3 Heroin for scientific research purposes.

AUTHORITY: The provisions of this Part 306 issued under sec. 1402, 70 Stat. 572; 18 U.S.C. 1402.

SOURCE: The provisions of this Part 306 appear at 33 F.R. 14828, Oct. 3, 1968, unless otherwise noted.

§ 306.1 Forfeiture of heroin.

All heroin heretofore lawfully possessed by any registrant and not surrendered in accordance with 18 U.S.C. 1402 after the 16th day of November 1956 shall be seized and forfeited to the United States without compensation.

§ 306.2 Disposition of surrendered and forfeited heroin.

All heroin acquired by the United States pursuant to section 1402 of title 18 of the United States Code shall be disposed of in accordance with the provisions of 4733 of the Internal Revenue Code of 1954.

§ 306.3 Heroin for scientific research purposes.

Any heroin acquired under the provisions of section 1402 of title 18 of the United States Code, shall be available, in the discretion of the Director, Bureau of Narcotics and Dangerous Drugs, for scientific research purposes in accordance with the provisions of section 4733 of the Internal Revenue Code of 1954.

PART 307—MANUFACTURING OF NARCOTIC DRUGS

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307.123 Formula for fixing individual manufacturing quotas.

307.124 Provisional manufacturing quotas.

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307.131 Exception from applicability of license and quota provisions.

MANUFACTURE OF NARCOTIC PRECURSORS

307.141 Narcotic precursors.

IMPORTATION OF NARCOTIC DRUGS

307.151 Importation of narcotic drugs for scientific purposes.

AUTHORITY: The provisions of this Part 307 issued under sec. 2, 35 Stat. 614, sec. 6, 56 Stat. 1046, secs. 4, 15, 16, 17, 74 Stat. 57, 66, 67; 21 U.S.C. 173, 188e, 182, 513, 514, 26 U.S.C. 4731.

SOURCE: The provisions of this Part 307 appear at 33 F.R. 14829, Oct. 3, 1968, unless otherwise noted.

GENERAL PROVISIONS

§ 307.51 Hearings.

To the extent that a hearing under the regulations in this part is required pursuant to the provisions of the Administrative Procedure Act (60 Stat. 237), such hearing shall be conducted in accordance therewith. The Director may specify such procedural rules as may be necessary from time to time to secure the efficient and expeditious conduct of hearings.

§ 307.52 Practice before Bureau of Narcotics and Dangerous Drugs by former employees.

(a) *Matters pending while employed.* No person having served as an agent, Regional Director, administrative officer, attorney or in any other capacity with the Bureau of Narcotics and Dangerous Drugs shall, within 2 years after the termination of his employment with the

Bureau, practice or in any manner act as an attorney or agent or as the employee of an attorney or agent in any matter pending during the period of his employment therein, unless he shall first obtain the written consent of the Director. This consent will not be granted unless it appears that the applicant for such consent did not give personal consideration to the matter or gain knowledge of the facts involved during and by reason of his employment in the Bureau of Narcotics and Dangerous Drugs.

(b) *Practice before Bureau.* For the purpose of this section, practice before the Bureau shall include the preparation of any statement, opinion or other paper by any attorney, accountant, chemist, pharmacologist or other expert filed with the Director.

§ 307.53 Definitions.

As used in this part:

"Act" means the Narcotics Manufacturing Act of 1960, Pub. Law 86-429 (74 Stat. 55).

"Bureau" means the U.S. Bureau of Narcotics and Dangerous Drugs.

"Director" means the Director, Bureau of Narcotics and Dangerous Drugs.

"Licensee" means a person granted a license under section 8 of Act to manufacture a basis class of narcotic drug.

"Manufacture" means the production of a narcotic drug, either directly or indirectly, by extraction from substances of vegetable origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.

"Narcotic", "narcotics", or "narcotic drugs" means any of the substances defined as narcotic drugs in section 4731(a) of the Internal Revenue Code of 1954, as amended by section 4(a) of the Narcotics Manufacturing Act of 1960.

"Person" includes an individual, partnership, corporation, association, trust, or other institution or entity.

"1912 Convention" means the International Opium Convention for the Suppression of the Abuses of Opium and other Drugs signed at the Hague, January 23, 1912, and entered into force with respect to the United States, February 11, 1915.

"1925 Convention" means the International Opium Convention signed at Geneva, February 19, 1925 to which the United States is not a party.

"1931 Convention" means the Convention for Limiting the Manufacture and

Regulating the Distribution of Narcotic Drugs, concluded at Geneva, July 13, 1931, and entered into force with respect to the United States July 9, 1933.

"1946 Protocol" means the protocol amending the Conventions of 1912, 1925 and 1931, signed at Lake Success on December 11, 1946, and entered into force with respect to the United States, August 12, 1947.

"1948 Protocol" means the protocol bringing under international control drugs outside the scope of the 1931 Convention, signed at Paris, November 19, 1948, and entered into force with respect to the United States, September 11, 1950.

§ 307.54 Delegation of functions.

Reorganization Plan No. 1 of 1968 issued by the President, effective April 8, 1968 (Presidential Documents, 33 F.R. 5611), provides in part as follows:

Section 1. Transfer of functions from Treasury Department. There are hereby transferred to the Attorney General:

(a) Those functions of the Secretary of the Treasury which are administered through or with respect to the Bureau of Narcotics.

(b) All functions of the Bureau of Narcotics, of the Commissioner of Narcotics, and of all other officers, employees and agencies of the Bureau of Narcotics.

(c) So much of other functions or parts of functions of the Secretary of the Treasury and the Department of the Treasury as is incidental to or necessary for the performance of the functions transferred by paragraphs (a) and (b) of this section.

INTERNATIONAL CONTROL OF NARCOTIC DRUGS

§ 307.61 Notifications, findings and decisions under the 1948 Protocol.

(a) *Notification given.* The United States is obligated, as a signatory state Party to the 1948 Protocol to notify the Secretary-General of the United Nations whenever it considers that a drug which is or may be used for medical or scientific purposes is liable to the same kind of abuse and productive of the same kind of harmful effects as the drugs specified in Article 1, Paragraph 2 of the 1931 Convention and is not covered by that Convention. The notification to the Secretary-General of the United Nations shall be made only after the Director has found and proclaimed such drug to be an "opiate" in accordance with the procedure prescribed by section 4731(g) of the Internal Revenue Code of 1954, as amended by section 4(b) of the Narcotics Manufacturing Act of 1960.

(b) *Notification received.* When the United States receives notification from the Secretary-General of the United Nations pursuant to Article 1 or 2 of the 1948 Protocol based on a decision of the World Health Organization or of the Commission on Narcotic Drugs of the Economic and Social Council that a drug which is or may be used for medical or scientific purposes and which is liable to the same kind of abuse and productive of the same kind of harmful effects as the drugs specified in Article 1, Paragraph 2 of the 1931 Convention, and is not covered by the 1931 Convention, is capable of producing addiction or of conversion into a drug capable of producing addiction, the Director shall cause to be published in the FEDERAL REGISTER such decision of the World Health Organization or Commission on Narcotic Drugs, unless such drug has already been determined to be an "opiate" in accordance with section 4731(g) of the Internal Revenue Code of 1954, as amended by section 4(b) of the Narcotics Manufacturing Act of 1960. From the time of such publication, the drug will be subject to the same control as an "opiate" in the same manner as if it had been so determined and proclaimed by the Director pursuant to the procedure set forth in section 4731(g) of the Internal Revenue Code of 1954, as amended by section 4(b) of the Narcotics Manufacturing Act of 1960.

§ 307.62 Findings by United Nations organs.

(a) *Arguments opposed to finding or decision.* Any person interested in the domestic manufacture and distribution for medical or scientific purposes of a drug which becomes subject to control by virtue of the procedure set forth in § 307.61(b), may submit to the Director, Bureau of Narcotics and Dangerous Drugs written data, views, briefs and arguments opposed to such finding or decision. The Director shall transmit such written data, views, briefs and arguments to the Department of State for transmittal to the Secretary-General of the United Nations for consideration of the World Health Organization or the Commission on Narcotic Drugs, as the case may be, (under Article 3 of the 1948 Protocol) as the written opposition of such interested party, and not necessarily as the views of the United States.

(b) *Revised finding or decision.* If, after the submission of written data,

views, and argument to the Secretary-General of the United Nations in accordance with paragraph (a), the United States receives a revised finding or decision that the drug in question is not capable of producing addiction or conversion into a drug capable of producing addiction and that the provisions of the 1931 Convention shall not apply to such drug, the Director, Bureau of Narcotics and Dangerous Drugs shall cause such revised findings or decision to be published in the FEDERAL REGISTER within ninety (90) days of receipt thereof. From the time of such publication, such drug shall cease to be an "opiate", unless the Director has previously initiated an "opiate" procedure pursuant to section 4731(g) of the Internal Revenue Code of 1954, as amended by section 4(b) of the Narcotics Manufacturing Act of 1960.

§ 307.63 Withdrawal of narcotic drug from international control.

General: When the United States receives a revised finding or decision (under Article 3 of the 1948 Protocol) that a drug already subject to the federal narcotic laws as an "opiate" is not capable of producing addiction or of conversion into a drug capable of producing addiction and that the provisions of the 1931 Convention shall not apply to such drug, the Director, Bureau of Narcotics and Dangerous Drugs may, in his discretion, cause to be published in the FEDERAL REGISTER such revised finding or decision and, from the time of publication, such drug shall cease to be an "opiate". If on the other hand the Director, in his discretion, does not cause such revised finding or decision to be published in the FEDERAL REGISTER, the drug in question shall continue to be an "opiate".

BASIC CLASSES OF NARCOTIC DRUGS

§ 307.71 Modification of list of basic class of narcotic drugs.

(a) *Definition of "basic class" of narcotic drug.* The term "basic class" of narcotic drug means any class of narcotic drug which has been included in the list enumerated in section 3(g) of the Narcotics Manufacturing Act of 1960, as such list may be altered from time to time by adding to, subtracting from, or further defining any such class.

(b) *Alteration of a basic class.* Whenever the Director, Bureau of Narcotics and Dangerous Drugs shall, either upon his own motion or upon the

application of an interested party, determine that a narcotic drug as defined in section 4731 of the Internal Revenue Code of 1954, as amended by section 4 of the Narcotics Manufacturing Act of 1960, on the basis of its chemical structure and content possesses an addiction-forming or addiction-sustaining liability or convertibility into an addicting drug so great as to present a hazard, if manufactured and distributed, to the public health and safety, he may alter the classification set forth in section 3(g) of this Act by subtracting such basic class from existing classification or he may further define such basic class, as the case may be. The Director, prior to making such alteration, shall cause to be published in the FEDERAL REGISTER a notice as to this proposed subtraction or further definition of a basic class. Such notice shall also apprise interested parties of their right to request a hearing as to the proposed alteration of a basic class.

(c) *Addition of a new basic class to existing classification.* No new basic class of narcotic drug shall be added by the Director to the established enumeration unless he shall first have determined that;

(1) Such drug is a narcotic drug as defined by section 4731 of the Internal Revenue Code of 1954, as amended by section 4 of the Narcotics Manufacturing Act of 1960, or has caused to be published in the FEDERAL REGISTER a determination to this effect pursuant to section 5 of this Act; and

(2) To permit the manufacture of such drug will not be contrary to the public health and safety.

§ 307.72 Establishment of a new basic class of narcotic drug.

(a) *Request to establish a new basic class of narcotic drug.* A person interested in having a new basic class of narcotic drug established, as provided in § 307.71, shall file a formal written request therefor with the Director, Bureau of Narcotics and Dangerous Drugs on Bureau Form 187.

(b) *Preparation of Bureau Form 187.* The applicant for the establishment of a new basic class of narcotic drug in preparing Bureau Form 187 shall, to the extent available, render the following information called for on the form:

(1) Generic name for drug;

(2) International non-proprietary name of the drug;

(3) Chemical name or description (structural formula);

(4) General description and composition;

(5) Therapeutic action and uses;

(6) Advantages, if any, over similar drugs already in use;

(7) Known or suspected habituation or addiction potentials;

(8) Known side effects, if any, and precautions desirable in its use;

(9) Methods of administration and recommended dosage;

(10) Nature of applicant's interest in the drug.

(c) *Submission of Bureau Form 185.* The applicant for the establishment of a new basic class of narcotic drug, in addition to the filing of Bureau Form 187, shall prepare and file Bureau Form 185. The purpose of this form is to provide the Director with whatever information is available respecting the chemical formulas, physical properties and general identification of new narcotic drugs and their closely related analogs, on which the Bureau is called upon to take some action, particularly new synthetics and newly prepared opium derivatives, whose properties are not yet published in standard chemical or pharmaceutical reference works.

(d) *Addition of new basic class by Director.* Where the Director, on his own initiative, determines in accordance with paragraph (c) of § 307.71, that the addition of a new basic class of narcotic drug to the existing classification would not be contrary to the public health and safety, he shall cause a notice to this effect to be published in the FEDERAL REGISTER. The notice shall also apprise interested parties that they may request a hearing as to the proposed addition of a new basic class of narcotic drug to the existing classification, as enumerated in section 3(g) of the Act.

(e) *Granting of application to establish a new basic class.* If on the basis of all the information before him, the Director determines that the approval of an application for the addition of a new basic class to the existing classification would be consistent with the law and the public health and safety, he shall cause to be published in the FEDERAL REGISTER a notice to the effect that an application to establish a new basic class of narcotic drug has been made by a named applicant, specifying the class of narcotic drug involved and apprising all interested parties of their

right to request a hearing as to the proposed addition of a new basic class to the existing classifications. The notice shall indicate that in the absence of evidence convincing the Director that such course is inappropriate, he intends to grant the application.

(f) *Final determination to establish a new basic class.* The Director after having determined under paragraph (d) or (e) of this section that it is consistent with law and the public health and safety to establish a new basic class of narcotic drug to the existing classification, shall cause to be published in the FEDERAL REGISTER a final notice to this effect.

(g) *Denial of application.* If, on the basis of all of the information before him, the Director determines that the approval of an application for the addition of a new basic class to the existing classification would not be consistent with law and the public health and safety, he may deny such application. Prior to denying such application, the Director shall afford the applicant an opportunity to present any additional evidence relevant to the application. If after such additional evidence is presented, the Director determines that it would now be consistent with law and the public health and safety to grant such application, the provisions of paragraphs (e) and (f) of this section shall apply.

(h) *Opportunity for hearing.* If the Director continues to be of the opinion that the granting of the application would not be consistent with law and the public health and safety, he shall afford the applicant an opportunity for a hearing, causing a notice to this effect to be published in the FEDERAL REGISTER.

§ 307.73 List of basic classes of narcotic drugs.

The following substances and their salts constitute the list of basic classes of narcotic drugs:

1. Opium, powdered, granulated, or decocted, or tinctures or extracts of opium.
2. Mixed alkaloids of opium.
3. Morphine.
4. Codeine.
5. Thebaine.
6. Narcotine (noscapine).
7. Papaverine.
8. Cotarnine.
9. Narceine.

10. Ethylmorphine.
11. Apomorphine.
12. Nalorphine (N-allylnormorphine).
13. Hydromorphone (dihydromorphinone).
14. Metopon (methyl dihydromorphinone).
15. Dihydrocodeine.
16. Hydrocodone (dihydrocodeinone).
17. Oxycodone (dihydrohydroxycodone).
18. Cocaine.
19. Ecgonine.
20. Pethidine (meperidine, isonipicaine) 1-methyl-4-phenylpiperidine-4-carboxylic acid ethylester).
21. Alphaprodine (alpha-1, 3-dimethyl-4-phenyl-4-propionoxypiperidine).
22. Methadone (amidone) (6-dimethylamino-4, 4-diphenyl-3-heptanone).
23. Isomethadone (isoamidone) (6-dimethylamino-5-methyl-4, 4-diphenyl-3-hexanone).
24. Levorphan and racemorphan (3-hydroxy-N-methylmorphinan).
25. Levomethorphan and racemethorphan (3-methoxy-N-methylmorphinan).
26. Anileridine (Ethyl 1-[2-(p-amino phenyl)-ethyl]-4-phenyl piperidine-4-carboxylate).
27. Phenazocine (2'-Hydroxy-5, 9-dimethyl-2-(2-phenylethyl)-6, 7-benzomorphan).
28. Dihydromorphine.
29. Diphenoxylate (Ethyl 1-(3-cyano-3, 3-diphenylpropyl)-4-phenyl-4-piperidinecarboxylate).
30. Metazocine (2'-Hydroxy-2, 5, 9-trimethyl-6, 7-benzomorphan).
31. Oxymorphone (14-Hydroxydihydromorphinone).
32. Pholcodine (Morpholinyl-ethylmorphine).
33. Piminodine (Ethyl-4-phenyl-1-[3-(phenylamino)-propyl]-4-piperidine carboxylate).
34. Norpethidine (ethyl 4-phenyl-4-piperidinecarboxylate).
35. Fentanyl (1-phenethyl-4-N-propionylanilino piperidine).

MANUFACTURE OF NARCOTIC DRUGS

§ 307.81 Restriction on manufacture of narcotic drugs.

General: Except as provided in § 307.83, it shall be unlawful for any person to engage in the manufacture of any narcotic drug or cause or permit another to engage in the manufacture of any narcotic drug unless:

(a) Such narcotic drug is included in a "basic class" of narcotic drug (see § 307.71); and

(b) Such person holds a currently effective license for the manufacture of such basic class of narcotic drug issued pursuant to section 8 of the Act (see § 307.90); and

(c) Such person holds a currently effective manufacturing quota with respect to such basic class of narcotic drug, as set forth in section 11 of the Act (see § 307.121).

§ 307.82 Omission of a narcotic drug from a basic class.

(a) No narcotic drug shall be manufactured unless it is included within a basic class enumerated in section 3(g) of the Narcotics Manufacturing Act of 1960, or established pursuant to section 6 of the Act.

(b) The fact that the Director shall have (1) determined that a drug is a narcotic drug, or (2) caused a finding or decision with respect to any drug or other substance to be published in the FEDERAL REGISTER pursuant to section 5 of the Narcotics Manufacturing Act of 1960 (see § 307.61), shall not require the Director to add such narcotic drug to the classification set forth in section 3(g) of the Act (see § 307.71 as to modification of list of basic class of narcotic drugs), or to grant a manufacturing quota pursuant to section 11 of the Act (see § 307.121), for such narcotic drug, if he finds that it would be contrary to the public health and safety.

§ 307.83 Manufacturing for scientific research and testing.

(a) *Manufacture for scientific research.* The Director, Bureau of Narcotics and Dangerous Drugs shall exempt from the provisions of § 307.90, any person desirous of the manufacturing a narcotic drug exclusively for research in the development of manufacturing processes for the drug, or for chemical, pharmacological or medical testing of such drug, for fitness for medical or scientific use and for determination of its suitability for general manufacture and distribution for medical or scientific use.

(b) *Authorization to manufacture.* Written authorization from the Director to manufacture a narcotic drug for scientific purposes must be obtained prior to the undertaking of such manufacture. The Director shall grant such authorization only to those public officials who have evidenced their exemption from registration and payment of tax (26 CFR 151.221) with the District Director of the Internal Revenue Service or to persons registered in Class I or Class VI, under section 4722 of the

Internal Revenue Code of 1954, as amended, and who otherwise meet the standards for licensing under subsection (a) of section 8 of the Narcotics Manufacturing Act of 1960.

(c) *Application for authorization to manufacture.* A person desiring to obtain authorization to manufacture a narcotic drug for scientific purposes shall file an application therefor on Bureau Form 190 in duplicate, which form is available at the office of the Director, Bureau of Narcotics and Dangerous Drugs, Washington, D.C. 20537. If the drug to be manufactured is produced by chemical synthesis, whether or not from narcotic materials, the application shall be accompanied by an outline of the process of synthesis on Form 186, identifying the substances from which it is to be made and those resulting from each successive step of the process, and indicating in each instance whether the substance is isolated and weighed or measured or whether it remains in solution in a continuing process of manufacture. The applicant need not disclose on this form any technical detail of the process which he regards as an important trade secret, but in order that the Director may discharge his responsibility under the law with respect to narcotic precursors the applicant must identify each substance used and each substance resulting from the successive stages of manufacture. Information disclosed on Form 186 will be held in confidence by the Bureau.

(d) *Limitations on authorization.* Authorization to manufacture under this section will be limited to narcotic drugs not readily available to the researcher from sources within the United States, except where the development of new or improved methods of production is the object of the research to be undertaken. In addition, the Director may specify a limitation on the quantity of narcotic drug to be manufactured under this section of the regulations.

(e) *Reports required.* Persons authorized to manufacture under this section of the regulations and who are Class I registrants shall render a quarterly report to the Director on Bureau Form 810 and its supplements in accordance with 26 CFR 151.261. Those persons who are Class VI registrants shall render to the Director semi-annual reports on Bureau Form 192, as of June 30 and December 31 of

each year, to be submitted not later than the 15th of the month following, accounting for the manufacture and use or other disposition of the drugs so manufactured.

(f) *Disposition of drugs manufactured.* All such drugs manufactured under this section of the regulations shall be used in research or otherwise disposed of, as authorized by the Director, within 5 years from the date of manufacture, unless an extension of time for completion of the research has been requested in writing and granted by the Director.

(g) *Suspension or revocation of authorization.* Any authorization granted by the Director under this section of the regulations shall be subject to suspension or revocation in accordance with the procedure set forth in §§ 307.99 and 307.100 as to suspension or revocation of licenses to manufacture.

MANUFACTURERS' LICENSES

§ 307.90 License to manufacture narcotic drugs; generally.

(a) Every manufacturer of a basic class or classes of narcotic drug shall obtain a license for each such basic class on or before January 1, 1961, if then already engaged in such manufacture. All other persons desiring to engage in the manufacture of a basic class or classes of narcotic drug after January 1, 1961 shall obtain appropriate licenses for each such basic class prior to undertaking such manufacture. Issuance of a license for the manufacture of any one basic class of narcotic drug shall not entitle the licensee to engage in any transaction with respect to any other basic class of narcotic drug.

(b) A person desiring to obtain a license as provided in paragraph (a) of this section shall prepare and file an application for such a license in accordance with the procedure set forth in § 307.92.

§ 307.91 Registration as a prerequisite to issuance of a license.

In addition to the conditions precedent for the issuance of a license to manufacture a particular basic class of narcotic drug as provided in § 307.90, each applicant for a license must be registered as a Class I registrant pursuant to the provisions of sections 4721 and 4722 of the Internal Revenue Code of 1954, as amended (see 26 CFR Part 121 et seq.).

§ 307.92 Requirements for license applications.

(a) *Who may file.* Any person may file an application for a license to manufacture a basic class of narcotic drug under section 8 of the Narcotics Manufacturing Act of 1960.

(b) *Filing of applications.* All applications for licenses must be filed in the office of the Director, Bureau of Narcotics and Dangerous Drugs, Washington, D.C. 20537. Application shall be made on Bureau Form 188 in duplicate which form is available at the above address. If the drug to be manufactured is produced by chemical synthesis, whether or not from narcotic materials, the application shall be accompanied by an outline of the process of synthesis on Form 186, identifying the substances from which it is to be made and those resulting from each successive step of the process, and indicating in each instance whether the substance is isolated and weighed or measured or whether it remains in solution in a continuing process of manufacture. The applicant need not disclose on this form any technical detail of the process which he regards as an important trade secret, but in order that the Director may discharge his responsibility under the law with respect to narcotic precursors the applicant must identify each substance used and each substance resulting from the successive stages of manufacture. Information disclosed on Form 186 will be held in confidence by the Bureau.

(c) *Separate applications.* An applicant who files separate applications to manufacture more than one class of narcotic drug need not repeat information on each application. He may make reference on any application to information which he has furnished on another application, identifying such other application by either file number, or if there has been no file number assigned, by basic class.

(d) *Subscription of applications.* Each application, or amendment thereto, and each written statement of fact required by the Director from any applicant to enable the Director to determine whether an application should be granted or denied, shall be personally signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if an association or corporation.

(e) *Contents of applications.* (1) Each application shall include all information called for by Forms 186 and 188 unless the information called for is inapplicable, in which case this fact shall be indicated.

(2) The Director may require an applicant to submit such documents and written statements of fact pertinent to the subject matter of the application, as in the Director's judgment may be necessary, or to amend the application to make it more definite and certain.

(f) *Acceptance of applications for filing.* (1) Applications submitted for filing are dated by the office of the Director upon receipt and then forwarded to the Office of Compliance where an administrative examination is made to ascertain whether the applications are complete. Applications found to be complete or substantially complete are accepted for filing and are given a file number, which file number shall be transmitted to the applicant to be used on all future correspondence related to the application. In case of minor defects as to completeness, the applicant will be requested to supply the missing information. Applications which are not substantially complete will be returned to the applicant.

(2) Acceptance of an application for filing merely means that it has been the subject of a preliminary review by the Director's administrative staff as to completeness and has no relevance to whether the application will be granted or denied. Such acceptance will not preclude the subsequent request for further information.

(g) *Defective applications.* (1) Applications which are determined to be patently not in accordance with these regulations or the Director's specific requirements as to a particular applicant, unless accompanied by an appropriate request for waiver, will be considered defective and will not be accepted for filing. If it is ascertained that an application has been inadvertently accepted for filing, the filing will be cancelled. Requests for waiver or exception desired shall set forth the reasons in support thereof, and will be accepted or rejected in the discretion of the Director.

(2) If an applicant is requested by the Director to file any additional documents or information pertinent to the application not included in the prescribed application form, a failure to

comply with such request will be deemed to render the application defective and the filing of such application will be cancelled.

(h) *Amendments to applications.* (1) Any application may be amended as a matter of right prior to the date of the receipt of notice from the Director establishing a date for a hearing as requested by the applicant in accordance with § 307.93(d).

(2) Requests to amend an application after it has been designated for hearing will be considered only upon written permission by the Director, and will be granted only for good cause shown.

(i) *Withdrawal of applications.* (1) Any application may, upon request of the applicant, be withdrawn as a matter of right prior to the date of receipt of notice from the Director establishing a date for a hearing as requested by the applicant in accordance with § 307.93(d). An applicant's request for the return of an application that has been accepted for filing will be regarded as a request to withdraw the application.

(2) Requests to withdraw an application after it has been designated for a hearing will be granted only for good cause shown.

(3) Failure to prosecute an application or failure to respond to official correspondence or request for additional information will be treated as a request by the applicant for withdrawal of his application.

§ 307.93 Action upon applications.

(a) *Notice of intention to grant application.* If after appropriate consideration, the Director finds that it would be consistent with the public interest to grant any application filed pursuant to § 307.92, he shall so notify the applicant. This notification, however, shall not be construed as granting the application.

(b) *Protest of grant of application.* After notification is given to the applicant, as provided in paragraph (a) of this section, the Director shall cause to be published in the FEDERAL REGISTER a notice to the effect that a named applicant has applied for a license to manufacture a particular basic class of narcotic drug, and that such application is being favorably considered. He shall at the same time mail a copy of this notice to every person who then holds an effective license to manufacture

a narcotic drug in the basic class to which the application applies or who has a pending application therefor on file. Within twenty days after the notice is published in the FEDERAL REGISTER, any interested person may file a written protest with both the Director and the applicant against favorable consideration of the application. Any such protest shall specify with particularity the facts relied upon as showing that a license if granted to the applicant would not be in the public interest. Such interested person may request a hearing as to his protest. The Director shall, within twenty days after the filing of a timely protest, designate a date for a hearing. The Director may require of the applicant that he file with the Director and the person making the protest, a written statement setting forth the grounds, if any, for his opposition to the protest. If such statement is required by the Director, the applicant must file it within twenty days after the demand upon him is made by the Director. Failure on the part of the applicant to submit such statement will be grounds for denial of the application.

(c) *Action on denial of license.* If upon examination of any application prepared and filed by the applicant in accordance with § 307.92, the Director is unable to find that it would be consistent with the law and the public interest to grant the application, he shall notify the applicant that he is denying the application and shall state the grounds and reasons for his action.

(d) *Right of hearing after denial of license.* Following notice of denial, as set forth in paragraph (c) of this section, the applicant within twenty days from receipt thereof, may present in writing any reasons for disagreeing with the Director's denial of the application. If the Director thereafter determines that is appropriate to give favorable consideration to the application, the provisions of paragraphs (a) and (b) of this section shall apply. If the Director adheres to his decision to deny the application, he shall afford the applicant an opportunity to be heard. If the applicant elects to have a hearing, the Director shall specify a date for the hearing and shall appropriately notify the applicant and each licensee who holds an effective license to manufacture the basic class of narcotic drug to which the application relates and every person

who has on file an application to manufacture the basic class of narcotic drug involved. The Director shall also cause to be published in the FEDERAL REGISTER a notice to the same effect.

(e) *Joinder of parties and consolidation of hearings.* All interested persons are permitted to participate in any hearing under this section and may be compelled by the Director to do so or waive their rights to be heard. The Director may direct that more than one application to manufacture a basic class of narcotic drug be consolidated for the purpose of a hearing. After consolidation, an application will be retained for hearing notwithstanding that prior to hearing any other application with which it has been consolidated has been dismissed, or amended or otherwise removed from the hearing.

§ 307.94 Factors governing issuance of licenses.

In determining whether to issue a license to an applicant to manufacture a particular basic class of narcotic drug, under § 307.90, the Director shall be governed by whether the issuance of the license would tend to achieve the objectives set forth in section 8 of the Narcotics Manufacturing Act of 1960.

§ 307.95 Period of validity of license.

The Director shall designate the form which the license to be issued pursuant to § 307.90 shall take. The license once issued, shall not require any renewal and shall remain in effect, subject only to annual renewal of registration as required in section 8(b) of the Narcotics Manufacturing Act of 1960, unless otherwise revoked or suspended pursuant to section 9 of the Act (see §§ 307.99-307.100), or voluntarily surrendered.

§ 307.96 Assignment or transfer of licenses.

No license nor any right granted thereunder shall be assigned or otherwise transferred except upon such conditions as the Director may specifically designate and then only pursuant to his written consent.

§ 307.97 Warning to licensee for failure to comply.

(a) *Failure to comply, generally.* Where a licensee has failed to comply with any of the provisions of these regulations or has failed to operate in accordance with any provision of the

federal narcotic laws and regulations, the Director, Bureau of Narcotics and Dangerous Drugs may serve written notice upon such licensee calling his attention to the facts or conduct of such licensee without serving an order to show cause as provided in § 307.98. The licensee may then be accorded an opportunity to demonstrate or achieve compliance with all lawful requirements, and to render a full and complete explanation as to the matter brought to his attention by the Director.

(b) *Willful failure to comply.* Where the Director, Bureau of Narcotics and Dangerous Drugs considers the licensee's failure to comply with any of the provisions of these regulations or his failure to operate in accordance with any provision of the federal narcotic laws and regulations is willful or contrary to the public health and safety, the Director shall issue an order to show cause, pursuant to § 307.98.

§ 307.98 Orders to show cause.

(a) Before revoking any license, the Director shall serve upon the licensee an order to show cause why an order of revocation should not be issued. Any such order to show cause shall contain a statement of the basis thereof, and shall call upon such licensee to appear before the Director at a time and place stated in the order, but in no event less than thirty days after the date of receipt of such order, and give evidence upon the matter specified therein.

(b) In order to avail himself of the opportunity to be heard, the licensee shall within thirty days of the date of the receipt of the order file with the Director a written statement that he will appear in accordance with the order and will present evidence on the matter specified in the order. If the licensee fails to file such written statement within the time specified in this paragraph, the right to a hearing shall be deemed to have been waived.

(c) Where a hearing is waived under paragraph (b) of this section, or where the licensee has failed to appear after having stated that he would do so, the allegations of fact contained in the order to show cause will be deemed to be correct.

(d) Where a hearing is waived, not under paragraph (b) of this section, but rather by written formal waiver, the licensee may submit to the Director a written statement in mitigation or

justification within thirty days of the date of receipt of the order to show cause.

(e) Any order of revocation issued pursuant to this section of the regulations by the Director shall include a statement by him of his findings and grounds and reasons therefor and shall:

(1) Specify the effective date of the order; and

(2) Cause such order to be served on the licensee.

(f) Any proceeding under this section shall be independent of, and not in lieu of, criminal prosecution or other proceedings under this Act or any other law of the United States.

§ 307.99 Suspension of licenses.

(a) The Director may suspend any license, when or at any time after he issues an order to show cause under § 307.98, in any case where he finds that the public health, safety or interest requires such suspension.

(b) Where the Director orders a license suspended under paragraph (a) of this section, the licensee shall send the license to the Director in Washington, D.C., promptly upon receipt of the notice of suspension.

(c) Any suspension ordered by the Director, as provided in this section of the regulations, shall continue in effect until the conclusion of any revocation proceeding, including judicial review thereof, if any, unless sooner withdrawn by the Director, or dissolved by a court of competent jurisdiction.

§ 307.100 Revocation of licenses.

(a) Any license issued pursuant to section 8 of the Narcotics Manufacturing Act of 1960 may be revoked by the Director if the licensee

(1) Has been convicted of violating or conspiring to violate any law of the United States or of any State where the offense involves any activity or transaction with respect to narcotic drugs; or

(2) Has violated or failed to comply with any duly promulgated regulation relating to narcotic drugs, and such violation or failure to comply reflects adversely on the licensee's reliability and integrity with respect to narcotic drugs.

(b) In the case of a licensee who is the holder of more than one license issued pursuant to section 8 of the Act, the Director may revoke under paragraph (a) of this section one or all of the licenses issued to such licensee.

AUTHORITY TO SEIZE NARCOTIC DRUGS, ORDER FORMS AND TAX STAMPS

§ 307.111 Sealing and safeguarding of narcotic drugs.

(a) The Director, Bureau of Narcotics and Dangerous Drugs on or after ordering the suspension or revocation of a licensee's license under § 307.99 or § 307.100 may order that all narcotic drugs, whether or not taxes have been paid thereon, owned or possessed by such licensee and all unused order forms and narcotic tax stamps owned or possessed by such licensee be placed under seal under the supervision of a representative of the Bureau of Narcotics and Dangerous Drugs pending final disposition of the revocation proceeding.

(b) The representative of the Bureau referred to in paragraph (a) of this section, shall, in the presence of the licensee or his representative, prepare an inventory, in triplicate, of all items thus placed under seal. The original inventory shall be forwarded to the Director, Bureau of Narcotics and Dangerous Drugs, the duplicate copy shall be forwarded to the narcotic Regional Director of the district wherein the sealing takes place and the triplicate copy shall be given to the affected licensee.

(c) A licensee may make no disposition of any item placed under seal. The licensee shall be responsible for safeguarding all sealed items to insure against their disposition and to protect them against being tampered with.

§ 307.112 Forfeiture of narcotic drugs.

(a) When a revocation order, under § 307.100, becomes final, all narcotic drugs, unused order forms and tax stamps relating to narcotic drugs, owned or possessed by the affected licensee, shall be forthwith confiscated, and when confiscated shall be deemed to be forfeited to the Government.

(b) Representatives of the Bureau of Narcotics and Dangerous Drugs when confiscating narcotic drugs, unused order forms and tax stamps, shall determine whether there has been any disposition of or tampering with any such items that had been sealed pursuant to § 307.111.

(c) At the time of confiscating narcotic drugs, unused order forms and tax stamps which have not previously been ordered sealed and safeguarded under § 307.111, the representatives of the Bureau of Narcotics and Dangerous Drugs

who are confiscating the items shall, in the presence of the licensee or his representative, prepare an inventory in triplicate of the items being confiscated. The original inventory shall be forwarded to the Director, Bureau of Narcotics and Dangerous Drugs, the duplicate copy shall be forwarded to the narcotic Regional Director of the district wherein the confiscation was made and the triplicate copy shall be given to the licensee from whom the confiscation was made, and shall be retained by him for a period of not less than 2 years.

(d) Representatives of the Bureau of Narcotics and Dangerous Drugs at the time of confiscating narcotic drugs pursuant to this section may, as the Director, Bureau of Narcotics and Dangerous Drugs directs, either destroy accumulated narcotic wastes and undesired narcotic drugs or dispose of such wastes and drugs pursuant to the procedures set forth in paragraph (e) of this section.

(e) All confiscated items not destroyed shall be delivered to the narcotic Regional Director of the district wherein the confiscation takes place. The narcotic Regional Director will forward the narcotic drugs thus confiscated to the Director, Bureau of Narcotics and Dangerous Drugs (Drugs Disposal Committee) for proper disposition in accordance with the provisions of 26 CFR 151.491. Confiscated unused order forms and tax stamps shall be forwarded to the District Director of the Internal Revenue Service of the district wherein the licensee was registered for cancellation of such order forms and for disposition of the tax stamps. No refund will be allowed for tax stamps forfeited to the Government under this section of the regulations.

MANUFACTURING QUOTAS

§ 307.121 Manufacturing quotas for basic classes of narcotic drugs; generally.

(a) In order to carry out the treaty obligations of the United States, the Director, Bureau of Narcotics and Dangerous Drugs shall, on or before June 1, of each year, make determinations of the total quantity of each basic class of narcotic drug necessary to be manufactured during that calendar year to provide for the estimated medical and scientific needs of the United States, for lawful export requirements, and for the

establishment and maintenance of reserve stocks.

(b) In fixing yearly manufacturing quotas for each basic class of narcotic drug, the Director, Bureau of Narcotics and Dangerous Drugs shall consider the total needs for the procurement of such drugs for further manufacturing or processing by registered manufacturers who do not hold quotas to manufacture such basic class of narcotic drug. In order that such information may be available to the director each registered manufacturer who does not hold a manufacturing quota shall on or before November 30, notify the Director in writing on Bureau Form 194 of the amount of each basic class of narcotic drug which he desires to procure in the following year for further manufacturing or processing. The Director shall notify each person who has filed Bureau Form 194 whether the request thereon will be relied upon by the Director in fixing the annual manufacturing quotas. When the Director states that he will rely upon any such forms he shall also state the amount which he will take into account and such amount shall be known as the "purchase quota" of the person filing the form. Such purchase quotas will be based upon the applicant's previous yearly requirements and upon his reasonably anticipated requirements. A purchase quota may be increased by the Director upon request and upon a showing of need therefor.

(c) Notwithstanding the provisions of (b) of this section, Bureau Form 194 need not be filed by any registered manufacturer who uses less than one kilogram of all basic classes of narcotic drugs annually.

§ 307.122 Individual manufacturing quotas.

(a) *Fixing of individual manufacturing quotas.* The Director, Bureau of Narcotics and Dangerous Drugs shall upon application fix annual manufacturing quotas for each licensee holding a license to manufacture each basic class of narcotic drug and in so doing shall be governed by the provisions of section 11 of the Narcotics Manufacturing Act of 1960.

(b) *Reducing individual manufacturing quotas.* The Director, Bureau of Narcotics and Dangerous Drugs, after having established individual manufacturing quotas for a basic class of narcotic drug may reduce an individual man-

ufacturing quota which he has previously fixed, so as to prevent the aggregate of the manufacturing quotas outstanding or to be granted from exceeding the established quota for the basic class of narcotic drug.

(c) *Production in excess of quota.* No person shall knowingly manufacture any narcotic drug in any quantity in excess of any quota which he holds. When a licensee who under a quota as originally fixed, or as reduced by the Director, Bureau of Narcotics and Dangerous Drugs under paragraph (b) of this section, has already manufactured a basic class of narcotic drug in excess of the quota, such excess shall be subtracted by the Director, Bureau of Narcotics and Dangerous Drugs from the licensee's manufacturing quota for the following year.

(d) *Proportionate reduction of manufacturing quota.* Any reduction of an individual manufacturing quota shall be in the same proportion as the reduction of the aggregate of the established quota for the basic class of narcotic drug or in the proportion that a quota to a new licensee may require in order to keep the aggregate of the individual quotas from exceeding the established quota for the basic class of narcotic drug.

§ 307.123 Formula for fixing individual manufacturing quotas.

(a) *Time for fixing of quotas.* Upon application therefor, the Director, Bureau of Narcotics and Dangerous Drugs shall, on or before June 1 of each year fix individual manufacturing quotas for the manufacturing of each basic class of narcotic drug.

(b) *Sufficiency of manufacturing quotas.* Subject to the right of the Director, Bureau of Narcotics and Dangerous Drugs to reduce, limit, suspend or revoke any manufacturing quota, any quota established for a licensee for the manufacture of a basic class of narcotic drug shall be sufficient to cover the licensee's estimated requirement for the calendar year in question as to—

- (1) His "net disposal" (as defined in paragraph (c)) for such calendar year;
- (2) His inventory at the close of such calendar year; and subject to such other factors as the Director may determine should be taken into consideration in arriving at a proper quota under all the circumstances (i.e., licensee's current net disposal rate, the trend of such net disposal rate during the preceding

calendar year or years, the licensee's production cycle and current inventory position, the economic and physical availability of raw materials used by the licensee in the production of such basic class of narcotic drug, yield and stability problems, emergency situations such as catastrophes and strikes, and any other factors which the Director deems appropriate to consider in arriving at the proper quota under the circumstances).

(c) *Definition of "net disposal".* The term "net disposal" means the quantity of a basic class of narcotic drug sold, exchanged, given away, used in the production of another basic class of narcotic drug for which the manufacturer is licensed, or otherwise disposed of (as such or contained in or combined with other drugs compounded by the manufacturer of such basic class) by the manufacturer during a stated period, less the quantity of any such basic class of narcotic drug returned to the manufacturer by a customer and any quantity sold or transferred to another licensed manufacturer of the same basic class of narcotic drug.

(d) *Definition of "inventory".* The term "inventory" means all factory and branch stocks (whether held by the manufacturer under Class I or Class II registration as provided in 26 CFR 151.41) of a basic class of narcotic drug manufactured or otherwise acquired by a licensee, whether in bulk, marketable packages, or contained in pharmaceutical preparations in the possession of the licensee and all subsidiary companies, if any, of such licensee.

(e) *Establishment of manufacturing quotas.* Subject to the right of the Director, Bureau of Narcotics and Dangerous Drugs to reduce, limit, suspend or revoke any manufacturing quota, the quota for each licensed manufacturer shall not be less than the sum of—

- (1) Such licensed manufacturer's net disposal of such basic class of narcotic drug during the immediately preceding calendar year or the average of the three immediately preceding calendar years in which such manufacturer produced such basic class of narcotic drug, whichever is greater; and
- (2) One-half of such manufacturer's net disposal of such basic class of narcotic drug during the immediately preceding calendar year;

less such manufacturer's inventory of such basic class of narcotic drug on December 31 of the preceding calendar year.

(f) *Manufacturing quotas for new licensees.* Subject to the right of the Director, Bureau of Narcotics and Dangerous Drugs to reduce, limit, suspend or revoke any manufacturing quota, the Director, upon application therefor, shall fix a quota for any licensed manufacturer of a basic class of narcotic drug who has not manufactured such basic class of narcotic drug during one or more of the three immediately preceding calendar years, in an amount adequate to cover such manufacturer's reasonably anticipated requirements for the current calendar year.

§ 307.124 Provisional manufacturing quotas.

(a) A licensed manufacturer, between January 1 of any year and the time when he receives a quota for such year under § 307.123 may manufacture a provisional quota of the basic class of narcotic drug for which he is licensed.

(b) The provisional quota referred to in paragraph (a) of this section, except as provided in paragraph (c) of this section shall be not more than 75 per centum of whichever of the following is greater:

- (1) Such licensee's aggregate net disposal of such basic class of narcotic drug during the twelve months immediately preceding September 30 of the preceding year; or
- (2) Twelve times such licensee's average monthly net disposal of such basic class of narcotic drug for the thirty-three months immediately preceding September 30 of the preceding year.

(c) The Director, Bureau of Narcotics and Dangerous Drugs, may, for good cause, raise or lower the provisional quota percentage provided for in paragraph (b) of this section. Any increase or decrease in percentage provided for by the Director shall apply to the provisional quotas of all licensees for the basic class of narcotic drug involved.

§ 307.125 Application for individual manufacturing quotas.

(a) Each person desirous of manufacturing a basic class of narcotic drug for which he holds a currently effective manufacturing license, shall file an application for an individual manufacturing quota on Bureau Form 189 for

each such basic class of narcotic drug. Bureau Form 189 shall be filed with the Director, Bureau of Narcotics and Dangerous Drugs no later than March 1 of each year in which the licensee desires to manufacture such basic class of narcotic drug.

(b) Any person who is not desirous of manufacturing a basic class of narcotic drug for which he holds a currently effective manufacturing license, shall notify the Director, Bureau of Narcotics and Dangerous Drugs no later than March 1 of any year in which he does not desire to manufacture such basic class of narcotic drug.

(c) Any person who after having filed an application for an individual manufacturing quota under paragraph (a) of this section, decides not to manufacture such basic class of narcotic drug or to discontinue the manufacture of such basic class of narcotic drug, shall forthwith notify the Director, Bureau of Narcotics and Dangerous Drugs in writing, to this effect.

§ 307.126 Increase in individual manufacturing quotas.

(a) Any licensee who holds a manufacturing quota for a basic class of narcotic drug may file an application on Bureau Form 189 with the Director, Bureau of Narcotics and Dangerous Drugs for an increase in such manufacturing quota in order for him to meet his estimated net disposal, inventory and other requirements during the remainder of such calendar year.

(b) The Director, Bureau of Narcotics and Dangerous Drugs, in passing upon a licensee's application for an increase in his manufacturing quota, shall take into consideration any occurrences since the filing of such licensee's initial quota application that may require an increased manufacturing rate by such licensee during the balance of the calendar year. In passing upon such application the Director may also take into consideration the amount, if any, by which his determination of the total quantity for the basic class of narcotic drug to be manufactured under § 307.121, exceeds the aggregate of all the individual manufacturing quotas for the basic class of narcotic drug, and the equitable distribution of such excess among other licensees.

INCIDENTAL MANUFACTURE OF NARCOTIC DRUGS

§ 307.131 Exception from applicability of license and quota provisions.

(a) Any licensee who, incidentally but necessarily, manufactures a narcotic drug as a result of his manufacture of a basic class of narcotic drug for which he holds a license and manufacturing quota under the regulations in this part, shall be exempt from the requirement of a license and quota under the regulations in this part as to such resulting narcotic drug.

(b) No license or quota shall be required for any quantity of narcotic drug which incidentally but necessarily results from the manufacture of any non-narcotic substance not covered by the regulations in this part.

(c) Any incidentally but necessarily resulting narcotic drug, within the meaning of paragraphs (a) or (b) of this section which is a basic class of narcotic drug, shall be disposed of in the following ways only:

(1) By transfer to another manufacturer who holds a license to manufacture such basic class of narcotic drug. Before such transfer can be made, however, the manufacturer desirous of making such transfer shall first apply to the Director, Bureau of Narcotics and Dangerous Drugs, in writing for approval to transfer specified quantities of such resulting narcotic drugs to a specified transferee or transferees. No transfer is authorized unless the Director approves such transfer in writing in advance thereof.

(2) By shipment to the narcotic Regional Director as excess and undesired narcotic drugs pursuant to 26 CFR 151.474; or

(3) By destruction in the presence of a representative of the Bureau of Narcotics and Dangerous Drugs authorized by the Director, Bureau of Narcotics and Dangerous Drugs, to witness such destruction.

(d) Any incidentally but necessarily resulting narcotic drug within the meaning of paragraph (a) or (b) of this section which is not a basic class of narcotic drug, may be disposed of in one of the following ways only:

(1) By shipment to the narcotic Regional Director as excess and undesired narcotic drugs pursuant to 26 CFR 151.474; or

(2) By destruction in the presence of a representative of the Bureau of Nar-

cotics and Dangerous Drugs, authorized by the Director, Bureau of Narcotics and Dangerous Drugs, to witness such destruction.

(e) A manufacturer may retain a resulting narcotic drug within the meaning of paragraph (a) or (b) of this section only for such period of time as is reasonably necessary for him to make disposition of such drug in the manner provided in this section.

MANUFACTURE OF NARCOTIC PRECURSORS

§ 307.141 Narcotic precursors.

(a) *Definition of "narcotic precursor."* The term "narcotic precursor" means a substance other than a narcotic drug which the Director has found to be

(1) An immediate chemical precursor of a narcotic drug;

(2) Produced primarily for use in the manufacture of a narcotic drug; and

(3) Used or likely to be used, in the manufacture of a narcotic drug by persons other than persons licensed under section 8 of the Narcotics Manufacturing Act of 1960, to manufacture such narcotic drug.

Before finding a substance to be a narcotic precursor, the Director shall give due notice in the FEDERAL REGISTER and afford an opportunity for public hearing to interested persons.

(b) *Requirements as to persons engaging in transactions with respect to narcotic precursors.* Any person who is engaged in the manufacture, compounding, packaging, selling, dealing in or giving away of a narcotic precursor, as defined in paragraph (a) of this section, shall:

(1) Maintain records as prescribed in paragraph (d) of this section; and

(2) Prepare and submit an annual report on Bureau Form 193 on or before February 15 of each year.

(c) *Exception to applicability of paragraph (b).* The provisions of paragraph (b) of this section shall not apply to a person manufacturing a narcotic precursor who holds a license to manufacture a basic class of narcotic drug under section 8 of the Narcotics Manufacturing Act of 1960, provided that the narcotic precursor manufactured by such licensee is to be used exclusively by him for the manufacture of the basic class of narcotic drug for which he holds a license.

(d) *Procedure as to maintenance of records and preparation of annual report.* The manufacturer of a substance

which has been declared a narcotic precursor shall keep for a period of not less than two years such records as will enable him to supply the Director accurate information as to the quantity of such precursor manufactured or otherwise acquired by him, his dispositions thereof, the names and addresses of the persons to whom supplied, the quantity supplied to each and the use for which intended. The annual report on Form 193 shall include a summary of this information for the calendar year.

IMPORTATION OF NARCOTIC DRUGS

§ 307.151 Importation of narcotic drugs for scientific purposes.

(a) *Exemption for scientific purposes.* Notwithstanding the provisions of § 302.1 of this chapter, the Director of Narcotics and Dangerous Drugs may issue a formal permit to certain classes of persons desiring to import any narcotic drug or drugs (including crude opium and coca leaves) for scientific purposes only.

(b) *Application for import permit.* Application for a permit to import shall be made to the Director on Bureau Form 191. The applicant for such import permit shall also prepare and submit to the Director, Bureau Form 185 (Drug Identification Sheet), where the substance to be imported is a narcotic drug not described in the standard reference works on drugs and chemicals.

(c) *Limitation on authorization to import.* Imports under this section will be limited to narcotic drugs not readily available to the applicant from sources within the United States, unless questions of origin, types or particular methods of production are elements of the research objectives. Each importation desired must be separately applied for and be covered by a separate import permit. Applicants for import permits licensed under section 8 of the Narcotics Manufacturing Act of 1960, who as part of their manufacturing business maintain branch or subsidiary manufacturing establishments in foreign countries, or are themselves a branch or subsidiary of a foreign parent organization, may be issued import permits for occasional imports of samples of the products of these foreign branches, subsidiaries or parent organizations for the purpose of research or spot check analyses to establish or maintain proper chemical and therapeutical standards of their products. However, an applican

will not be granted import permits to make continuous or regular imports of samples of recurring batches or lots of the same product for routine factory controls.

(d) *Disposition.* All drugs imported under this section shall be used in research or otherwise disposed of as authorized by the Director, within 5 years from the date of their import, unless an extension of time for completion of the research has been granted by the Director.

(e) *Reports.* Persons importing narcotic drugs under this section shall render to the Director semiannual reports on Bureau Form 192, as of June 30 and December 31 of each year, to be submitted not later than the 15th of the month following, accounting for the importation and use or other disposition of the narcotic drug or drugs so imported.

PART 308—[Reserved]

PART 315—ENFORCEMENT OF THE DRUG ABUSE CONTROL AMENDMENTS OF 1965 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Sec.

315.1 General regulation.

315.2 Presentation of views under section 305 of the act.

SOURCE: The provisions of this Part 315 appear at 33 F.R. 14836, Oct. 8, 1968, unless otherwise noted.

§ 315.1 General regulation.

(a) The provisions of regulations promulgated under the act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 201 of the act shall be applicable also to such terms when used in regulations promulgated under the act.

(Sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 371; Reorg. Plan No. 1 of 1968, 33 F.R. 5611)

§ 315.2 Presentation of views under section 305 of the act.

(a) Presentation of views under section 305 of the act shall be private and informal. These views presented shall be confined to matters relevant to the contemplated proceeding. Such views may

be presented by letter or in person by the person to whom the notice was given, or by his representative.

(b) Upon request, seasonably made, by the person to whom a notice appointing a time and place for the presentation of views under section 305 of the act has been given, or his representative, such time or place or both such time and place, may be changed if the request states reasonable grounds thereof. Such request shall be addressed to the office of the Bureau of Narcotics and Dangerous Drugs which issued the notice.

(Sec. 305, 52 Stat. 1045, as amended; 21 U.S.C. 335 and Reorg. Plan No. 1 of 1968)

PART 316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Subparts A—E—[Reserved]

Subpart F—Public Hearings

Sec.

316.48 Purpose of holding public hearings.

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AUTHORITY: The provisions of this Subpart F issued under sec. 3(a)(2), 74 Stat. 374; 15 U.S.C. 1262 and Reorganization Plan No. 1 of 1968 (33 F.R. 5611).

SOURCE: The provisions of this Part 316 appear at 33 F.R. 14836, Oct. 8, 1968, unless otherwise noted.

Subparts A—E—[Reserved]

Subpart F—Public Hearings

§ 316.48 Purpose of holding public hearings.

Procedure for the issuance, amendment, or repeal of regulations under sections 201(v) (2)(C) and (3) (procedure for listing habit-forming drugs and drugs having a potential for abuse), and 502(d) (habit-forming drugs) of the Federal Food, Drug, and Cosmetic Act, is described in section 701(e)(1) of the Federal Food, Drug, and Cosmetic Act. Public hearings contemplated by this Subpart F arise only through the rule-making provisions cited and will be granted only where adverse effect and/or reasonable grounds can be shown. Hearings will be limited to the issues raised by the objections filed within the statutory time limits, or extended as specified in order of the Director.

RULES OF PRACTICE AND PROCEDURE FOR FILING PROPOSALS, PETITIONS, OBJECTIONS, AND HOLDING PUBLIC HEARINGS UNDER SECTION 701 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO DRUG ABUSE CONTROL AMENDMENTS OF 1965

GENERAL INFORMATION

§ 316.51 Scope of rules.

The sections in this Subpart F govern the practice and procedures in proceedings and hearings conducted pursuant to section 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, et seq., as amended; 21 U.S.C. 301-392).

§ 316.52 Definitions.

As used in this Subpart F the following terms shall have the meanings specified:

(a) The term "act" means the Federal Food, Drug, and Cosmetic Act.

(b) The term "Department" means the Department of Justice.

(c) The term "Attorney General" means the Attorney General of the United States, and any officer, employee or agency of the Department of Justice duly authorized by the Attorney General (directly or indirectly by means of one or more redelegations of authority) to act in his stead.

(d) The term "Director" means the Director of the Bureau of Narcotics and Dangerous Drugs.

(e) The term "person" includes an individual, partnership, corporation, and association.

(f) The term "presiding officer" means the Director or a hearing examiner appointed as provided in the Administrative Procedure Act (60 Stat. 235; 5 U.S.C. 1001 et seq.).

(g) The term "Hearing Clerk" means the hearing clerk of the Department.

(h) The term "FEDERAL REGISTER" means the publication provided for by the Federal Register Act of July 26, 1935, and acts supplementary thereto and amendatory thereof (44 U.S.C. 301-314).

(i) The term "proceeding" means any action taken pursuant to section 701(e) (1) of the act for the issuance, amendment, or repeal of any regulation issued pursuant to sections 201(v) (2) (C) and (3), and 502(d).

(j) The term "hearing" means any hearing held pursuant to section 701(e) (3) of the act.

(k) Any term not defined in this section shall have the definition set forth in section 201 of the act.

§ 316.53 Filing; address; hours; papers to be filed.

Documents required or permitted to be filed in, and correspondence relating to, proceedings governed by the regulations in this Subpart F shall be filed with the Hearing Clerk, Bureau of Narcotics and Dangerous Drugs, Room 613, 633 Indiana Avenue, Washington, D.C. 20537. This Office is open Monday through Friday from 8:30 a.m. to 5 p.m., eastern standard or daylight saving time, whichever is effective in the District of Columbia at the time, except on national legal holidays.

§ 316.54 Inspection of records.

Subject to the provisions of law restricting public disclosure of information, all documents filed in the docket in any proceeding may be inspected and copied in the office of the Hearing Clerk.

§ 316.55 Information; special instructions.

Information regarding procedure under these rules and instructions supplementing these rules in special instances will be furnished on application to the Hearing Clerk.

§ 316.56 Use of gender and number.

Words importing the singular number may extend and be applied to the plural. Words importing the masculine gender may be applied to the feminine gender.

§ 316.57 Waiver, suspension, amendment of rules.

The Director or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this Subpart F, by announcement at the hearing or by notice in advance of the hearing, if he determines that no party will be unduly prejudiced and the ends of justice will thereby be served.

APPEARANCE, PRACTICE, AND BURDEN OF PROOF

§ 316.58 Appearance.

Any interested person may appear in person or by or with counsel or other duly qualified representative in any proceeding or hearing and may be heard with respect to matters relevant to the issues under consideration.

§ 316.59 Authority for representation.

Any individual acting in a representative capacity in any proceeding may be required by the Director or the presiding officer to show his authority to act in such capacity.

§ 316.60 Written appearance.

Any interested person desiring to appear at any hearing or prehearing conference shall, within the time specified in the notice of hearing, file with the presiding officer a written notice of appearance as specified in § 316.64 setting forth his name, address, and interest. If any interested person desires to be heard through a representative, such person or such representative shall file with the presiding officer a written appearance setting forth the name, address, and employment of such person. The written notice of appearance shall conform to the form set forth in § 316.64. Any person or representative shall state with particularity in the notice of appearance his interest in the proceeding and shall set forth the objection or issue concerning which such person desires to be heard.

§ 316.61 Practice defined.

Practice before the Director shall comprehend all matters connected with any

proceeding or hearing conducted pursuant to section 701 of the act (21 U.S.C. 371).

§ 316.62 Conduct at hearings.

Disrespectful, disorderly, or contumacious language or contemptuous conduct, refusal to comply with directions, continued use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct at any hearing before the Director or a presiding officer, shall constitute grounds for immediate exclusion from the hearing.

§ 316.63 Burden of proof.

(a) At any hearing held as provided in section 701 of the act, the originator of the proposal or petition for the issuance, amendment, or repeal of any regulation contemplated under section 701 (e) (1) of the act, shall be, within the meaning of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)), the proponent of the rule or order, and accordingly shall have the burden of proof.

(b) Any adversely affected person filing an objection pursuant to section 701 (e) (2) of the act, which objection proposes the substitution of a new provision for that provision objected to, shall have the burden of proof in relation to the new provision so proposed.

§ 316.64 Form of written appearance.

DEPARTMENT OF JUSTICE
BUREAU OF NARCOTICS AND DANGEROUS DRUGS

In the matter of:
(Identify the matter in which the appearance is being filed, as set forth in the notice of hearing.)

Docket No. _____ written appearance.
Pursuant to the provisions of § 316.60 of the regulations governing the procedure in the referenced matter, please enter the appearance of the undersigned,

(Name. Please type or print)

(Street address)

(City and State)

appearing in behalf of,

(Name)

(Street address)

(City and State)

(A) (Give a specific statement of the interest of the undersigned in the proceeding.)

(B) (Set forth the specific objection or issue concerning which the undersigned desires to be heard.)

All notices to be sent pursuant to this appearance should be addressed to:

(Name)

(Street address)

(City and State)

(Signature of principal)

(Signature of authorized counsel or representative)

FILING PETITIONS, PUBLICATION OF PROPOSALS AND PETITIONS, FILING OBJECTIONS AND REQUESTS FOR HEARINGS

§ 316.65 Procedure for filing petitions.

(a) Petitions for the issuance, amendment, or repeal of any regulation subject to the provisions of section 701(e) of the act shall be submitted in quintuplicate to the Director. If any part of the material submitted is in a foreign language it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's mailing address to which a copy of the notice contemplated by section 701(e) (2) of the act may be sent.

(b) Petitions shall include the following data and be submitted in the following form:

(Date)

DIRECTOR BUREAU OF NARCOTICS AND DANGEROUS DRUGS,
Post Office Box 2079,
South Eads Street Station,
Arlington, Va. 22202.

DEAR SIR: The undersigned _____, submits this petition pursuant to section 701(e) (1) (B) of the Federal Food, Drug, and Cosmetic Act with respect to the issuance (amendment or repeal) of a regulation under _____ (the blank to be filled in with the appropriate section of the Federal Food, Drug, and Cosmetic Act: Sections 201(v) (2), 502(d)).

Attached hereto, in quintuplicate and constituting a part of this petition, are the following:

(A) The proposed regulation in the form proposed by the petitioner.

(B) A statement of the grounds upon which the petitioner relies for the issuance

(amendment or repeal) of the regulation. (Such grounds shall include a reasonably precise statement of the facts relied upon by the petitioner. If it appears that reasonable grounds for the action proposed are not stated in the petition, the petition will be denied.)

(C) If the petition seeks the amendment or repeal of an existing regulation, a reference to the section of Title 21, Chapter II of the Code of Federal Regulations where it appears.

Very truly yours,

(Petitioner)

Per -----

(Indicate authority)

Mail address -----

This petition must be signed by the petitioner or by his attorney or authorized representative, or (if a corporation) by an authorized official.

All petitions shall be submitted in triplicate. A single copy will not be accepted for filing.

(c) The Director shall notify the petitioner promptly after its receipt of acceptance or nonacceptance of a petition, and if not accepted the reason therefor. A petition shall not be accepted for filing if any of the data prescribed in paragraph (b) of this section are lacking or are not set forth so as to be readily understood. If petitioner desires, he may supplement a deficient petition after notification of deficiency. The proposal contained in any petition filed with the Director for the issuance, amendment, or repeal of any regulation subject to the provisions of section 701(e) of the act, and any proposal initiated by the Director under section 701(e) (1) (A) shall be published in the FEDERAL REGISTER as provided in § 316.66.

§ 316.66 Proposals and petitions.

(a) The Director, under the authority delegated to him by the Attorney General (28 CFR 0.200), on his own initiative or upon petition filed with him by any interested person stating reasonable grounds therefor, shall publish in the FEDERAL REGISTER any proposal or petition to issue, amend, or repeal any regulation contemplated under the following sections of the act: Sections 201(v) (2) (C) and (3), and 502(d).

(b) Such published notice will provide for a time period of not less than 30 days within which all interested persons may present their views and comments thereon in writing.

(c) As soon as practicable after the expiration of the time for filing views and comments the Director shall publish in the FEDERAL REGISTER his order acting upon such proposal or petition. Except as provided in § 316.67, this order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under this section.

§ 316.67 Objections to the Director's order and requests for hearings.

(a) On or before the 30th day after the date of the publication of the Director's order in the FEDERAL REGISTER as specified in § 316.66(c), any person who will be adversely affected by such order, if placed in effect, may submit objections thereto to the Director and request a public hearing on the stated objections.

(b) These objections shall be accepted for filing only when they comply with all the following provisions:

(1) Objections shall be received by the Hearing Clerk if postmarked on or before the 30th day after the date of publication of the Director's order in the FEDERAL REGISTER.

(2) Each objection to a provision of the Director's order shall be separately numbered.

(3) Objections must establish that the objector will be adversely affected by the order.

(4) Objections must specify with particularity the provisions of the order to which objection is taken.

(5) Objections must be supported by reasonable grounds which, if true, are adequate to justify the relief sought.

(c) If the statement of objections is not accepted for filing because of failure to comply with paragraph (b) of this section, the Director shall so inform the objector and state the reasons for refusing to file the objections.

(d) If objections to the Director's order issued pursuant to a petition are filed by a person other than the petitioner, the Bureau of Narcotics and Dangerous Drugs shall mail a copy of the objections to the petitioner at the address given in the petition. Petitioner shall have 2 weeks from the date of receipt of the objections to make written reply.

(e) As soon as practicable after the time for filing objections has expired, the Director shall publish a notice in the FEDERAL REGISTER specifying those parts

of the order that have been stayed by the filing of objections or, if no objections have been filed, stating that fact.

PUBLIC HEARINGS AND NOTICE THEREOF

§ 316.68 Hearings under section 701(e) of the act.

(a) Under the authority delegated to him by the Attorney General (28 CFR 0.201), the Director on his own initiative or upon a petition of any interested person adversely affected stating reasonable ground therefor, shall hold a public hearing for the purpose of receiving evidence relevant and material to the issues raised by objections filed pursuant to § 316.67 to any proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of the act: Sections 201(v) (2) (C) and (3), 502(d).

(b) Concurrently, with the action taken pursuant to § 316.67, if a proceeding is stayed by the filing of objections, and a public hearing is requested, the Director shall cause to be published in the FEDERAL REGISTER a notice reciting the receipt of objections, those parts of the order that have been stayed by the filing of objections, and announcing that a public hearing will be held to receive evidence on the issues raised by such objections.

§ 316.69 Notice of hearing.

(a) As soon as practicable after a request for a public hearing has been filed, the Director shall cause to be published in the FEDERAL REGISTER a notice of hearing.

(b) The notice of hearing shall set forth the following information:

(1) A statement of the provisions of the order to which objections have been filed, and a summary of the objections.

(2) A statement of the issues raised by the objections.

(3) The designation of the presiding officer to conduct the hearing.

(4) The place where the hearing will be held.

(5) The time within which written appearances must be filed.

(6) The time (not earlier than 30 days after the date of publication of the notice of hearing in the FEDERAL REGISTER) when the hearing will commence.

§ 316.70 Time and place of hearing.

The hearing will commence at the place and time announced in the notice

of hearing, but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without other notice than announcement thereof by the presiding officer at the hearing.

DESIGNATION, POWERS, RESPONSIBILITIES, AND DUTIES OF PRESIDING OFFICER

§ 316.71 Presiding officer.

A presiding officer shall preside over all hearings held pursuant to section 701 of the act. The presiding officer shall be either the Director or a hearing examiner qualified under section 11 of the Administrative Procedure Act and designated by the Director to conduct the hearing.

§ 316.72 Commencement of functions.

The functions of the presiding officer shall commence upon his designation and terminate upon the certification of the record to the Director.

§ 316.73 Authority of presiding officer.

Hearings shall be conducted in an informal but orderly manner in accordance with this Subpart F and the requirements of the Administrative Procedure Act, and where such sections or the Administrative Procedure Act are inapplicable or incomplete, in accordance with the directions of the presiding officer. The presiding officer shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. He shall have all powers necessary to these ends, including (but not limited to) the power to:

(a) Arrange and issue notice of the date, time, and place of hearings and prehearing conferences, and, upon proper notice to change the date, time, and place of hearings and prehearing conferences previously set.

(b) Hold conferences to settle, simplify, or fix the issues in a proceeding, or to consider other matters that may aid in the expeditious disposition of the proceeding.

(c) Require parties to state their position with respect to the various issues in the proceeding.

(d) Administer oaths and affirmations.

(e) Regulate the course of the hearing and the conduct of counsel therein.

(f) Examine witnesses and direct witnesses to testify.

(g) Receive, rule on, exclude, or limit evidence.

(h) Fix the time for filing motions, petitions, briefs, findings, or other items in matters pending before him.

(i) Rule on motions and other procedural items pending before him.

(j) Take any action permitted to the presiding officer as authorized by this Subpart F or in conformance with the provisions of the Administrative Procedure Act (5 U.S.C. 1001 to 1011).

PREHEARING AND OTHER CONFERENCES

§ 316.74 Prehearing conference.

The presiding officer on his own motion, or on the motion of any party or his representative, may direct all parties or their representatives to appear at a specified time and place for a conference for:

(a) The simplification of the issues.
(b) The possibility of obtaining stipulations, admission of facts, and documents.

(c) The possibility of limitation of the number of expert witnesses.

(d) The identification, and if practicable, the scheduling of witnesses to be called.

(e) The advance submission at the prehearing conference of all documentary evidence in quintuplicate to be marked for identification. (When portions only of a document are to be relied upon, the offering party shall prepare the pertinent excerpts thereof, adequately identified, and shall supply copies of such excerpts together with the original document to the presiding officer for examination and study by all other parties and for use by opposing counsel for purpose of cross-examination.)

(f) Such other matters as may aid in the expeditious disposition of the proceeding.

§ 316.75 Exclusion of witnesses and documentary evidence.

The failure to identify witnesses and submit documentary evidence at the prehearing conference in accordance with the requirements of § 316.74 of this Subpart F may result in the testimony or documents not being heard or received in evidence, in the absence of a showing that the offering party had good cause for the failure to produce the documents or identify the witnesses.

§ 316.76 Prehearing order.

The presiding officer may have the prehearing conference reported verbatim

and shall make an order reciting the action taken at the conference, the agreements made by the parties or their representatives, the schedule of witnesses, and a statement of the issues for hearing. Such order shall control the subsequent course of the proceeding unless modified for good cause by subsequent order.

§ 316.77 Other conferences.

The presiding officer may also direct all parties and their representatives to appear at conferences at any reasonable time during the hearing, with a view to simplification, clarification, or shortening of the hearing.

HEARING PROCEDURES

§ 316.78 Statements of position.

The presiding officer may require parties to exchange written statements of position, with copies to all other parties, prior to the beginning of a hearing. These statements should include a showing of the theory of the party submitting this statement and will not be subject to cross-examination.

§ 316.79 Evidentiary purpose of hearing.

The hearing is directed to receiving factual evidence and expert opinion testimony related to the issues, in the proceeding. Argument will not be received into evidence; rather, it should be presented in opening or closing statements of counsel, memoranda, or briefs, as determined by the presiding officer.

§ 316.80 Submission of documentary evidence and identification of witnesses subsequent to prehearing conference.

(a) All documentary evidence not submitted at the prehearing conference shall be submitted to the presiding officer as soon as possible, with a showing that the offering party had good cause for failing to produce the documents at the prehearing conference. If the presiding officer determines that good cause does exist, the documents shall be submitted to the parties sufficiently in advance of the offer of such documents for introduction into the record to permit study and preparation of cross-examination and rebuttal evidence.

(b) The authenticity of all published documents submitted in advance shall be deemed admitted unless written ob-

jection thereto is filed with the presiding officer upon notice to the other parties within the time specified by the presiding officer in accordance with this section, except that a party will be permitted to challenge such authenticity at a later time upon a showing of good cause for failure to have filed such written objection.

(c) Any witness identification not submitted at the prehearing conference shall be submitted to the presiding officer as soon as available, with a showing that the offering party had good cause for failing to produce the identification at the prehearing conference. If the presiding officer determines that good cause does exist, the identification shall be submitted to the parties to the hearing as soon as possible.

§ 316.81 Submission and receipt of evidence.

(a) *Witnesses.* The presiding officer may direct that summaries of the direct testimony of witnesses be prepared in writing and served in advance of the hearing. If so directed, such summaries shall be served on all parties, a copy to the presiding officer as directed. Witnesses will not be permitted to read summaries of their testimony into the record and all witnesses shall be available for cross-examination. Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) *Scope of testimony.* When necessary to prevent undue prolongation of the hearing, the presiding officer may limit the number of times any witness may testify, the repetitious examination and cross-examination of witnesses, or the amount of corroborative or cumulative evidence.

(c) *Evidence.* The presiding officer shall admit only evidence that is relevant, material, reliable, and not unduly repetitious.

(d) *Opinion testimony.* Opinion testimony shall be admitted when the presiding officer is satisfied that the witness is properly qualified.

(e) *Documents to be filed.* The presiding officer shall file as exhibits copies of the following documents:

(1) The proposal to issue, amend, or repeal a regulation as published in the FEDERAL REGISTER, described in § 316.66(a).

(2) The order of the Director as published in the FEDERAL REGISTER, described in § 316.66(c).

(3) The notice of receipt of objections as published in the FEDERAL REGISTER, described in § 316.67(e).

(4) The notice of public hearing as published in the FEDERAL REGISTER, described in § 316.69

(5) The prehearing order, if any, as described in § 316.76.

(6) Any other document necessary to show the basis for the hearing.

§ 316.82 Inspection of documents.

All documents constituting the record bearing on the matter or matters in controversy, and not entitled to protection under section 301(j) of the act, accumulated up to the start of the hearing shall be open for inspection by interested persons during office hours in the office of the hearing clerk.

§ 316.83 Objections.

If any person objects to the admission or rejection of any evidence or to other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection, and the transcript shall not include extended argument or debate thereon except as ordered by the presiding officer. A ruling of the presiding officer on any such objection shall be a part of the transcript, together with such offer or proof as has been made.

§ 316.84 Affidavits.

Upon a showing of their relevancy, materiality, and competency, affidavits may be marked as exhibits at the prehearing conference. Every interested person shall be permitted to examine all affidavits that have been so filed and to file counteraffidavits with the presiding officer, within a period of time to be fixed by the presiding officer, not more than 15 days following the close of the hearing. Subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006), these affidavits may be admitted into evidence. If so admitted, the Director and presiding officer will consider the lack of opportunity for cross-examination in determining the weight to be attached to statements made in the form of affidavits.

§ 316.85 Samples.

Samples may be displayed at the hearing and may be described for purposes of the record, but shall not be admitted in evidence as exhibits.

§ 316.86 Exceptions to rulings.

Exceptions to rulings of the presiding officer are unnecessary. It is sufficient that a party, at the time the ruling of the presiding officer is sought, makes known the action that he desires the presiding officer to take, or his objection to an action taken, and his grounds therefor.

§ 316.87 Official notice.

Where official notice is taken or is to be taken of a material fact not appearing in the evidence of record, any party, on timely request, shall be afforded opportunity to show the contrary.

§ 316.88 Offer of proof.

An offer of proof made in connection with an objection taken to any ruling of the presiding officer rejecting or excluding proffered oral testimony shall consist of a statement of the substance of the evidence which counsel contends would be adduced by such testimony; and, if the excluded evidence consists of evidence in documentary or written form, a copy of such evidence shall be marked for identification and shall accompany the record as the offer of proof.

§ 316.89 Appeal from ruling of presiding officer.

Rulings of the presiding officer may not be appealed to the Director prior to his consideration of the entire proceeding, except with the consent of the presiding officer and where he certifies on the record or in writing that the allowance of an interlocutory appeal is clearly necessary to prevent exceptional delay, expense, or prejudice to any party or substantial detriment to the public interest. If an appeal is allowed, any party may file a brief with the Director within such period that the presiding officer directs. No oral argument will be heard unless the Director directs otherwise.

THE RECORD**§ 316.90 Official transcript; indexing of record.**

(a) *Official transcript.* Testimony given at a public hearing shall be reported verbatim. The Department will make provision for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purposes. Any person desiring a copy of the transcript of the testimony and exhibits taken at the hearing or of

any part thereof shall be entitled to the same upon application to the official reporter and upon payment of the costs thereof.

(b) *Indexing of record.* (1) Whenever it appears to the presiding officer that the record of hearing will be of such length that an index to the record will permit a more orderly presentation of the evidence and reduce delay, the presiding officer shall require counsel for the parties to prepare a daily topical index which will be available to the presiding officer and all parties. Preparation of such an index shall be apportioned among all counsel present in such manner as appears just and proper in the circumstances.

(2) The index should include each topic of testimony upon which evidence is taken, the name of each witness testifying upon the topic, the page of the record at which each portion of his testimony appeared, and the number of each exhibit relating to the topic. The index should also contain the name of each witness, followed by the topics upon which he testified and the page of the record at which such testimony appears.

§ 316.91 Exhibits.

All written statements, charts, tabulations, reports, documents, and similar data offered in evidence at the hearing shall be marked for identification, and upon a showing satisfactory to the presiding officer of the authenticity, relevancy, materiality, and reliability, shall be received in evidence, subject to section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)). Exhibits shall be submitted in quintuplicate. In case the required number of copies are not made available, the presiding officer shall exercise his discretion in determining whether the exhibit will be read in evidence or whether additional copies will be required to be submitted within a time to be specified by the presiding officer. Where relevant and material matter offered into evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter will be excluded and will be segregated insofar as practicable, subject to the direction of the presiding officer.

§ 316.92 Record of the hearing.

The record of the hearing will include the transcript of the testimony, includ-

ing any exhibits, together with any written arguments, briefs, or memoranda of law filed with the presiding officer. As soon as practicable after the close of the hearing, the complete record of the hearing shall be filed in the office of the hearing clerk.

§ 316.93 Correction of record.

At the close of the hearing, the presiding officer shall afford witnesses and their counsel time (not longer than 30 days, except in unusual cases) in which to submit written proposed corrections of the transcript, pointing out errors that may have been made in transcribing the testimony. The presiding officer shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony.

§ 316.94 Record for decision.

The transcript of testimony and exhibits together with any written arguments that may have been filed in the proceeding, including rulings, shall constitute the exclusive record for decision.

BRIEFS, REQUESTS FOR FINDINGS, DECISIONS, EXCEPTIONS, ORAL ARGUMENT: FINAL ORDER

§ 316.95 Briefs.

The time for filing briefs and reply briefs (if permitted) with the presiding officer shall be fixed by him. The person submitting a brief shall file five copies with the hearing clerk. Briefs shall include a statement of position on each issue as supported by the evidence of record, together with specific and complete citations of the pages of the transcript and exhibits, together with citations of authorities relied upon. Briefs shall contain proposed findings of fact and conclusions of law when requested by the presiding officer.

§ 316.96 Decisions.

As soon as practicable after the time for filing of briefs has expired, the presiding officer shall prepare a report and shall certify the record together with his report to the Director.

§ 316.97 Tentative order.

(a) As soon as practicable thereafter the Director shall prepare and cause to be published in the FEDERAL REGISTER his tentative order, including detailed find-

ings of fact and conclusions upon which it is based.

(b) The tentative order shall specify a reasonable time (ordinarily not to exceed 60 days), within which any party of record may file exceptions to the proposed order. The exceptions shall point out with particularity the alleged errors in said order and shall contain a specific reference to the pages of the transcript of the testimony or to exhibits on which exceptions are based. Such exceptions may be accompanied by a memorandum or brief in support thereof and if oral argument on the exceptions is desired, such a request shall be made with the exceptions. The Director will grant or deny oral argument in his discretion.

§ 316.98 Final order.

As soon as practicable after the time for filing exceptions has passed, the Director shall cause to be published in the FEDERAL REGISTER his final order in the proceeding, which shall set forth detailed findings of fact and conclusions upon which the order is based. This order shall specify the date on which it shall take effect. (Sec. 701(e)(3), Federal Food, Drug, and Cosmetic Act.)

JUDICIAL REVIEW**§ 316.101 Copies of petitions for judicial review.**

The Chief Counsel, Bureau of Narcotics and Dangerous Drugs, Department of Justice has been designated as the officer upon whom copies of petitions for judicial review, filed pursuant to section 701(f)(1) of the act, shall be served. Such officer shall be responsible for filing in the court the record of the proceedings on which the final order is based. The record of the proceeding shall be certified by the Director.

JUDICIAL STANDARDS OF PRACTICE**§ 316.102 Conduct.**

Parties and their representatives appearing in hearings held pursuant to section 701 of the act, whether or not members of the bar, are expected to conduct themselves with honor and dignity and observe judicial standards of practice and ethics. They should not indulge in offensive personalities, unseemly wrangling, or intemperate accusations or characterizations. A representative of any party should use his best efforts to restrain his client from improprieties in connection with proceeding.

§ 316.104 **Ex parte communications.**

If any official of the Bureau of Narcotics and Dangerous Drugs is contacted by any individual in private or public life concerning any matter which is the subject of a public hearing, the official who is contacted shall prepare a memorandum setting forth the substance of the conversation and shall file this memorandum in the appropriate public docket file.

PARENT SUBSTANCE—BARBITURIC ACID

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative or its salts ¹
5-Allyl-5-cyclopentenylbarbituric acid.....		Cyclopal. Cyclophen. Sandoptal.
5-Allyl-5-isobutylbarbituric acid.....	Allylbarbituric acid.	
	Allylisobutylbarbituric acid.	
5-Allyl-5-isopropylbarbituric acid.....	Aprobarbital.	Alurate.
	Allylisopropylbarbituric acid.	Numal.
	Allylisopropylmalonylurea.	
5-Allyl-5-isopropyl-1-methylbarbituric acid.....		Narconumal.
5-(2-Bromoallyl)-5-isopropyl-1-methylbarbituric acid.		Eunarcen.
5-(2-Bromoallyl)-5-(1-methylbutyl)-barbituric acid.	β -Bromoallyl sec-amylbarbituric acid.	Sigmodal. Ectidion. R239.
5-sec-Butyl-5-(2-bromoallyl)-barbituric acid.....	Butallylonal.....	Fernoston. Fernocton.
5,5-Diallylbarbituric acid.....	Diallyl barbituric acid.....	Dial. Allobarbitol. Allobarbitone. Curral. Diadol. Deba. Dormonal. Hypnogene. Malonal. Medinal. Sedeval. Veronal. Uronal. Vesperial.
5,5-Diethylbarbituric acid.....	Barbital..... Barbitone. Diethylbarbituric acid. Diethylmalonylurea.	Cyclonal Sodium. Dorico Soluble. Evipal Sodium. Evipan Sodium. Hexanastab. Hexobarbitone Sodium. Methenexyl Sodium. Proponal.
1,5-Dimethyl-5-(1-cyclohexenyl)-barbituric acid.....	Hexobarbital sodium.....	Etoval. Neonal Butobarbital. Soneryl. Butisol Sodium. Cyclobarbitone. Namuron. Palinum. Phanodorm. Phanodorm. Tetrahydrophenobarbital. Pental.
5,5-Dipropylbarbituric acid.....	Dipropylbarbituric acid.....	Hebaral. Ortal Sodium Amytal.
5-Ethyl-5-butylbarbituric acid.....	Butethal..... Butobarbital.	Ipral. 844.
5-Ethyl-5-sec-butylbarbituric acid.....	Butabarbitol sodium.....	Embotal. Nembotal. Napethal. Pentyl.
5-Ethyl-5-(1-cyclohexenyl)-barbituric acid.....	Cyclobarbitol.....	Intraval Sodium. Nesdonal Sodium. Pentothal Sodium. Thiothal Sodium.
5-Ethyl-5-cyclopentenyl-barbituric acid.....		
5-Ethyl-5-hexylbarbituric acid.....	Hexethal sodium.....	
5-Ethyl-5-isoamylbarbituric acid.....	Amobarbital.....	
5-Ethyl-5-isopropylbarbituric acid.....	Probarbital.....	
5-Ethyl-5-(1-methylbutyl)-barbituric acid.....	Pentobarbital sodium..... Soluble pentobarbital.	
5-Ethyl-5-(1-methylbutyl)-2-thiobarbituric acid.....	Thiopental sodium..... Thiopentone sodium.	

PART 319—HABIT-FORMING DRUGS

§ 319.1 Habit-forming drugs which are chemical derivatives of barbituric acid, a substance specified in section 502(d) of the Federal Food, Drug, and Cosmetic Act.

Each of the following substances is a derivative of barbituric acid, a chemical derivative of a substance named in section 502(d) of the Federal Food, Drug, and Cosmetic Act is hereby designated as habit-forming:

PARENT SUBSTANCE—BARBITURIC ACID—Continued

Chemical description of derivative	Common or official name of chemical derivative or its salts	Some trade or other names of chemical derivative or its salts ¹
5-Ethyl-5-(1-methyl-1-butenyl)-barbituric acid.....	Vinbarbital.....	Delyval Sodium.
5-Ethyl-5-phenylbarbituric acid.....	Phenobarbital..... Phenobarbitone. Phenylethylmalonylurea.	Barbenyl. Barbiphenyl. Dorminal. Euneryl. Gardenal. Luminal. Nunol. Neurobarb. Phenonyl. Somonal.
5-Ethyl-5-phenyl-1-methylbarbituric acid.....	Mephobarbital.....	Mebaral. Phemitone. Prominal.
5-Ethyl-5-(1-piperidyl)-barbituric acid.....		Eldoral.
5-Isopropyl-5-(2-bromoallyl)-barbituric acid.....	Propallylonal.....	Noctal. Nostal.
5-Methyl-5-phenylbarbituric acid.....	Phenylmethylbarbituric acid.....	Rutonal.
All lithium, sodium, potassium, magnesium, calcium, strontium, and ammonium salts of the foregoing chemical derivatives of barbituric acid.		
Sodium-5-allyl-5-(1-methylbutyl)-barbiturate.....	Secobarbital sodium..... Soluble secobarbital.	Seconal Sodium. Evronal Sodium

All salts of the foregoing chemical derivatives formed by replacing the sodium with lithium, potassium, magnesium, calcium, strontium, or ammonium radical.

¹This list of trade or other names is not a complete list of the many proprietary names under which the designated habit-forming chemical derivatives are distributed.

(Sec. 502, 52 Stat. 1050, as amended; 21 U.S.C. 352) [33 F.R. 14841, Oct. 3, 1968]

PART 320—DEPRESSANT AND STIMULANT DRUGS; DEFINITIONS, PROCEDURAL AND INTERPRETATIVE REGULATIONS

Sec. 320.1	Definitions and interpretations.
320.2	Criteria applicable to terms used or defined in § 320.1.
320.3	Listing of drugs defined in section 201(v) of the act.
320.4	Procedure for the issuance, amendment, or repeal of regulations defining substances as habit forming or has having a potential for abuse.
320.5	Substances exempt from the definition of depressant or stimulant drug.
320.6	Registration of producers and certain wholesalers of depressant or stimulant drugs.
320.7	Procedures for exempting depressant or stimulant drugs from the provisions of section 511 of the act.
320.8	Combination drugs; exemptions from section 511 of the act.
320.16	Records required to be maintained under section 511(d) of the act.
320.17	Persons required to establish, prepare, and maintain records specified in section 511(d)(1) of the act.
320.18	Label symbol.

Sec. 320.19	Advisory committees; appointment; procedure; fees.
320.20	Exportation.

AUTHORITY: The provisions of this Part 320 issued under secs. 201(v), 511, 701, 52 Stat. 1055, as amended, 79 Stat. 227 et seq.; 21 U.S.C. 321(v), 360a, 371, and Reorg. Plan No. 1 of 1968 (33 F.R. 5611).

SOURCE: The provisions of this Part 320 appear at 33 F.R. 14842, Oct. 3, 1968, unless otherwise noted.

§ 320.1 Definitions and interpretations.

(a) The term "act" means the Federal Food, Drug, and Cosmetic Act approved June 25, 1938 (52 Stat. 1040 et seq., as amended; 21 U.S.C. 301-392).

(b) "Department" means the Department of Justice.

(c) "Attorney General" means the Attorney General of the United States, and any officer, employee or agency of the Department of Justice duly authorized by the Attorney General (directly or indirectly by means of one or more redelegations of authority) to act in his stead.

(d) "Director" means the Director of the Bureau of Narcotics and Dangerous Drugs.

(e) "Person" includes individuals, partnerships, corporations, and associations.

(f) The Bureau of Narcotics and Dangerous Drugs is the organizational unit established within the Department of Justice charged with the administration of the Drug Abuse Control Amendments of 1965 (Public Law 89-74, 79 Stat. 226 et seq.).

(g) The term "depressant or stimulant drug" means any drug which contains any quantity of:

(1) Barbituric acid or any of the salts of barbituric acid.

(2) Any derivative of barbituric acid which has been designated by the Director under section 502(d) of the act as habit-forming.

(3) Amphetamine or any of its optical isomers.

(4) Any salt of amphetamine or any salt of an optical isomer of amphetamine.

(5) Any substance which the Director, after investigation, has found to be, and by regulation designated as, habit-forming because of its stimulant effect on the central nervous system.

(6) Any substance which the Director, after investigation, has found to have, and by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(h) The terms "manufacture, compounding, or processing of a drug", "manufacturing, compounding, or processing of a depressant or stimulant drugs", and "manufacture, compound, or process any depressant or stimulant drug" as used in sections 301(q) (1), 304 (a) (2) (D), and 511(a) of the act mean the manufacture, preparation, propagation, compounding, or processing of a drug by chemical, physical, biological, or by any other means, including manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process. The terms include labeling, relabeling, repackaging, or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(i) The term "wholesaling, jobbing, or distributing of depressant or stimulant drugs" covers any system of selling or distributing of any depressant or stimu-

lant drug to any person who is not the ultimate user or consumer of the drug. Wholesalers include jobbers and medical supply houses who may not be required to obtain licenses as drug wholesalers under some state laws.

(j) The term "controlled substance" means those drugs or substances designated under section 201(v) of the act and the regulations thereunder as subject to the Drug Abuse Control Amendments of 1965 (Public Law 89-74, 79 Stat. 226 et seq.), and includes such substances in bulk, in finished form, semiprocessed form, in finished packages, and preparations containing any amounts of such substance.

§ 320.2 Criteria applicable to terms used or defined in § 320.1.

(a) In determining whether a drug has a "stimulant effect" on the central nervous system, the Director will consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:

- (1) Extended wakefulness.
- (2) Elation, exhilaration, or euphoria (exaggerated sense of well-being).
- (3) Alleviation of fatigue.
- (4) Insomnia, irritability, or agitation.
- (5) Apprehension or anxiety.
- (6) Flight of ideas, loquacity, hypomania, or transient deliria.

(b) In determining whether a drug has a "depressant effect" on the central nervous system, the Director will consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:

- (1) Calming effect or relief of emotional tension or anxiety.
- (2) Drowsiness, sedation, sleep, stupor, coma, or general anesthesia.
- (3) Increase of pain threshold.
- (4) Mood depression or apathy.
- (5) Disorientation, confusion, or loss of mental acuity.

(c) In determining whether a drug is "habit forming", the Director will consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:

- (1) A psychological or physical dependence on the drug (compulsive use).

(2) Euphoria (exaggerated sense of well-being).

(3) Personality changes.

(4) Transient psychoses, deliria, twilight state, or hallucinoses.

(5) Chronic brain syndrome.

(6) Increased tolerance or a need or desire to increase the drug dosage.

(7) Physical dependence or a psychic dependence evidenced by a desire to continue taking the drug for the sense of improved well-being that it engenders.

(8) Pharmacological activity similar or identical to that of drugs previously designated as habit forming.

(d) In determining whether a drug has a "hallucinogenic effect", the Director will consider, among other relevant factors, whether there is substantial evidence that it may produce hallucinations, illusions, delusions, or alteration of any of the following:

(1) Orientation with respect to time or place.

(2) Consciousness, as evidenced by confused states, dreamlike revivals of past traumatic events, or childhood memories.

(3) Sensory perception, as evidenced by visual illusions, synesthesia, distortion of space and perspective.

(4) Motor coordination.

(5) Mood and affectivity, as evidenced by anxiety, euphoria, hypomania, ecstasy, autistic withdrawal.

(6) Ideation, as evidenced by flight of ideas, ideas of reference, impairment of concentration and intelligence.

(7) Personality, as evidenced by depersonalization and derealization, impairment of conscience and of acquired social and cultural customs.

(e) The Director may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:

(1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the

safety of other individuals or of the community; or

(2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or

(4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

§ 320.3 Listing of drugs defined in section 201(v) of the act.

(a) The Director designates all drugs, unless exempted by regulations in this part, containing any amount of the following substances as depressant or stimulant drugs:

(1) Barbituric acid or any salt of barbituric acid.

(2) Derivatives of barbituric acid which have been designated in § 319.1 of this chapter as habit forming pursuant to section 502(d) of the act.

(3) Dextroamphetamine, levoamphetamine, or amphetamine (racemic) or any salt of dextroamphetamine, levoamphetamine, or amphetamine (racemic). Amphetamine is known chemically as *d*-, *l*- or *dl*- α -methylphenethylamine. It has been declared by such designations as *d*-amphetamine, *l*-amphetamine, or *dl*-amphetamine followed by the name of the salt. The following is a partial list of amphetamine products:

Established name or other non-proprietary designation

Amphetamine phosphate-----

Amphetamine salts or optical isomers of amphetamine salts.

Some trade or other names

Actemin, Aktedron, Amphate, Biphetamine, Dieta-
mine, Monophos, Profetamine Phosphate, Race-
phen, Raphetamine Phosphate.

<i>Established name or other non-proprietary designation</i>	<i>Some trade or other names</i>
Amphetamine sulfate-----	Alentol, Amphoids-S, Benzadrine Sulfate, Linampheta, Psychoton, Simpamina, Amphetamine Sulfate.
Dextroamphetamine carboxymethyl-cellulose salt.	
Dextroamphetamine hydrochloride.	
Dextroamphetamine phosphate-----	Dextro-Profetamine.
Dextroamphetamine sulfate-----	Adrizine, Am-Dex, D-Amfetasil, Amitrene, Amphetamine, Ampherex, Amphex, Amsustain, D-Ate Ph. 747, Betafedrina, d-Betaphedrine, Cendex Cenules, D-Citramine, Cradex, Dadex, D.A.S., Dexalone, Dexamphetamine, Dexedrine, Dex-OB, Dex-Sule, Dexten, Dextrosule, Diocurb, Domafate, Evrodex, Hetamine, Lowedex, Maxiton, Medex, Nilox, Obesedrin, Obesonil, Pellcaps, Pomadex, Simpamina-D, Sympamin, Tydex, Zamitam Plateau.
Dextroamphetamine tannate-----	Tamphetamin, Synatan.
Dibasic amphetamine phosphate-----	Bar-Dex.
Dibasic dextroamphetamine phosphate.	
Levoamphetamine -----	Ad-Nil, Amphetamine-M, Lavabo, Levamphetamine, Levonor.
Levoamphetamine succinate-----	Cydril.

(b) The Director has investigated and designates all drugs, unless exempted by regulations in this part, containing any amount of the following substances as having potential for abuse and habit-forming because of their stimulant effect on the central nervous system:

<i>Established name</i>	<i>Some trade and other names</i>
d-, dl - Methamphetamine and their salts.	d-, dl-Desoxyephedrine and their salts.
Phenmetrazine and its salts.	Preludin.

(c) The Director has investigated and designates all drugs, unless exempted by regulations in this part, containing any amount of the following substances as having a potential for abuse because of their:

<i>Established name or other nonproprietary designation</i>	<i>Some trade and other names</i>
Chloral betaine----	Beta-Chlor.
Chloral hydrate----	Chloral.
Chlordiazepoxide and its salts.	Librium.
Chlorhexadol -----	Lora.
Diazepam -----	Valium.
Ethchlorvynol -----	Placidyl.
Ethinamate -----	Valmid.
Glutethimide -----	Doriden.

<i>Established name or other nonproprietary designation</i>	<i>Some trade and other names</i>
Lysergic acid.	
Lysergic acid amide.	
Meprobamate ----	Apascal, Atraxin, Biobamat, Calmiren, Cirpon, Cyron, Ecuaniil, Equanil, Equanil LA, Harmonin, Mepantin, Mepavlon, Meproleaf, Meprosin, Meprospan, Meprotrabs, Miltown, Nervonus, Neuramate, Oasil, Pameco, Panediol, Perequill, Perquietil, Pertranquil, Placidon, Probamyl, Quaniil, Quilate, Sedabamate, Sedazil, Urbil, Viobamate.
Methyprylon -----	Noludar.
Paraldehyde -----	
Petrichloral -----	Periclor.
Phencyclidine and its salts.	1- (1-Phencyclohexyl) Piperidine; Sernyl; Sernylan; GP-121; CI-395; PCP; "Peace Pill."
Sulfondiethylmethane.	Tetronal.
Sulfonethylmethane.	Trional.
Sulfonmethane ---	Sulfonal.

(2) Stimulant effect on the central nervous system:

<i>Established name</i>	<i>Some trade and other names</i>
Methylphenidate and its salts.	Methyl a-Phenyl-2-piperidine acetate; a-Phenyl-2-piperidine acetic acid methyl ester; a-Phenyl-a-(2-piperidyl) acetic acid methyl ester; Methyl a-Phenyl-a-(2-piperidyl) acetate; Methylphenidyl Acetate; Ritalin (R) hydrochloride; Ritalin; Phenidylate; 4311/b; Centedrin; c 43-IIC: Meridil.
Bufotenine and its salts.	3-(β-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N,N-dimethylserotonin; 5-hydroxy-N-dimethyltryptamine; mappine.
DET and its salts--	N,N-Diethyltryptamine.
DMT -----	Dimethyltryptamine.
DOM (STP) -----	4-Methyl-2,5-dimethoxyamphetamine; 4-methyl-2,5-dimethoxy-α-methylphenethylamine and "STP".
Ibogaine and its salts.	7-Ethyl-8,8a,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido (1',2':1,2 azepino (4,5-b) indole; tabernanthe iboga.
LSD-25; LSD-----	d-Lysergic acid diethylamide.
Mescaline and its salts.	
Peyote.	
Phencyclidine and its salts.	1-(1-Phencyclohexyl) Piperidine; Sernyl; Sernylan; GP-121; CI-395; PCP; "Peace Pill."
Psilocybin; psilocbin.	
Psilocyn; psilocin--	

Synthetic equivalents of the substances contained in the plant, or in the resinous extractives of *Cannabis*, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

Δ¹ cis or trans tetrahydrocannabinol, and their optical isomers.

Δ² cis or trans tetrahydrocannabinol, and their optical isomers.

Δ⁸ tetrahydrocannabinol, and its optical isomers.

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.)

The listing of peyote in this subparagraph does not apply to nondrug use in bona fide religious ceremonies of the Native American Church; however, persons supplying the product to the Church are required to register and maintain appropriate records of receipts and disbursements of the article.

[33 F.R. 14842, Oct. 3, 1968, as amended at 34 F.R. 4888, 4889, Mar. 6, 1969; 34 F.R. 15295, Oct. 1, 1969]

NOTE: The provisions of § 320.3(c) as they apply to any drug because it contains any amount of chlordiazepoxide or its salts, or diazepam were stayed, 31 F.R. 7174, May 17, 1966. Meprobamate was similarly stayed, 33 F.R. 3635, Mar. 1, 1968.

§ 320.4 Procedure for the issuance, amendment, or repeal of regulations defining substances as habit forming or as having a potential for abuse.

(a) Under the provisions of section 201(v) (2) and (3) of the act, the Director, under authority delegated to him by the Attorney General (28 CFR 0.200), is authorized to conduct investigations and promulgate regulations for the purpose of:

- (1) Designating any drug containing any quantity of any substance as habit forming because of its stimulant effect on the central nervous system; or
- (2) Designating any drug containing any quantity of any substance as having a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(b) Proceedings for the issuance, amendment, or repeal of regulations issued pursuant to section 201(v) of the act are subject to the public procedures provided in section 701(e) of the act and the provisions for judicial review set forth in sections 701 (f) and (g).

(c) The procedures to be followed for filing petitions requesting the issuance, amendment, or repeal of any regulation provided for in section 201(v) (2) and (3) of the act, publication of proposals in the FEDERAL REGISTER, comments thereon, publication of orders, filing objections, requests for a public hearing, procedures governing public hearings, proposed orders, exceptions, final orders,

and judicial review are set forth in Part 316 of this chapter.

§ 320.5 Substances exempt from the definition of depressant or stimulant drug.

Any substance now included or which may be hereafter included within the classification stated in section 4731 of the Internal Revenue Code of 1954 (26 U.S.C. 4731) and marihuana as defined in section 4761 of the Internal Revenue Code of 1954 (26 U.S.C. 4761) is not a depressant or stimulant drug as defined in this part.

§ 320.6 Registration of producers and certain wholesalers of depressant or stimulant drugs.

Section 510 of the act requires every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, processing, wholesaling, jobbing, selling, or distributing of any depressant or stimulant drug to register with the Commissioner of Food and Drugs his name, place of business, and all such establishments. The procedure for registration is prescribed in Part 132 of Title 21, Chapter I.

§ 320.7 Procedures for exempting depressant or stimulant drugs from the provisions of section 511 of the act.

(a) Section 511(f) (1) of the act authorizes the Director, under authority delegated to him by the Attorney General to exempt by regulation any depressant or stimulant drug from all or part of section 511 of the act upon a finding that regulation of the manufacture, compounding, processing, possession, or distribution of such drug is not necessary for the protection of the public health.

(b) A proposal to exempt any depressant or stimulant drug from the application of all or part of section 511 of the act may be initiated by the Director or

by any interested person. Any interested person may file a petition seeking such exemption, stating reasonable grounds therefor. Upon receipt of such a petition, or on his own initiative at any time, the Director will publish a notice of proposed rulemaking and invite written comments. After consideration of all available data, including any comments submitted, the Director may issue a regulation granting or refusing the exemption effective on a date specified therein. Whenever the Director concludes, either at the time of publication of the notice of proposed rulemaking or after considering the written comments submitted, that granting or refusing the exemption requires a more thorough development of the facts than is possible in a written presentation, he may call a public hearing for that purpose. When such a public hearing is called, the procedural regulations for public hearings contained in Part 316 of this chapter shall apply. If the Director for good cause finds; and incorporates the finding and a brief statement of the reasons therefor in an order, that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, he may issue the final regulation forthwith.

§ 320.8 Combination drugs; exemptions from section 511 of the act.

The following combination drugs are exempt from the requirements of section 511 of the act:

(a) The following drugs in unit-dosage form, and any other drug of the quantitative composition shown below for one of the following drugs or which is the same except that it contains a lesser quantity of controlled substances, and which may be lawfully sold over-the-counter without a prescription, are exempt from the requirements of section 511 (b), (c), and (e) and the recordkeeping requirements of section 511(d) (1) of the act:

EXEMPTED OVER-THE-COUNTER DRUGS

Trade name or other designation	Composition	Manufacturer or supplier
Amodrine.....	Tablet: Phenobarbital, 8 mg.; aminophylline, 100 mg.; racephedrine hydrochloride, 25 mg.	G. D. Searle & Co.
Bronkaid.....	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl gualacolate, 100 mg.; theophylline, 100 mg.; theophylline, 10 mg.	Drew Pharmacal Co., Inc.
Bronkotab Elixir.....	Elixir (5 cc): Phenobarbital, 4 mg.; ephedrine sulfate, 12 mg.; glyceryl gualacolate, 50 mg.; theophylline, 15 mg.; chlorpheniramine maleate, 1 mg.	Breon Laboratories Inc.
Bronkotabs.....	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl gualacolate, 100 mg.; theophylline, 100 mg.; theophylline, 10 mg.	Do.

EXEMPTED OVER-THE-COUNTER DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Primatene.....	Tablet: Phenobarbital, ½ gr.; ephedrine, ¾ gr.	Whitehall Laboratories.
Tedral.....	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral Anti-H.....	Tablet: Phenobarbital, 8 mg.; chlorpheniramine maleate, 2 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Tedral one-half Strength.....	Tablet: Phenobarbital, 4 mg.; theophylline, 65 mg.; ephedrine hydrochloride, 12 mg.	Do.
Tedral Pediatric Suspension.....	Suspension (5 cc): Phenobarbital, 4 mg.; ephedrine hydrochloride, 12 mg.; theophylline, 65 mg.	Do.
Tedral suppositories double strength.....	Suppository: Phenobarbital, 16 mg.; theophylline, 260 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tedral suppositories regular strength.....	Suppository: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Verequad.....	Tablet: Phenobarbital, 8 mg.; theophylline calcium salicylate, 130 mg.; ephedrine hydrochloride, 24 mg.; glyceryl gualacolate, 100 mg.	Knoll Pharmaceutical Co.
Verequad.....	Suspension (5 cc): Phenobarbital, 4 mg.; theophylline calcium salicylate, 65 mg.; ephedrine hydrochloride, 12 mg.; glyceryl gualacolate, 50 mg.	Do.

(b) The following drugs in unit dosage form, and any other drug of the quantitative composition shown below for one of the following drugs or which is the same except that it contains a lesser quantity of controlled substances, and

which are restricted by law to dispensing on prescription, are exempt from the requirements of section 511 (c) and (e) and the recordkeeping requirements of section 511(d) (1) of the act:

EXEMPTED PRESCRIPTION DRUGS

Trade name or other designation	Composition	Manufacturer or supplier
A.E.A.....	Tablet: Amobarbital, 25 mg.; aminophylline, 120 mg.; ephedrine hydrochloride, 25 mg.	Haack Laboratories, Inc.
Alased.....	Tablet: Phenobarbital, 16.2 mg.; homatropine methylbromide, 3.6 mg.; aluminum hydroxide gel, dried, 7½ gr.; magnesium trisilicate, 2½ gr.	Norgine Laboratories, Inc.
Alcitex.....	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, ¼cc gr.; calcium carbonate, 3½ gr.; magnesium carbonate, 2½ gr.; cerium oxalate, ½ gr.	Paul B. Elder Co., Inc.
Algoson.....	Tablet: Butabarbital sodium, 7.5 mg.; acetaminophen, 300 mg.	McNeil Laboratories Inc.
Alhydrox.....	Tablet: Phenobarbital, ¼ gr.; aluminum hydroxide, 5 gr.; atropine sulfate, ¼cc gr.	Physicians Supply Co.
Alkasans.....	Tablet: Phenobarbital, 8.0 mg.; atropine sulfate, 0.06 mg.; kaolin-alumina gel, 500 mg.	P. J. Noyes Co.
Alsical.....	Powder (60 gr.): Phenobarbital, ¼ gr.; belladonna extract, ¼ gr.; calcium carbonate, 24 gr.; magnesium trisilicate, 15 gr.; magnesium oxide, 10 gr.; aluminum hydroxide gel, dried, 10 gr.	Dorsey Laboratories.
Alubelap.....	Tablet: Phenobarbital, 8 mg.; aluminum hydroxide gel, dried, 300 mg.; belladonna extract, 4 mg.	Haack Laboratories, Inc.
Aludrox SA Suspension.....	Suspension (5 cc.): Butabarbital, 8 mg.; ambutoxium bromide, 2.5 mg.	Wyeth Laboratories.
Aludrox SA Tablets.....	Tablet: Butabarbital, 8 mg.; ambutoxium bromide, 2.5 mg.	Do.
Alu-Mag.....	Tablet: Phenobarbital, ¼ gr.; aluminum hydroxide gel, dried, 2½ gr.; magnesium trisilicate, 2½ gr.; belladonna leaf extract, ¼ gr.	Norsal Laboratories, Inc.
Alumazen.....	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; magnesium trisilicate, 500 mg.; aluminum hydroxide gel, dried, 250 mg.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Aluminum hydroxide, magnesium trisilicate, and kaolin with phenobarbital and atropine sulfate.....	Tablet: Phenobarbital, ¼ gr.; aluminum hydroxide, 2 gr.; magnesium trisilicate, 4 gr.; kaolin, colloidal, 2 gr.; atropine sulfate, ¼cc gr.	Buffalo Pharmaceutical Supply Corp.
Aminodrox with Phenobarbital.....	Tablet: Phenobarbital, 15 mg.; aminophylline, 0.1 gm.; aluminum hydroxide gel, dried, 0.12 gm.	The S. E. Massengill Co.
Aminodrox-Forte with Phenobarbital.....	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.; aluminum hydroxide gel, dried, 250 mg.	Do.
Aminophylline and Amytal.....	Capsule: Amobarbital, 32 mg.; aminophylline, 0.1 gm.	Eli Lilly and Co.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Aminophylline with pentobarbital.	Suppository: Pentobarbital sodium, 100 mg.; aminophylline, 500 mg.	G. D. Searle & Co.
Aminophylline and phenobarbital.	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	The Zemmer Co.
Do.	Tablet: Phenobarbital, ¼ gr.; aminophylline, 100 mg.	The Blue Line Chemical Co.
Aminophylline with phenobarbital.	Tablet: Phenobarbital, 16 mg.; aminophylline, 100 mg.	H. E. Dubin Laboratories, Inc.
Do.	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	G. D. Searle & Co.
Do.	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.	Do.
Aminophylline with phenobarbital.	Tablet: Phenobarbital, 30 mg.; aminophylline, 200 mg.	Do.
Amobarbital and PETN.	Capsule: Amobarbital, 50 mg.; pentaerythritol tetranitrate, 30 mg.	Meyer Laboratories, Inc.
Ampyrox with Butabarbital Sodium (AMPYROX).	Tablet: Butabarbital sodium, 15 mg.; scopalamine methylnitrate, 2 mg.	Paul B. Elder Co., Inc.
Ampyrox with Butabarbital Sodium, Elixir.	Elixir (5 cc.): Butabarbital sodium, 10 mg.; scopalamine methylnitrate, 1 mg.	Do.
Amsed (NAP-37)	Tablet: Phenobarbital, ¼ gr.; hyoscyne hydrobromide, 0.0072 mg.; atropine sulfate, 0.024 mg.; hyoscyamine hydrobromide, 0.128 mg.	North American Pharmacal, Inc.
Amsodyne.	Tablet: Phenobarbital, ¼ gr.; extract belladonna leaves, ¼ gr.; aspirin, 5 gr.; caffeine, ¼ gr.	Paul B. Elder Co., Inc.
Antacia No. 3 with Phenobarbital and Atropine.	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, ¼60 gr.; calcium carbonate, 5 gr.; magnesium hydroxide, 5 gr.	Meyers and Co.
Antispasmodic.	Tablet (purple): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1037 mg.; homatropine methylbromide, 0.567 mg.; hyoscyne hydrobromide, 0.0065 mg.	Hydrex Co., Inc.
Antispasmodic-Enzyme.	Tablet: Phenobarbital, 8.1 mg.; hyoscyamine sulfate, 0.0519 mg.; homatropine methylbromide, 0.2885 mg.; hyoscyne hydrobromide, 0.0033 mg.; pancreatin, 100 mg.; pepsin, 150 mg.	Do.
Antrocol.	Tablet or capsule: Phenobarbital, 16 mg.; atropine sulfate, 0.324 mg.; colloidal sulfur, 22 mg.	Wm. P. Poythress & Co., Inc.
Aqualin-Plus, Children.	Suppository: Pentobarbital sodium, ¼ gr.; theophylline, 1¼ gr.	The Wm. A. Webster Co.
Aqualin-Plus No. 1.	Suppository: Pentobarbital sodium, ¼ gr.; theophylline, 3¼ gr.	Do.
Aqualin-Plus No. 2.	Suppository: Pentobarbital sodium, 1½ gr.; theophylline, 7½ gr.	Do.
Aqualin-Plus No. 2A.	Suppository: Pentobarbital sodium, ¼ gr.; theophylline, 7½ gr.	Do.
Asmabar.	Tablet: Butabarbital, 20 mg.; ephedrine sulfate, 25 mg.; theophylline hydroxide, 130 mg.	The Blue Line Chemical Co.
Asmacol.	Tablet: Butabarbital, 15 mg.; aminophylline, 180 mg.; phenylpropanolamine hydrochloride, 25 mg.; chlorpheniramine maleate, 2 mg.; aluminum hydroxide gel, dried, 60 mg.; magnesium trisilicate, 60 mg.	The Vale Chemical Co., Inc.
Asperase, Modified with Phenobarbital.	Tablet: Phenobarbital, 0.008 gm.; acetylsalicylic acid, 0.6 gm.	P. J. Noyes Co.
Atropal.	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, ¼60 gr.; magnesium trisilicate, 2½ gr.; aluminum hydroxide gel, dried, 2½ gr.	Neisler Laboratories, Inc.
Atrosilital.	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.; magnesium trisilicate, 0.5 gm.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Banthine with Phenobarbital.	Tablet: Phenobarbital, 15 mg.; methantheline bromide, 60 mg.	G. D. Searle & Co.
Barbatro No. 1.	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	The S. E. Massengill Co.
Barbatro No. 2.	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.25 mg.	Do.
Barbeloid.	Tablet: Amobarbital sodium, 20 mg.; hyoscyamine sulfate, 0.125 mg.; hyoscyne hydrobromide, 0.007 mg.; homatropine methylbromide, 0.5 mg.	The Vale Chemical Co., Inc.
Barbidonna Elixir.	Elixir (5 cc.): Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopalamine hydrobromide, 0.0074 mg.	Mallinckrodt Pharmaceuticals, Division of Mallinckrodt Chemical Works.
Barbidonna Tablets.	Tablet: Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopalamine hydrobromide, 0.0074 mg.	Do.
Barboma Elixir.	Elixir (100 cc.): Phenobarbital, 0.4 gm.; homatropine methylbromide, 33.8 mg.	The Blue Line Chemical Co.
Barboma Tablets.	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, ¼48 gr.	Do.

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EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Bardase.	Tablet or elixir (4 cc.): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1 mg.; hyoscyne hydrobromide, 0.007 mg.; atropine, 0.020 mg.; Taka-Diastase, 162.0 mg.	Parke, Davis & Co.
Bar-Don Elixir.	Elixir (30 cc.): Phenobarbital, 100 mg.; hyoscyamine hydrobromide, 0.60 mg.; hyoscyne hydrobromide, 0.042 mg.; atropine sulfate, 0.12 mg.	Warren-Teed Pharmaceuticals Inc.
Bar-Don Tablets.	Tablet: Phenobarbital, 16.670 mg.; hyoscyamine hydrobromide, 0.10 mg.; hyoscyne hydrobromide, 0.007 mg.; atropine sulfate, 0.020 mg.	Do.
Belap No. 0.	Tablet: Phenobarbital, 8 mg.; belladonna extract, 8 mg.	Haack Laboratories, Inc.
Belap No. 1.	Tablet: Phenobarbital, 15 mg.; belladonna extract, 8 mg.	Do.
Belap Ty-Med.	Tablet: Amobarbital, 50 mg.; homatropine methylbromide, 7.5 mg.	Do.
Belladenal.	Tablet: Phenobarbital, 50 mg.; bellafoline, 0.25 mg.	Sandoz Pharmaceuticals.
Do.	Elixir (15 cc.): Phenobarbital, 15.6 mg.; bellafoline, 0.078 mg.	Do.
Bellatol Elixir.	Elixir (5 cc.): Butabarbital sodium, 20 mg.; tincture belladonna, 0.83 cc.	The Zemmer Co.
Bellergal.	Tablet: Phenobarbital, 20 mg.; ergotamine tartrate, 0.3 mg.; levorotatory alkaloids of belladonna, 0.1 mg.	Sandoz Pharmaceuticals.
Do.	Tablet: Phenobarbital, 40 mg.; ergotamine tartrate, 0.6 mg.; levorotatory alkaloids of belladonna, 0.2 mg.	Do.
Beplete with Belladonna Elixir.	Elixir (4 cc.): Phenobarbital, 15 mg.; vitamin B ₁ , 1.5 mg.; vitamin B ₂ , 1 mg.; vitamin B ₆ , 0.33 mg.; vitamin B ₁₂ , 1.66 mg.; niacinamide, 10 mg.; pantothenol, 0.2 mg.; belladonna alkaloids, 0.2 mg.	Wyeth Laboratories.
Bexadonna.	Tablet: Phenobarbital, 16 mg.; homatropine methylbromide, 10 mg.; hyoscyne hydrobromide, 0.0065 mg.; hyoscyamine sulfate, 0.1 mg.	Bexar Pharmaceuticals.
Bilamide.	Tablet: Phenobarbital, ¼ gr.; dried ox bile, 2 gr.; dehydrocholic acid, 2 gr.; homatropine methylbromide, ¼48 gr.	Norgine Laboratories, Inc.
Bintrin.	Tablet: Butabarbital sodium, 15.0 mg.; nitroglycerin, 0.3 mg.; pentaerythritol tetranitrate, 10.0 mg.	The Vale Chemical Co., Inc.
Bioxatphen.	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; bismuth subnitrate, 120 mg.; cerium oxalate, 120 mg.	The Zemmer Co.
Bismuth, belladonna, and phenobarbital.	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladonna leaf, ¼ gr.	The Bernard Co.
Buffadyne A-S.	Tablet: Amobarbital, 15 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; homatropine methylbromide, 2.5 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Lemmon Pharmacal Co.
Buffadyne with Barbiturates.	Tablet: Secobarbital sodium, 8 mg.; amobarbital, 8 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Do.
Bunesia.	Tablet: Butabarbital sodium, 10 mg.; homatropine methylbromide, 2.5 mg.; magnesium hydroxide, 300 mg.	McNeil Laboratories, Inc.
Buren.	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; scopalamine hydrobromide, 0.0065 mg.; atropine sulfate, 0.0194 mg.; hyoscyamine sulfate, 0.1037 mg.	B. F. Ascher & Co., Inc.
Burrizem.	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.1 mg.; rutin, 20 mg.; mannitol hexanitrate, 30 mg.	The Zemmer Co.
Butabarbital and hyoscyamine sulfate.	Tablet or elixir (5 cc.): Butabarbital, 15 mg.; hyoscyamine sulfate, 0.125 mg.	Meyer Laboratories, Inc.
Do.	Capsule: Butabarbital, 45 mg.; hyoscyamine sulfate, 0.375 mg.	Do.
Butibel.	Tablet or elixir (5 cc.): Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (hyoscyamine sulfate, 0.138 mg.; hyoscyne hydrobromide, 0.027 mg.; atropine sulfate, 0.067 mg.).	Do.
Butibel R-A.	Tablet: Butabarbital sodium, 30 mg.; belladonna extract, 30 mg.	Do.
Butibel-Gel Suspension.	Suspension (15 cc.): Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.187 mg.); activated attapulgit, 1.5 gm.; pectin, 75 mg.	Do.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Butibel-Gel Tablets-----	Tablet: Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.0935 mg.); activated attapulgite, 500 mg.; pectin, 45 mg.	Do.
Butibel-Zyme-----	Tablet: Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (total alkaloids 0.187 mg.); proteolytic enzyme standardized, 10 mg.; amylolytic enzyme standardized, 20 mg.; cellulolytic enzyme standardized, 5 mg.; lipolytic enzyme standardized, 100 mg.; iron ox bile (45% cholic acid), 30 mg.	Do.
Butizetic-----	Tablet: Butabarbital sodium, 15 mg.; acetaminophen, 200 mg.; phenacetin, 150 mg.; caffeine, 30 mg.	Do.
Cafergot P-B-----	Tablet: Phenobarbital sodium, 30 mg.; ergotamine tartrate, 1 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.125 mg.	Sandoz Pharmaceuticals.
Do-----	Suppository: Pentobarbital, 60 mg.; ergotamine tartrate, 2 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.25 mg.	Do.
Cal-Ma-Phen-----	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 5 gr.; magnesium hydroxide, 5 gr.; atropine sulfate, ¼ gr.	Physicians Supply Co.
Cantil with Phenobarbital-----	Tablet: Phenobarbital, 16 mg.; mepenzolate bromide, 25 mg.	Lakeside Laboratories, Inc.
Carbonates No. 3 with Phenobarbital and Atropine.	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.11 mg.; calcium carbonate, 224 mg.; magnesium carbonate, 160 mg.; bismuth subcarbonate, 32 mg.	P. J. Noyes Co.
Cardalin-Phen-----	Tablet: Phenobarbital, ¼ gr.; aminophylline, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Neisler Laboratories, Inc.
Cardilate-P-----	Tablet: Phenobarbital, 15 mg.; erythrityl tetranitrate, 10 mg.	Burroughs Wellcome & Co. (U.S.A.) Inc.
Cholarace-----	Tablet: Pentobarbital, 27.5 mg.; oxtriphylline, 200 mg.; racophedrine, 20 mg.	Warner-Chilcott Laboratories.
Co-Elorine 25-----	Capsule: Amobarbital, 8 mg.; tricyclamol chloride, 25 mg.	Eli Lilly and Co.
Co-Elorine 100-----	Capsule: Amobarbital, 16 mg.; tricyclamol chloride, 100 mg.	Do.
Cold Preparation, Special-----	Tablet: Phenobarbital, 8.1 mg.; chlorpheniramine maleate, 2 mg.; pseudoephedrine hydrochloride, 60 mg.; salicylamide, powder, 300 mg.	Knight Pharmacal Co.
Corenil-----	Tablet: Racemic methamphetamine hydrochloride, 1.25 mg.; elistin (carbinoxamine maleate), 2 mg.; belladonna extract, 8 mg.	McNeil Laboratories, Inc.
Covadil-----	Tablet: Butabarbital sodium, 20 mg.; pentaerythritol tetranitrate, 15 mg.	The Blue Line Chemical Co.
Dactil with Phenobarbital-----	Tablet: Phenobarbital, 16 mg.; piperidolate hydrochloride, 50 mg.	Lakeside Laboratories, Inc.
Dainite-----	Tablet: Pentobarbital sodium, ¼ gr. aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Neisler Laboratories, Inc.
Dainite-KI-----	Tablet: Phenobarbital, ¼ gr.; aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; potassium iodide, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Dainite Night-----	Tablet: Phenobarbital, ¾ gr.; pentobarbital sodium, ¼ gr.; aminophylline, 4 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Dainite Pediatric-----	Tablet: Phenobarbital, ¼ gr.; aminophylline, 1 gr.; ephedrine hydrochloride, ¼ gr.; aluminum hydroxide gel, dried, ¼ gr.; benzocaine, ¼ gr.	Do.
Daricon PB-----	Tablet: Phenobarbital, 15 mg.; oxyphenycdimine hydrochloride, 5 mg.	Pfizer Laboratories.
Diatraegus-----	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerin, ¼ gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims	Buffington's, Inc.
Dia-Tropine-----	Tablet: Diallylbarbituric acid, ¼ gr.; atropine sulfate, ¼ gr.; magnesium carbonate, 2½ gr.; calcium carbonate, 3½ gr.; bismuth subcarbonate, 1 gr.	Do.
Dilantin with Phenobarbital-----	Capsule: Phenobarbital, ¼ gr.; diphenylhydantoin sodium, 0.1 gm.	Parke, Davis & Co.
Do-----	Capsule: Phenobarbital, ¼ gr.; diphenylhydantoin sodium, 0.1 gm.	Do.
Dolonil-----	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; hyoscyamine hydrobromide, 0.3 mg.	Warner-Chilcott Laboratories.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Donabarb-----	Tablet: Phenobarbital, ¼ gr.; powder extract belladonna, ¼ gr.	Paul B. Elder Co., Inc.
Donaphen, New Special Donaphen.	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.024 mg.; scopolamine hydrobromide, 0.0072 mg.; hyoscyamine hydrobromide, 0.128 mg.	Burt Krone Co.
Donna-Sed Elixir-----	Elixir (5 cc.): Phenobarbital, 16.2 mg.; hyoscyamine hydrobromide, 0.1037 mg.; atropine sulfate, 0.0194 mg.; hyosine hydrobromide, 0.0065 mg.	North American Pharmacal, Inc.
Donnasep-----	Tablet: Phenobarbital, 8.1 mg.; phenazopyridine hydrochloride, 50.0 mg.; methenamine mandelate, 500 mg.; hyoscyamine sulfate, 0.0519 mg.; atropine sulfate, 0.0097 mg.; hyosine hydrobromide, 0.0033 mg.	A. H. Robins Co., Inc.
Donphen-----	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1 mg.; atropine sulfate, 0.02 mg.; scopolamine hydrobromide, 6 µg.	Lemmon Pharmacal Co.
Dormitol-HM-----	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, ¼ gr.; strontium bromide, 1 gr.	Buffington's Inc.
Dynapin with Phenobarbital-----	Tablet: Phenobarbital, 15 mg.; nitroglycerin, 0.5 mg.; pentaerythritol tetranitrate, 15 mg.	Key Pharmacal Co.
Edrisal-----	Tablet: Dextroamphetamine sulfate, 2.5 mg.; aspirin, 0.16 gm.; phenacetin 0.16 gm.	Smith Kline & French Laboratories.
Elmaloin with Phenobarbital-----	Capsule: Phenobarbital, 15 mg.; diphenylhydantoin, 1½ gr.	Paul B. Elder Co., Inc.
Ephedrine and sodium phenobarbital.	Tablet: Sodium phenobarbital, ¼ gr.; ephedrine sulfate, ¾ gr.	The Vale Chemical Co., Inc.
Ephedrine sulfate and phenobarbital.	Tablet: Phenobarbital, 15 mg.; ephedrine sulfate, 25 mg.	The Zemmer Co.
Ephedrine with Phenobarbital.	Tablet: Phenobarbital, ¼ gr.; ephedrine sulfate, ¾ gr.	P. J. Noyes Co.
Ercapital-----	Tablet: Phenobarbital, 7.5 mg.; ergotamine tartrate, 0.5 mg.; caffeine, 50 mg.	The Blue Line Chemical Co.
Ethrava-trate-----	Tablet: Mephobarbital, 10 mg.; pentaerythritol tetranitrate, 20 mg.; ethavrine hydrochloride, 30 mg.	North American Pharmacal, Inc.
Eu-Phed-Amin-----	Tablet: Phenobarbital, 30 mg.; aminophylline, 0.1 gm.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.1 gm.	Warren-Teed Pharmaceuticals Inc.
Eu-Phed-Ital-----	Tablet: Phenobarbital sodium, 30 mg.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.12 gm.	Do.
Fensobel-----	Tablet: Phenobarbital, 8.1 mg.; belladonna extract, 2.95 mg.; aluminum hydrochloride gel, dried, 63 mg.; magnesium trisilicate, 63 mg.; bismuth subcarbonate, 32.5 mg.; magnesium carbonate, 252 mg.; precipitated calcium carbonate, 203.5 mg.; malt diastase, 12.5 mg.; peppermint oil, 3 mg.	United States Vitamin & Pharmaceutical Corp.
Franol-----	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine hydrochloride, 32 mg.	Winthrop Laboratories.
Genegestic Capsules-----	Capsule: Methamphetamine hydrochloride, 1.2 mg.; chlorpheniramine maleate, 3.8 mg.; phenacetin, 120.0 mg.; salicylamide, 180.0 mg.; caffeine, 30.0 mg.; ascorbic acid, 50.0 mg.	General Pharmaceutical Products, Inc.
Homechol-----	Tablet: Pentobarbital sodium, 8.0 mg.; homatropine methylbromide, 2.5 mg.; dehydrocholic acid, 60.0 mg.; ox bile extract, 150.0 mg.	Lemmon Pharmacal Co.
Homadonna-----	Tablet or elixir (5 cc.): Phenobarbital, 16 mg.; homatropine methylbromide, 2.5 mg.	Mallinckrodt Pharmaceuticals, Division of Mallinckrodt Chemical Works.
Homopent-----	Tablet: Pentobarbital sodium, 15 mg.; homatropine methylbromide, 2.5 mg.; magnesium trisilicate, 300 mg.	Lemmon Pharmacal Co.
Hovizyme-----	Tablet: Methamphetamine hydrochloride, 0.5 mg.; conjugated estrogen-equine, 0.125 mg.; methyl testosterone, 1.25 mg.; amylase, 10.0 mg.; protease, 5.0 mg.; cellulase, 2.0 mg.; nicotinyl alcohol tartrate, 7.5 mg.; dehydrocholic acid, 50.0 mg.; ascorbic acid, 50.0 mg.; ferrous fumarate, 6.0 mg.	Ayerst Laboratories.
H-P-A (Modified)-----	Tablet: Phenobarbital, ¼ gr.; aspirin, 5 gr.; extract hyoscyamus, ½ gr.	Paine Drug Co.
Hybephen-----	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyosine hydrobromide, 0.0094 mg.	The S. E. Massengill Co.
Hybephen Elixir-----	Elixir (5 cc.): Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyosine hydrobromide, 0.0094 mg.	Do.
Hydrochol Plus-----	Tablet: Amobarbital, 15 mg.; dehydrocholic acid, 200 mg.; scopolamine methylnitrate, 0.8 mg.; ox bile desiccated, 50 mg.	Paul B. Elder Co., Inc.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Hytrona Antispasmodic Elixir	Elixir (5 cc.): Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Pitman-Moore.
Hytrona Antispasmodic Tablets	Tablet: Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Do.
Ilocalm	Tablet: Mephobarbital, 30 mg.; methscopolamine nitrate, 2.5 mg.; <i>d</i> -calcium pantothenate, 25 mg.	Warren-Teed Pharmaceuticals Inc.
Isordil with Phenobarbital	Tablet: Phenobarbital, 15 mg.; isosorbide dinitrate, 10 mg.	Ives Laboratories Inc.
Isofranol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 10 mg.	Winthrop Laboratories.
Isofranol, Mild	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 5 mg.	Do.
Isuprel Compound Elixir	Elixir (15 cc.): Phenobarbital, 6 mg.; isoproterenol hydrochloride, 2.5 mg.; ephedrine sulfate, 12 mg.; theophylline, 45 mg.; potassium iodide, 150 mg.	Do.
Kaphebel	Tablet: Phenobarbital, $\frac{1}{4}$ gr.; belladonna root, $\frac{1}{4}$ gr.; kaolin colloidal, $\frac{7}{8}$ gr.	Paul B. Elder Co., Inc.
Kanumodic	Tablet: Pentobarbital, 8 mg.; methscopolamine nitrate, 2 mg.; cellulose, 9 mg.; pancreatin, 500 mg.; glutamic acid hydrochloride, 200 mg.; ox bile extract, 100 mg.; pepsin, 150 mg.	Dorsey Laboratories.
Kavatrane	Tablet: Phenobarbital sodium, $\frac{1}{4}$ gr.; veratrum veride, $\frac{1}{4}$ gr.; mistletoe, $\frac{1}{4}$ gr.; hawthorn tincture, 30 minims; sodium nitrite, 1 gr.	Key Pharmacol Co.
Kie with Phenobarbital	Tablet: Phenobarbital, 16 mg.; potassium iodide, 400 mg.; ephedrine sulfate, 24 mg.	Laser Inc.
Kiophyllin	Tablet: Phenobarbital, 15 mg.; aminophyllin, 150 mg.; potassium iodide, 125 mg.	G. D. Searle & Co.
Luftodil Suspension	Suspension (5 cc.): Phenobarbital, 8 mg.; theophylline, 50 mg.; ephedrine hydrochloride, 12 mg.; glyceryl guaiacolate, 100 mg.	Mallinckrodt Pharmaceuticals, Division of Mallinckrodt Chemical Works.
Luftodil Tablets	Tablet: Phenobarbital, 16 mg.; theophylline, 100 mg.; ephedrine hydrochloride, 24 mg.; glyceryl guaiacolate, 200 mg.	Do.
Lufyllin-EP	Tablet: Phenobarbital, 16 mg.; lufyllin (diphylline), 100 mg.; ephedrine hydrochloride, 16 mg.	Do.
Magnesium hydroxide-phenobarbital compound	Tablet: Phenobarbital sodium, 15 mg.; magnesium hydroxide, 300 mg.; atropine sulfate with aromatics, 0.12 mg.	McNeil Laboratories, Inc.
Malglyn Compound	Tablet or suspension (5 cc.): Phenobarbital, 16.2 mg.; belladonna alkaloids, 0.162 mg.; dihydroxy aluminum aminoacetate, 0.5 gm.	Brayten Pharmaceutical Co.
Manniphen	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The Vale Chemical Co., Inc.
Manniphen with Rutin	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.; rutin, 20 mg.	Do.
Mannitol hexanitrate with phenobarbital	Tablet: Phenobarbital, $\frac{1}{4}$ gr.; mannitol hexanitrate, $\frac{1}{4}$ gr.	P. J. Noyes Co.
Maxitol	Tablet: Phenobarbital, $\frac{1}{4}$ gr.; mannitol hexanitrate, $\frac{1}{4}$ gr.	The Blue Line Chemical Co.
Mediatric	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 15 mg.; rutin, 15 mg.; ascorbic acid, 15 mg.	Burt Krone Co.
Mediatric Liquid	Tablet or capsule: Methamphetamine hydrochloride, 1 mg.; conjugated estrogens-equine, 0.25 mg.; methyltestosterone, 2.5 mg.	Ayerst Laboratories.
Meprane Phenobarbital	Solution (15 cc.): Methamphetamine hydrochloride, 1 mg.; conjugated estrogens-equine, 0.25 mg.; methyltestosterone, 2.5 mg.	Do.
Mesopin-PB	Tablet: Phenobarbital, 16 mg.; promethestrol dipropionate, 1 mg.	Reed & Carnrick.
Metamine with Butabarbital	Tablet or elixir (5 cc.): Phenobarbital, 15 mg.; homatropine methylbromide, 5 mg.	Endo Laboratories Inc.
Do	Tablet: Butabarbital, 16.2 mg.; troinitrate phosphate, 2 mg.	Pfizer Laboratories.
Mexal	Tablet: Butabarbital, 48.6 mg.; troinitrate phosphate, 10 mg.	Do.
Monomeb	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The S. E. Massengill Co.
Mudrane	Tablet: Mephobarbital, 32 mg.; penthionate bromide, 5 mg.	Winthrop Laboratories.
Mudrane GG Elixir	Tablet: Phenobarbital, 21 mg.; potassium iodide, 195 mg.; aminophylline, 130 mg.; ephedrine hydrochloride, 16 mg.	Wm. P. Poythress & Co., Inc.
	Elixir (5 cc.): Phenobarbital, 5.4 mg.; theophylline, 20 mg.; ephedrine hydrochloride, 4 mg.; glyceryl guaiacolate, 26 mg.	Do.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Nactisol	Tablet: Butabarbital sodium, 15 mg.; poldine methylsulfate, 4 mg.	McNeil Laboratories, Inc.
Natrona Compound	Tablet: Phenobarbital, 15 mg.; extract hawthorn berries, 30 mg.; extract mistletoe, 15 mg.; sodium nitrite, 60 mg.; sodium bicarbonate, 0.2 gm.	The Zemmer Co.
Neocholan	Tablet: Phenobarbital, 8 mg.; dehydrocholic acid, 250 mg.; bile extract, 15 mg.; homatropine methylbromide, 1.2 mg.	Pitman-Moore.
Nergestic	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.10 mg.; magnesium trisilicate, 0.5 gm.	The S. E. Massengill Co.
Nitrased	Tablet: Secobarbital, 15 mg.; nitroglycerin, 0.4 mg.; pentaerythrityl tetranitrate, 15 mg.	Lemmon Pharmacol Co.
Nophesan Tablets	Tablet: Phenobarbital, 8 mg.; acetylsalicylic acid, 300 mg.	P. J. Noyes Co.
Novalene	Tablet: Phenobarbital, 16 mg.; ephedrine sulfate, 24 mg.; potassium iodide, 162 mg.; calcium lactate, 162 mg.	Lemmon Pharmacol Co.
Oxsorbil-PB	Capsule: Phenobarbital, 7.5 mg.; belladonna extract, 7.5 mg.; dehydrocholic acid, 32 mg.; desoxycholic acid, 32 mg.; ox bile extract, 65 mg.; sorbitan monooleate, 160 mg.; oleic acid, 180 mg.	Ives Laboratories, Inc.
Paminal Elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	The Upjohn Co.
Pamine PB Elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pamine PB, Half Strength	Tablet: Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pediatric Piptal Antipyretic	Solution (0.6 cc.): Phenobarbital 3 mg.; pipenzolate bromide, 5 mg.; acetaminophen, 60 mg.	Lakeside Laboratories, Inc.
Pediatric Piptal with Phenobarbital	Solution (0.5 cc.): Phenobarbital, 3 mg.; pipenzolate bromide, 2 mg.	Do.
Phenocetyl	Tablet: Phenobarbital, $\frac{1}{4}$ gr.; acetylsalicylic acid, 5 gr.	Paul B. Elder Co., Inc.
Pentaerythrityl tetranitrate with phenobarbital	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 10 mg.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Pentatrol with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	North American Pharmacal Co.
Pentraline	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.05 mg.; pentaerythrityl tetranitrate, 10 mg.	McNeil Laboratories, Inc.
Perbuzem	Tablet: Butabarbital sodium, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	The Zemmer Co.
Peribar L-A No. 1	Tablet: Phenobarbital, 48.6 mg.; pentaerythrityl tetranitrate, 30 mg.	Whittier Laboratories, Inc.
Peritrate with Phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Warner-Chilcott Laboratories.
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Peritrate with Phenobarbital SA	Tablet: Phenobarbital, 45 mg.; pentaerythrityl tetranitrate, 80 mg.	Do.
Phedorine	Tablet: Diallylbarbituric acid, 16 mg.; extract stramonium, 8 mg. (alkaloids 0.0015 gr.); ephedrine, 8 mg.; theophylline, 100 mg.	Buffington's, Inc.
Phenaphen Plus	Tablet: Phenobarbital, 16.2 mg.; phenacetin, 194 mg.; aspirin, 162 mg.; hyoscyamine sulfate, 0.031 mg.; pheniramine maleate, 12.5 mg.; phenylephrine hydrochloride, 10 mg.	A. H. Robins Co., Inc.
Phenobarbital and atropine	Tablet: Phenobarbital, $\frac{1}{4}$ gr.; atropine sulfate, $\frac{1}{400}$ gr.	The Blue Line Chemical Co.
Do	do.	Meyers & Co.
Do	do.	Faine Drug Co.
Do	Tablet: Phenobarbital, $\frac{1}{4}$ gr.; atropine sulfate, $\frac{1}{400}$ gr.	The Vale Chemical Co., Inc.
Phenobarbital with atropine sulfate	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.	The Zemmer Co.
Phenobarbital with atropine sulfate No. 2	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	Do.
Phenobarbital and atropine sulfate	Tablet: Phenobarbital, $\frac{1}{4}$ gr.; atropine sulfate, $\frac{1}{200}$ gr.	Buffington's, Inc.
Phenobarbital & Atropine No. 1	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 0.13 mg.	Pitman-Moore.
Phenobarbital & Atropine No. 2	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.65 mg.	Do.
Phenobarbital and Atropine Tablets	Tablet: Phenobarbital, 8 mg.; atropine sulfate, $\frac{1}{1000}$ gr.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; atropine sulfate, $\frac{1}{500}$ gr.	Do.
Phenobarbital and Atropine Tablets No. 2	Tablet: Phenobarbital, $\frac{1}{4}$ gr.; atropine sulfate, $\frac{1}{500}$ gr.	Do.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Phenobarbital and Atropine Tablets No. 3.	Tablet: Phenobarbital, ½ gr.; atropine sulfate, ¼ ₁₀₀ gr.	Do.
Phenobarbital and belladonna.	Tablet: Phenobarbital, ¼ gr.; belladonna leaves ½ gr. (total alkoids 0.0015 gr.).	The Vale Chemical Co., Inc.
Do.....	Tablet: Phenobarbital, ¼ gr.; belladonna extract, ¼ gr.	Paine Drug Co.
Do.....	Tablet: Phenobarbital, 16 mg.; belladonna extract, 8 mg.	Eli Lilly and Co.
Phenobarbital and Belladonna No. 2.	Tablet: Phenobarbital, ¼ gr.; belladonna extract, ¼ gr. (alkaloids 0.00156 gr.).	The Upjohn Co.
Phenobarbital with mannitol hexantrate.	Tablet: Phenobarbital, 7.5 mg.; mannitol hexantrate, 15 mg.; ascorbic acid powder, 25 mg.; rutin, 25 mg.	Paul B. Elder Co., Inc. (Harold M. Harter, D.V.M.)
Phenobarbital and mannitol hexantrate.	Tablet: Phenobarbital, ¼ gr.; mannitol hexantrate, ¼ gr.	Meyer Drug & Surgical Supply Co.
Phenobarbital Sodium Atropine No. 1.	Tablet: Phenobarbital sodium, 8 mg.; atropine sulfate, 60 µg.	McNeill Laboratories, Inc.
Phenobarbital Sodium Atropine No. 2.	Tablet: Phenobarbital sodium, 15 mg.; atropine sulfate, 120 µg.	Do.
Phenobarbital Sodium Atropine No. 3.	Tablet: Phenobarbital sodium, 20 mg.; atropine sulfate, 200 µg.	P. J. Noyes Co.
Phenobarbital and sodium nitrite.	Tablet: Phenobarbital, ¼ gr.; sodium nitrite, 1 gr.	Knoll Pharmaceutical Co.
Phenobarbital Theocalcin.....	Tablet: Phenobarbital, 15 mg.; theobromine calcium salicylate, 0.5 gm.	Flint Medical & Surgical Supply Co.
Phenodonna Tablets.....	Tablet: Phenobarbital, ¼ gr.; tincture belladonna, 6 minims.	North American Pharmacal Inc.
Phenodrox.....	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, ¼ ₁₀₀ gr.; magnesium trisilicate, 4 gr.; aluminum hydroxide gel, dried, 4 gr.	Lemmon Pharmacal Co.
Phyldrox.....	Tablet: Phenobarbital, 15 mg.; neothylline, 100 mg.; ephedrine sulfate, 25 mg.	Lakeside Laboratories, Inc.
Piptal PHB Elixir.....	Elixir (5cc.): Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Do.
Piptal PHB Tablets.....	Tablet: Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Schering Corp.
Prantal with Phenobarbital.....	Tablet: Phenobarbital, 16 mg.; diphepanil methylsulfate, 100 mg.	Ayerst Laboratories.
Premarin with Phenobarbital.....	Tablet: Phenobarbital, 32 mg.; conjugated estrogens-equine, 0.625 mg.	G. D. Searle & Co.
Probanthine with phenobarbital.	Tablet: Phenobarbital, 15 mg.; probanthine, 15 mg.	Do.
Probital.....	Tablet: Phenobarbital, 15 mg.; probanthine, 7.5 mg.	The Zemmer Co.
Propenite.....	Tablet: Pentobarbital sodium, 12 mg.; sodium nitrite, 60 mg.; hawthorn berries extract, 120 mg.; mistletoe extract, 60 mg.	Smith Kline & French Laboratories.
Prydonnal Spansule.....	Capsule: Phenobarbital, 65 mg.; belladonna alkaloids, 0.4 mg. (hyoscyamine sulfate, 0.305 mg.; atropine sulfate, 0.06 mg.; scopolamine hydrobromide, 0.035 mg.).	Knoll Pharmaceutical Co.
Quadrinal.....	Tablet: Phenobarbital, 24 mg.; ephedrine hydrochloride 24 mg.; theophylline calcium salicylate, 130 mg.; potassium iodide, 300 mg.	Do.
Do.....	Suspension (5 cc.): Phenobarbital, 12 mg.; ephedrine hydrochloride, 12 mg.; theophylline calcium salicylate, 65 mg.; potassium iodide, 160 mg.	Do.
Quintrate with Nitroglycerin and Phenobarbital.	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.; nitroglycerin, 0.4 mg.	Paul B. Elder Co., Inc. (Glynn A. Beard).
Quintrate with Phenobarbital.....	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Do.
Do.....	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Rheastat.....	Suspension (1 fluid ounce (32 cc.)): Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.; kaolin, colloidal, 5.76 gm.; pectin, 320 mg.; sodium (as Cl), 6 meq.; potassium (as Cl), 4 meq.	Mallinckrodt Pharmaceuticals Division of Mallinckrodt Chemical Works.
Robinul-PH.....	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 1.0 mg.	A. H. Robins Co., Inc.
Robinul-PH Forte.....	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 2.0 mg.	Do.
Ruhexatal.....	Tablet: Phenobarbital, 15 mg.; mannitol hexantrate, 30 mg.; ascorbic acid, 10 mg.; rutin, 20 mg.	Lemmon Pharmacal Co.
Rutol.....	Tablet: Phenobarbital, 8.0 mg.; mannitol hexantrate, 16 mg.; rutin, 10 mg.	Pitman-Moore.
Salisl with Phenobarbital.....	Tablet: Phenobarbital, ¼ gr.; acetylsalicylic acid, 5 gr.; magnesium trisilicate, 2 gr.	Paul B. Elder Co., Inc.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Sebella.....	Tablet: Phenobarbital, ¼ gr.; aluminum hydroxide, 5 gr.; belladonna extract, ¼ gr.	Wyeth Laboratories.
Sed-Tens.....	Tablet (12 hr.): Amobarbital, 50 mg.; homatropine methylbromide, 7.5 mg.	Lemmon Pharmacal Co.
Sibena.....	Tablet: Butabarbital sodium, 16 mg.; simethicone, 25 mg.; belladonna extract, 16 mg. (total alkaloids 0.20 mg.).	Plough Laboratories, Inc.
Sodium nitrite with phenobarbital.	Tablet: Phenobarbital sodium, ¼ gr.; sodium nitrite, 1 gr.; sodium bicarbonate, 2 gr.; hawthorn berries, fluid extract, ½ minim.	Paine Drug Co.
Do.....	Tablet: Phenobarbital, ¼ gr.; sodium nitrite, 1 gr.	Buffalo Pharmaceutical Supply Corp.
Spasticol PB.....	Tablet: Phenobarbital, 15 mg.; homatropine methylbromide, 2.5 mg.	Key Pharmaceuticals, Inc.
Spastosed.....	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.13 mg.; calcium carbonate, 227 mg.; magnesium hydroxide, 162 mg.	North American Pharmacal, Inc.
Special Formula 711.....	Tablet: 4-Ampetamine sulfate, 2.5 mg.; methphenesin, 500 mg.; salicylamide, 300 mg.	Detroit First Aid Co.
Synirin.....	Tablet: Pentobarbital, 8 mg.; aspirin, 324 mg.	Wm. P. Poythress & Co., Inc.
TOS.....	Tablet: Phenobarbital, 16 mg.; theobromine salicylate, 0.4 gm.; calcium salicylate, 0.06 gm.	Do.
Tedral-25.....	Tablet: Butabarbital, 25 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral S.A.....	Tablet: Phenobarbital, 25 mg.; theophylline, 180 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tensodin.....	Tablet: Phenobarbital, 15 mg.; ethaverine hydrochloride, 30 mg.; theophylline calcium salicylate, 200 mg.	Knoll Pharmaceutical Co.
Tensophen.....	Tablet: Phenobarbital, 16 mg.; nitroglycerin, 0.26 mg.; sodium nitrite, 32 mg.; podophyllin, 1 mg.; extract beef bile, 16 mg.	P. J. Noyes Co.
Thedrizem.....	Tablet: Phenobarbital, 8 mg.; theophylline, 100 mg.; ephedrine hydrochloride, 25 mg.	The Zemmer Co.
Theobarb.....	Tablet: Phenobarbital, 32 mg.; theobromine, 325 mg.	Mallinckrodt Pharmaceuticals, Division of Mallinckrodt Chemical Works.
Theobarb-R.....	Tablet: Phenobarbital, 10 mg.; reserpine, 0.1 mg.; theobromine, 324 mg.	Do.
Theobarb Special.....	Tablet: Phenobarbital, 16 mg.; theobromine, 325 mg.	P. J. Noyes Co.
Theobromine and phenobarbital.	Tablet: Phenobarbital, 16 mg.; theobromine, 0.3 gm.	The S. E. Massengill Co.
Theobromine-Phenobarbital.....	Tablet: Phenobarbital, 30 mg.; theobromine, 0.3 gm.	The Upjohn Co.
Do.....	Tablet: Phenobarbital, 32 mg.; theobromine, 324 mg.	Do.
Theobromine-Phenobarbital Compound.	Tablet: Phenobarbital, ¼ gr.; theobromine, 2½ gr.; potassium iodide, 2½ gr.; potassium bicarbonate, 2 gr.	Do.
Theobromine with Phenobarbital No. 1.	Tablet: Phenobarbital, 15 mg.; theobromine, 324 mg.	Buffington's Inc.
Theobromine and sodium acetate with phenobarbital.	Tablet: Phenobarbital, ¼ gr.; theobromine and sodium acetate, 3 gr.	Paul B. Elder Co., Inc.
Theobromine sodium salicylate with phenobarbital.	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 300 mg.	The Zemmer Co.
Theocardone No. 1.....	Tablet: Phenobarbital, 15 mg.; theobromine, 300 mg.	Haack Laboratories, Inc.
Theocardone No. 2.....	Tablet: Phenobarbital, 30 mg.; theobromine, 300 mg.	Do.
Theodide.....	Tablet: Phenobarbital, ¼ gr.; potassium iodide, 2½ gr.; theobromine sodium salicylate, 2½ gr.	The Vale Chemical Co., Inc.
Theoglycinate with Phenobarbital.	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.	Brayten Pharmaceutical Co.
Theoglycinate with Racephedrine and Phenobarbital.	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.; racephedrine hydrochloride, 24 mg.	Do.
Theoplaphen.....	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 0.2 gm.; calcium lactate, 0.1 gm.	The S. E. Massengill Co.
Theominal.....	Tablet: Phenobarbital, 32 mg.; theobromine, 320 mg.	Winthrop Laboratories.
Theominal M.....	Tablet: Phenobarbital, 15 mg.; theobromine, 320 mg.	Do.
Theominal R.S.....	Tablet: Phenobarbital, 10 mg.; theobromine, 320 mg.; alseroxylon, 1.5 mg.	Do.
Theophen.....	Tablet: Phenobarbital, ¼ gr.; theobromine sodium salicylate, 5 gr.; calcium carbonate, 2½ gr.	The Vale Chemical Co., Inc.
Theorate.....	Tablet: Phenobarbital, 16.2 mg.; theobromine, 324 mg.	Whittier Laboratories, Inc.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Thora-Dex No. 1.....	Tablet: Dextroamphetamine sulfate, 2 mg., chlorpromazine hydrochloride, 10 mg.	Smith Kline & French Laboratories. Do.
Thora-Dex No. 2.....	Tablet: Dextroamphetamine sulfate, 5 mg.; chlorpromazine hydrochloride, 25 mg.	P. J. Noyes Co.
Thymodyne.....	Tablet: Phenobarbital, 32 mg.; theophylline anhydrous, 130 mg.; ephedrine sulfate, 24 mg.	Wm. P. Poythress & Co., Inc.
Trocinate with Phenobarbital.....	Tablet: Phenobarbital, 16 mg.; thiphenamil hydrochloride, 100 mg.	Burroughs Wellcome & Co.
Tricoloid.....	Tablet: Phenobarbital, 16 mg.; tricyclamol chloride, 50 mg.	The Vale Chemical Co., Inc.
Triophen.....	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, ¼ ₆₀₀ gr.; magnesium trisilicate, 7 gr.	Neisler Laboratories, Inc.
Unitensen-Phen.....	Tablet: Phenobarbital, 15 mg.; cryptenamine, 1 mg.	Endo Laboratories Inc.
Valpin-PB.....	Tablet or elixir (5 cc.): Phenobarbital, 8 mg.; anisotropine methylbromide, 10 mg.	Buffington's, Inc.
Vasorutin.....	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerin, ½ ₆₀ gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims; rutin, 20 mg.	Neisler Laboratories, Inc.
Veraflex.....	Tablet: Phenobarbital, 15 mg.; cryptenamine, 65 CSR (carotid sinus reflex) units; rutin, 20 mg.	The Zemmer Co.
Veralzem.....	Tablet: Phenobarbital, 15 mg.; veratrum viride, 50 mg.; sodium nitrite, 60 mg.	Neisler Laboratories, Inc.
Veratrite.....	Tablet: Phenobarbital, ¼ gr.; cryptenamine, 40 CSR (carotid sinus reflex) units; sodium nitrite, 1 gr.	S. J. Tutag and Co.
Veritag.....	Tablet: Phenobarbital, 16 mg.; veratrum viride, 40 mg.; sodium nitrite, 65 mg.	Burt Krone Co.
Vertegus.....	Tablet: Phenobarbital, ¼ gr.; veratrum viride, ¼ gr.; sodium nitrite, 1 gr.; mistletoe, ½ gr.; hawthorn berries, ½ gr.	The Zemmer Co.
Veruphen.....	Tablet: Phenobarbital, 15 mg.; rutin, 20 mg.; veratrum viride, 15 mg.; sodium nitrite, 60 mg.	Lemmon Pharmacal Co.
Viritin.....	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; veratrum viride alkaloids, 1.5 mg.; rutin, 20 mg.	The Vale Chemical Co., Inc.
Weytabs No. 1.....	Tablet: <i>d,l</i> -Desoxyephedrine hydrochloride, 5 mg.; thyroid, 60 mg.; atropine sulfate, 0.125 mg.; aloin, 15 mg.	Do.
Weytabs No. 2.....	Tablet: <i>d,l</i> -Desoxyephedrine hydrochloride, 5 mg.; thyroid, 60 mg.; atropine sulfate, 0.125 mg.	Do.
Weytabs No. 3.....	Tablet: Phenobarbital, 15 mg.; <i>d,l</i> -desoxyephedrine hydrochloride, 5 mg.; thyroid 60 mg.	Warren-Teed Pharmaceuticals Inc.
W-T.....	Powder (4 gm.): Phenobarbital, 15 mg.; belladonna extract, 10 mg. (0.12 mg. belladonna alkaloids); benzocaine, 15 mg.; calcium carbonate, 1.55 gm.; magnesium oxide, 0.5 gm.; aluminum hydroxide gel, dried, 60 mg.	Do.
W-T.....	Tablet: Phenobarbital, ¼ ₆ gr.; belladonna extract, ¼ ₄ gr.; benzocaine, ¼ ₆ gr.; calcium carbonate, 6 gr.; magnesium trisilicate, 3¾ gr.; aluminum hydroxide gel, dried, 2½ gr.; chlorophyll extract, 1%.	Pitman-Moore.
Xaniophen.....	Tablet: Phenobarbital, 16.2 mg.; theobromine, 162 mg.; ethylenediamine dihydriodide, 32.4 mg.	The S. E. Massengill Co.
Zallogen Compound.....	Tablet: Phenobarbital, 8 mg.; tocampyl, 75 mg.; homatropine methylbromide, 2.5 mg.	The Upjohn Co.
Zantrate.....	Tablet: Cyclopentenylallylbarbituric acid, ¼ gr.; ephedrine sulfate, ¾ gr.; theophylline anhydrous, 2 gr.	The Zemmer Co.
Zem-Dab.....	Tablet: Butabarbital sodium, 10 mg.; dehydrocholic acid, 60 mg.; ox bile desiccated, 120 mg.; homatropine methylbromide, 2.5 mg.	Stayner Corp.
No. 23.....	Tablet: Phenobarbital, ¼ gr.; aminophylline, 3 gr.	Do.
No. 35.....	Tablet: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.; ephedrine sulfate, ¾ gr.	Do.
No. 36.....	Tablet: Pentabarbital sodium, ¾ gr.; ephedrine sulfate, ¾ gr.; aminophylline, 3 gr.	Do.
No. 65.....	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 66.....	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 75.....	Tablet: Phenobarbital, ¼ gr.; belladonna, ¼ gr.	Bariatric Corp.
No. 88.....	Tablet: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.	Stayner Corp.
No. 89.....	Tablet: Phenobarbital, ¼ gr.; aminophylline, ¼ gr.	Do.

EXEMPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
No. 111.....	Tablet: Phenobarbital, ¼ gr.; ephedrine sulfate, ¾ gr.	Do.
No. 136.....	Tablet: Phenobarbital, 20 mg.; homatropine methylbromide, 5 mg.	Do.
No. 643.....	Tablet: Phenobarbital, ¼ gr.; theophylline, 2 gr.; ephedrine hydrochloride, ¾ gr.	Do.
Rx. No. 4104.....	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 7¼ gr.; magnesium oxide, 4 gr.; atropine sulfate, ¼ ₆₀₀ gr.	The Zemmer Co.
Rx. No. 4105.....	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 10 gr.; atropine sulfate, ¼ ₆₀₀ gr.	Do.
Rx. No. 4108.....	Capsule: Phenobarbital, ¼ gr.; atropine sulfate, ¼ ₆₀₀ gr.; calcium carbonate, 6¼ gr.; magnesium oxide, heavy, 2 gr.	Do.
Rx. No. 4123.....	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladonna, ¼ gr.	Do.
Rx. No. 4126.....	Capsule: Pentabarbital sodium, 15 mg.; extract belladonna, 10 mg.	The Zemmer Co.
Rx. No. 4143.....	Capsule: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.; potassium iodide, 1 gr.	Do.
Rx. No. 4152.....	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, ¼ ₆₀₀ gr.	Do.
Rx. No. 4155.....	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, ¼ ₆₀₀ gr.; aluminum hydroxide gel, 3¾ gr.; kaolin, 3¾ gr.	Do.
Rx. No. 4170.....	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, ¼ ₆₀₀ gr.; calcium carbonate, 10 gr.	Do.
Rx. No. 4184.....	Capsule: Sodium butabarbital, 15 mg.; belladonna extract, 15 mg.	Do.

§ 320.16 Records required to be maintained under section 511(d) of the act.

(a) *Types of records*—(1) *Initial inventory*. Section 511(d) (1) of the act requires every person engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of any depressant or stimulant drug, as defined in section 201(v) of the act, to prepare upon the effective date of the section a complete and accurate record of all stocks of each such drug on hand and to keep such records for 3 years.

(i) An inventory is required as of February 1, 1966, of each drug containing any amount of barbiturate or amphetamine, unless exempted by regulation in this part.

(ii) An inventory is required of any drug on the effective date of an order issued after February 1, 1966, that designates such drug under section 201(v) of the act as a depressant or stimulant drug subject to control, unless exempted by regulation in this part.

(2) *Continuing records*. Section 511(d) (1) of the act also requires that on and after February 1, 1966, every person manufacturing, compounding, or processing any depressant or stimulant drug, as defined in section 201(v) of the act, shall prepare and keep for not less than 3 years a complete and accurate record of the kind and quantity of each

such drug manufactured, compounded, or processed and the date of such manufacture, compounding, or processing; and that every person selling, delivering, or otherwise disposing of any such drug shall prepare or obtain and keep for not less than 3 years a complete and accurate record of the kind and quantity of each such drug received, sold, delivered, or otherwise disposed of, the name and address of the person, and the registration number, if any, assigned to such person pursuant to section 510(e) of the act, from whom such drug was received, and to whom it was sold, delivered, or otherwise disposed of, including the date of such transaction.

(b) *Contents of records*. The records required under section 511(d) (1) of the act, and by regulations in this part, shall be considered incomplete and inadequate unless such records contain sufficient information to clearly show the kind and quantity of all stocks of each drug subject to these record-keeping requirements including, but not limited to, the following information:

(1) *Information required in initial inventory record*. (1) The kind and quantity, to the nearest unit weight consistent with the unit size, of all bulk depressant or stimulant drugs used in or capable of use in the production of drugs as defined in section 201(v) of the act, on hand as of February 1, 1966.

(ii) The kind and quantity of drugs in production on February 1, 1966, identified by batch number or other appropriate identifying number including the physical form which such in-process drugs are intended to take upon completion of the manufacturing process; for example, granulations, tablets, capsules, solutions, etc.

(iii) The kind and quantity of all such drugs in finished form on hand on February 1, 1966, including returned merchandise, transfers from other locations, orders prepared for shipment or delivery, or otherwise within the control of the registrant; for example, drugs in any controlled warehouse, or drugs in possession of employees and intended for distribution as professional samples. These records shall describe the finished form (for example, 10-milligram tablets or 10-milligram concentration per fluid ounce, if liquid), the number of units or volume in each package or container (for example, 100-tablet bottle or 3 fluid ounces), and the location of stocks.

(2) *Information required in continuing records of receipt or manufacture, compounding, or processing of controlled drugs.* (i) The kind and quantity, expressed in the nearest unit weight consistent with the unit size, of all bulk depressant or stimulant drugs in or capable of use in the production of drugs, as defined in section 201(v) of the act, on hand and in production, including the name and address of the person or firm from whom the drugs or substance is received and the date and quantity of material received. If any of this material is disposed of in any manner, or in any form, the details of disposition, including the name and address of the person to whom delivered, the date, quantity, and form in which disposed.

(ii) The kind and quantity of any depressant or stimulant drug as defined in section 201(v) of the act, in tablet, capsule, liquid, or any other finished form produced that is on hand, in production, or received. These records shall describe the form (tablet, capsule, etc.), the strength or potency per unit (for example, 10-milligram tablets), and the number of units in each package or container (for example, 100-tablet bottle), and the date of production, receipt, repackaging, or relabeling. These records shall include the name and address of the person from whom any such controlled substance was received and the

date, quantity, and kind of the material received.

(iii) Production records shall show date of manufacture, compounding, or processing, theoretical and actual yield, the quantity of loss during manufacture, if any, the quantity used for quality control, the identity by batch number or other appropriate identification and quantity of any product reworked for any reason and such other information as is necessary to account for all controlled substances used in the manufacturing process.

(3) *Information required in continuing records of wholesaling, jobbing, distributing, retailing, or other disposition.* The records required by section 511(d) of the act to be kept by each person selling, delivering, or otherwise disposing of any depressant or stimulant drug shall include the following information:

(i) The kind and quantity of each such drug received including imports, the name and address of the person from whom the drug is received, and the registration number, if any, assigned to any such person pursuant to section 510(e) of the act, and the date any such drug was received.

(ii) The kind and quantity of each such drug sold, delivered, or otherwise disposed of, including the name and address of the person to whom such drug was sold, delivered, or otherwise disposed of, the identity of any common carrier or transportation firm used in effecting such delivery, and the registration number, if any, assigned to any such person pursuant to section 510(e) of the act, and the date any such sale, delivery, or other disposition took place, including drugs exported to other countries.

(iii) (a) The term "kind" as used in this section means the established name, chemical name, or trade name for drugs which contain a single active ingredient, and for those drugs (for which there is no established or trade name) containing more than one active component, the established name, chemical name, or trade name for each active ingredient.

(b) The word "quantity" as used in this section means the number of individual packages or containers of the controlled substance (for example, 100 bottles, 5 dozen bottles), a description of the quantity of contents of each individual package or container (for example, 100-tablet bottle, 50-pound drum), and a statement of the potency of a single unit within the individual pack-

age or container (for example, 10-milligram tablet), resulting in the following type of quantity designation (fifty 100-tablet bottles of 10-milligram tablets; two 50-pound drums of 10-milligram tablets; 3 dozen 25-tablet bottles of 10-milligram tablets). If the semiprocessed controlled substance is a granulation, a meaningful quantitative statement of the amount of such substance present is required.

(iv) With regard to the records required by section 511(d)(1) of the act, the law states "no separate records nor set form or forms for any of the foregoing records shall be required as long as records containing the required information are available."¹ Ordinary business records kept by legitimate businessmen are maintained so that inspection of the records is possible and practicable in a reasonable length of time. Among others, an automatic data processing system will be considered adequate providing the system is capable of separating and identifying all records containing the specific information required by section 511(d) of the act and the regulations contained in this part in a reasonable time, or provided the system itself is capable of producing such information in a reasonable time. Other recordkeeping systems that permit the records specified in section 511(d)(1) of the act to be identified and reviewed or copied in a reasonable time also will be regarded as adequate. To account for controlled drugs dispensed on prescription, either the usual consecutively numbered prescription file, or a separate prescription file, will be acceptable.

§ 320.17 Persons required to establish, prepare, and maintain records specified in section 511(d)(1) of the act.

Pursuant to the provisions of section 511(a) and (d)(1) of the act, persons engaged in one or more or any combination of the following activities in relation to depressant or stimulant drugs, as defined in section 201(v) of the act and regulations thereunder, are required to establish and maintain the initial inventory records and the continuing records described in this part:

¹The purpose of this provision as shown by reports of the Congressional Committee that considered the legislation is to insure that the ordinary business records kept by legitimate businessmen will be considered as adequate records.

(a) Persons engaged in manufacturing, preparation, propagation, compounding, or processing of such drugs in bulk, tablet, capsule, liquid, or other finished form.

(b) Persons, other than those exempted under section 511(d)(3) of the act, engaged in selling, transporting, delivering, wholesaling, jobbing, warehousing, distributing, or otherwise disposing of such drugs to any person who is not the ultimate user or consumer of the drug.

(c) Persons, other than those exempted under section 511(d)(3) of the act, engaged in manipulation, sampling, testing, repackaging, or otherwise changing the container, wrapper, or labeling of such drugs in furtherance of the distribution of such drugs from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(d) Pharmacies, hospitals, clinics, and public health agencies who have on hand or maintain a stock of such drugs for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practitioners licensed by law to administer such drugs in the course of their professional practice.

(e) Laboratories or research or educational institutions who use such drugs in research, teaching, or chemical analysis.

(f) Practitioners licensed by law to prescribe or administer such drugs, while acting in the course of their professional practice, who regularly engage in dispensing any such drug or drugs to their patients for which the patients are charged, either separately or together with charges for other professional services. The maintaining of small supplies of these drugs for dispensing or administering in the course of professional practice in emergency or special situations (for example, as a stopgap measure to tide patients over until a regular supply of drugs can be obtained by prescription from a pharmacy, or dispensing as trial doses to patients), will not be considered as regularly engaged in dispensing for a fee.

§ 320.18 Label symbol.

(a) All depressant and stimulant drugs within the meaning of section 201(v) of the act, which have not been exempted by the Director from the requirements

of section 511 (c) and (e) and the recordkeeping requirements of section 511(d)(1) of the act, shall bear the following symbol or modification:



The symbol in outline form is for use as a large, open-letter overprint.

(b) This symbol shall be prominently placed on the principal panel of the label and/or on the panel normally displayed on the shelf by users of the immediate container and on any retail carton or wrapper for such container of each such drug: *Provided, however, That:*

(1) The symbol is not required on the retail carton or wrapper if it is easily legible through such carton or wrapper; or

(2) In the case of ampules or other containers too small or otherwise unable to accommodate a label, the symbol may appear on the outer container from which they are removed for dispensing or use.

(c) The symbol shall be of contrasting color to the background on which it appears (no particular color is required), large enough for easy identification, placed preferably to the right of the title and adjacent to it, and at least as large as the largest letter in the title of the drug. Large open-letter overprinting of the symbol will be regarded as meeting the requirements.

(d) Compliance with the requirements of this section shall be as follows:

(1) All drugs subject to control on February 1, 1966, as set forth in paragraph (a) of this section, and packaged after September 1, 1966, must bear the symbol.

(2) All drugs brought under control after February 1, 1966, as set forth in paragraph (a) of this section, which are packaged on or after 180 days from the effective date of such control, shall bear the symbol.

§ 320.19 Advisory committees; appointment; procedure; fees.

(a) *Selection, appointment, qualifications, compensation.* (1) Whenever the Director deems necessary the referral to an advisory committee of any matter, with regard to determining whether a regulation under section 201(v) (2)(C)

or (3) of the act should be proposed, issued, amended, or repealed, whether such referral is made upon the Director's own initiative or upon the request of an interested person, the Director will request the National Academy of Sciences to select qualified experts willing to serve on the advisory committee. All such experts shall have had sufficient training and experience in pharmacology, psychiatry, internal medicine, anesthesiology, organic chemistry, sociology, psychology, or in other appropriate science to qualify them on the subject matter to be referred to them. The Director will request the National Academy of Sciences, when it furnishes the names of such experts, to supply a biographical sketch showing the background of their experience and their connection, if any, with academic and commercial institutions.

(2) Each advisory committee shall consist of not less than three experts qualified in the subject matter to be referred to the committee and of adequately diversified professional backgrounds. The Director may specify a larger number to serve. He shall appoint one member of the committee as chairman, and the chairman shall be the spokesman for the committee responsible for receiving and forwarding reports and for other functions of the Committee.

(3) The Director shall appoint the experts so selected and fix their compensation not to exceed the maximum permitted by other authority per day for each day or part thereof spent in committee meetings and in traveling to and from committee meetings held outside the city of their residence, plus necessary traveling and subsistence expenses while the experts are serving away from their place of residence. Subsistence expenses shall not exceed \$30 per day.

(b) *Procedure.* (1) The Director shall submit to the chairman of the advisory committee all available materials and information relevant to the matter that has been referred to the committee. If the referral of a matter to an advisory committee is made upon the request of an interested person, the Director shall furnish such person with copies of all materials and information that are furnished to the committee, except those materials which may have been transmitted to the Director by such person and such scientific libraries. The chairman of the committee shall acknowledge receipt of the information and readiness of the

committee to act. The date of acknowledgment of receipt of such information shall be considered the beginning of the period allowed for consideration by the committee. A copy of this acknowledgment shall be forwarded by the chairman of the committee to the interested person requesting referral of the matter to the committee. When the Director on his own initiative has referred to an advisory committee any matter concerning a drug which is the subject of a new-drug application, the chairman shall forward a copy of the acknowledgement to any holder of such an application.

(2) A secretariat to the advisory committees will be established by the Director. The secretariat shall furnish members of the committee with copies of any data received by the chairman. If the chairman of the committee believes that a meeting of the committee is necessary before making a recommendation, he shall so inform the Director. Such meetings shall be held in Washington, D.C., or at such other place as the Director shall furnish a suitable meeting place for the committee. If a meeting is held, the secretariat shall keep the minutes and provide clerical assistance.

(3) As soon as practicable, the advisory committee shall make an independent study of the data, and not later than 60 days after acknowledged receipt of such materials and information (unless the time has been extended as provided in subparagraph (4) of this paragraph), the chairman shall certify to the Director the report and recommendations of the committee, including any minority report, together with all underlying data and a statement of the reasons or basis for the recommendations. The report will include copies of all material considered by the committee, except that in the case of scientific literature readily available in scientific libraries proper reference may be made to it instead of furnishing actual copies. A copy of the report of the advisory committee will be supplied to the interested person who requested the referral to the advisory committee, if any there be.

(4) If at any time within 60 days the chairman believes that the advisory committee needs more time, he shall so inform the Director in writing, in which case he shall certify to the Director such report as provided for in subparagraph (3) of this paragraph within an additional 30 days.

(5) The chairman of the committee, after consultation with the committee members, will inform the National Academy of Sciences of the committee's opinion concerning the member who may best represent the committee at a hearing, if one occurs.

(6) More than one referral may be handled by a committee concurrently.

(7) An interested person whose request for a referral of a matter to an advisory committee has been granted in accordance with the provisions of this section, as well as representatives of the Department of Justice, shall have a right to consult with the committee in connection with such referred matter. Such person shall notify the chairman and, if practicable, make appointments through him. If any interested person discusses with or offers information to a committee member concerning a referred matter, such committee member shall make a written report of the discussion or offer and submit it to the committee to be made a part of the file of the committee.

(8) Except for discussions with authorized persons, the committee shall not disclose information, material, or data referred to it prior to publication of a regulation unless such disclosure is specifically authorized by the Director.

(c) *Fees.* (1) In the event of a referral of a matter under section 511(g) of the act to an advisory committee, the costs shall be borne by the person who requests the referral of the matter to the committee.

(2) The cost of the advisory committee shall include expenses of the secretariat, compensation of members, necessary travel and subsistence expenses of members, costs of duplicating documents referred to the committee, and other expenses arising by reason of referrals to the committee.

(3) An advance deposit shall be made in the amount of \$2,500 to cover the costs. Further advance deposits of \$2,500 each shall be made upon request of the Director when necessary to prevent arrears in the payment of such costs. Any deposits in excess of actual expenses will be refunded to the depositor.

(4) All deposits and fees required by the regulations in this section shall be paid by money order, bank draft, or certified check drawn to the order of the Treasurer of the United States, collectible at par at Washington, D.C. All deposits and fees shall be forwarded to the Financial Management Division, Bureau of

Narcotics and Dangerous Drugs, Washington, D.C. 20537, for deposit to the appropriation "Salaries and Expenses; Bureau of Narcotics and Dangerous Drugs."

(5) The Director may waive or refund such fees in whole or in part when in his judgment such action will promote the public interest.

(6) Any person who believes that payment of these fees will work a hardship on him may petition the Director to waive or refund the fees.

§ 320.20 Exportation.

(a) The provisions of section 801(d) of the act (21 U.S.C. 381 (d)), provide that a drug intended for export shall not be deemed to be adulterated or misbranded but that if such an article is sold or offered for sale in domestic commerce, it is not exempt from control. The provisions of Part 370 of Title 15 of the Code of Federal Regulations (15 CFR 370.2), contain the following definition: "U.S. Exporter. That person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the commodities and technical data out of the United States." Therefore, such exporter, who may be the manufacturer, compounder, processor, wholesaler, or distributor of the controlled substances will be deemed the "U.S. Exporter" under 15 CFR 370.2, and must comply with one of the following alternative procedures in order to insure that controlled substances "intended for export" are in fact exported:

(1) The "U.S. Exporter" will execute the Shipper's Export Declaration, Form 7525-V, if required by 15 CFR 379.1-379.13, and have the controlled substances delivered to a bonded carrier for delivery to the port or border for shipment directly to the consignee in the foreign country without shipping the substances to a "forwarding agent." A copy of the invoice describing the controlled substance must be attached to each copy of the Shipper's Export Declaration and these documents must accompany the shipment. Form 7525-V may be obtained at a cost of \$1 per 100 from any local Customs or Department of Commerce Field Office, and assistance in the execution of such Forms is also available at such offices. A "U.S. Exporter" may not, under any circumstances, physically release a shipment of controlled substances to anyone, includ-

ing the consignee, at his agent, within the United States.

(2) The "U.S. Exporter" may ship the controlled substances to a "forwarding agent" as defined in 15 CFR 379.4(f), who will execute the required Shipper's Export Declaration and further act as an exporting agent for the principal. When a "forwarding agent" is utilized, a copy of the invoice describing the controlled substance must be attached to each copy of the Shipper's Export Declaration and these documents must accompany the shipment. A "forwarding agent" may not, under any circumstances, release a shipment of controlled substances to anyone, including the consignee, or his agent, within the United States. The "forwarding agent" must either deliver the controlled substances to the port or border, or deliver the controlled substances to a bonded carrier approved by the principal for delivery to the port or border.

(b) In the event that controlled substances intended for export by a "U.S. Exporter" or a "forwarding agent" are introduced or delivered into domestic commerce before they are exported, such introduction or delivery shall be considered a domestic sale, delivery, or other disposition of a controlled substance under 21 U.S.C. 360a, and a prohibited act under 21 U.S.C. 331(q) (2).

[34 F.R. 19654, Dec. 13, 1969]

PART 330—SEIZURE, FORFEITURE, AND DISPOSITION OF VESSELS, VEHICLES, AND AIRCRAFT FOR DOMESTIC NARCOTIC AND MARIHUANA VIOLATIONS

Sec.	
330.1	Definitions.
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330.11	Handling of petitions.

AUTHORITY: The provisions of this Part 330 issued under sec. 8, 53 Stat. 1293, 49 U.S.C. 788; 5 U.S.C. 301; 28 U.S.C. 509, 510; and Reorganization Plan No. 1 of 1968—33 F.R. 5611. Other statutory provisions interpreted or applied are cited to text in parentheses.

SOURCE: The provisions of this Part 330 appear at 33 F.R. 16559, Nov. 14, 1968, unless otherwise noted.

§ 330.1 Definitions.

As used in the regulations in §§ 330.1 through 330.11, except as otherwise indicated by the content:

(a) The term "Act" means the Act of August 9, 1939 (53 Stat. 1291; 49 U.S.C. 781-788).

(b) The term "custodian" means the officer required under § 330.3 to take custody of particular property which has been seized pursuant to the Act.

(c) The term "property" means a vessel, vehicle, or aircraft within the scope of the Act.

(d) The terms "seizing officer," "officer seizing," etc., mean any officer, authorized and designated by § 330.2 to carry out the provisions of the Act, who initially seizes property or adopts a seizure initially made by any other officer or by a private person.

(e) The term "regional director" means the regional director of the Bureau of Narcotics and Dangerous Drugs, U.S. Department of Justice.

§ 330.2 Officers who will make seizures.

For the purpose of carrying out the provisions of the Act, all special agents of the Bureau of Narcotics and Dangerous Drugs of the Department of Justice are authorized and designated to seize such property as may be subject to seizure.

§ 330.3 Custody and other duties.

An officer seizing property under the Act shall store the property in a location designated by the custodian in the judicial district of seizure. The regional directors of the Bureau of Narcotics and Dangerous Drugs are designated as custodians to receive and maintain in storage all vessels, vehicles, and aircraft seized pursuant to the Act. The regional directors are also authorized to dispose of any property pursuant to the Act, and any other applicable statutes or regulations relative to disposal, and to perform such other duties regarding such seized property as are imposed on the collectors of customs and appraisers with respect to seizures under the customs laws.

(Sec. 605, 46 Stat. 754, 19 U.S.C. 1605; Sec. 609, 46 Stat. 755, 19 U.S.C. 1609)

§ 330.4 Appraisalment.

The custodian shall appraise the property to determine the domestic value at the time and place of seizure. The domestic value shall be considered the retail price at which such or similar prop-

erty is freely offered for sale. If there is no market for the property at the place of seizure, the domestic value shall be considered the value in the principal market nearest the place of seizure.

(Sec. 606, 46 Stat. 754, 19 U.S.C. 1606)

§ 330.5 Advertisement.

(a) If the appraised value does not exceed \$2,500, the custodian shall cause a notice of the seizure and of the intention to forfeit and sell or otherwise dispose of the property to be published once a week for at least three (3) successive weeks in a newspaper of general circulation in the judicial district in which the seizure occurred.

(b) The notice shall: (1) Describe the property seized and show the motor and serial numbers, if any; (2) state the time, cause, and place of seizure; and (3) state that any person desiring to claim the property may, within 20 days from the date of first publication of the notice, file with the custodian a claim to the property and a bond with satisfactory sureties in the sum of \$250.

(Sec. 607, 46 Stat. 754, as amended, 19 U.S.C. 1607)

§ 330.6 Requirements as to claim and bond.

(a) The bond shall be rendered to the United States, with sureties to be approved by the custodian, conditioned that in the case of condemnation of the property the obligor shall pay all costs and expenses of the proceedings to obtain such condemnation. When the claim and bond are received by the custodian, he shall, after finding the documents in proper form and the sureties satisfactory, transmit the documents, together with a description of the property and a complete statement of the facts and circumstances surrounding the seizure, to the United States Attorney for the judicial district in which the seizure was made for the purpose of proceeding to a condemnation of the property in the manner prescribed by law. If the documents are not in satisfactory condition when first received, a reasonable time for correction may be allowed. If correction is not made within a reasonable time the documents may be treated as nugatory, and the case shall proceed as though they had not been tendered.

(b) The filing of the claim and the posting of the bond does not entitle the claimant to possession of the property, however, it does stop the summary for-

feiture proceedings. The bond posted to cover costs may be in cash, certified check, or on Treasury Department Form 171 with satisfactory sureties. The costs and expenses secured by the bond are such as are incurred after the filing of the bond, including storage cost, safeguarding, court fees, marshal's costs, etc. (Sec. 608, 46 Stat. 755, 19 U.S.C. 1608)

§ 330.7 Summary forfeiture.

If the appraised value does not exceed \$2,500, and a claim and bond are not filed within the 20 days hereinbefore mentioned, the custodian shall declare the property forfeited. The custodian shall prepare the Declaration of Forfeiture and forward it to the Director of the Bureau of Narcotics and Dangerous Drugs as notification of the action he has taken. Thereafter, the property shall be retained in the custodian's district or delivered elsewhere for official use, or otherwise disposed of, in accordance with official instructions received by the custodian.

(Sec. 609, 46 Stat. 755, as amended, 19 U.S.C. 1609)

§ 330.8 Judicial forfeiture.

If the appraised value is greater than \$2,500 or a claim and satisfactory bond have been received for property appraised at \$2,500 or less, the custodian shall transmit a description of the property and a complete statement of the facts and circumstances surrounding the seizure to the U.S. Attorney for the judicial district in which the seizure was made for the purpose of instituting condemnation proceedings. The U.S. Attorney shall also be furnished the newspaper advertisements required by § 330.5.

(Sec. 610, 46 Stat. 755, 19 U.S.C. 1610)

§ 330.9 Petitions for remission or mitigation of forfeiture.

(a) Any person interested in any property within the scope of the Act and the regulations in §§ 330.1 through 330.11 which has been seized, or forfeited either summarily or by court proceedings, may file a petition for remission or mitigation of the forfeiture. Such petition shall be filed in triplicate with the regional director for the judicial district in which the seizure occurred. It shall be addressed to the Director of the Bureau of Narcotics and Dangerous Drugs and executed and sworn to by the person alleging interest in the property.

(b) The petition shall include the fol-

lowing: (1) A complete description of the property, including motor and serial numbers, if any, and the date and place of seizure; (2) the petitioner's interest in the property, which shall be supported by bills of sale, contracts, mortgages, or other satisfactory documentary evidence; and, (3) the facts and circumstances, to be established by satisfactory proof, relied upon by the petitioner to justify remission or mitigation.

(c) Where the petition is for restoration of the proceeds of sale, or for value of the property placed in official use, it must be supported by satisfactory proof that the petitioner did not know of the seizure prior to the declaration of condemnation of forfeiture and was in such circumstances as prevented him from knowing of the same.

(Secs. 613, 618, 46 Stat. 756, 757, as amended, 19 U.S.C. 1613, 1618)

§ 330.10 Time for filing petitions.

(a) In order to be considered as seasonably filed, a petition for remission or mitigation of forfeiture should be filed within 30 days of the receipt of the notice of seizure. If a petition for remission or mitigation of forfeiture has not been received within 30 days of the notice of seizure, the property will either be placed in official Government service or sold as soon as it is forfeited. Once property is placed in official use, or is sold, a petition for remission or mitigation of forfeiture can no longer be accepted.

(b) A petition for restoration of proceeds of sale, or for the value of property placed in official use, must be filed within 90 days of the sale of the property, or within 90 days of the date the property is placed in official use.

(Secs. 613, 618, 46 Stat. 756, 757, as amended; 19 U.S.C. 1613, 1618)

§ 330.11 Handling of petitions.

Upon receipt of a petition, the custodian shall request an appropriate investigation. The petition and the report of investigation shall be forwarded to the Director of the Bureau of Narcotics and Dangerous Drugs. If the petition involves a case which has been referred to the U.S. Attorney for the institution of court proceedings, the custodian shall transmit the petition to the U.S. Attorney for the judicial district in which the seizure occurred. He shall notify the petitioner of this action.

(Sec. 618, 46 Stat. 757, as amended, 19 U.S.C. 1618)