September 9, 1995

MEMORANDUM FOR HAROLD ICKES

FROM: JENNIFER O'CONNOR

SUBJECT: POSSIBLE CANCER DRUG EXECUTIVE ORDER

Attached is a final document from HHS that responds to our inquiry about a possible Executive Order (E.O.) directing the FDA to take actions to speed up the approval process for cancer drugs. The document explains that to initiate a process of drafting an E.O. would involve many actors at the FDA and that they would most likely return with a response that the process cannot be sped up because the FDA is already doing all it can to provide access to investigational drugs and get approvals out in an efficient manner. The memorandum also notes that because there are not special approval processes for cancer drugs specifically, any possible action we would take would be aimed at all drug approvals, not only cancer drug approvals.

The document explains also that because anti-cancer drugs are considered a priority, they are generally reviewed within a year. As of FY 1997, FDA will have a goal of reviewing them within six months. It notes that since the beginning of 1993, the FDA has received applications for 17 anti-cancer drugs. The FDA has either approved or given "approvable letters" to eight of these drugs (an approvable letter means that it is approved once labelling details are worked out), disapproved five of them and has pending action on nine of them. Of the nine pending action, none are overdue.

The document includes a chart of the nineteen approvals (or approvable letters) the Clinton Administration has issued to date for anti-cancer drugs, drugs that treat cancer-associated illnesses, or drugs approved for other purposes which the Administration then approved to fight cancer or cancer-related illnesses. Of these, so far in 1995, the Administration issued four approvable letters for new anti-cancer drugs, three approvals for drugs to fight cancer-related illnesses, and one approval of a drug previously approved for another purpose that is now approved for anti-cancer use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

MEMORANDUM TO HAROLD ICKES

FROM: Kevin Thurm

SUBJECT: Cancer Drugs

This is in response to your inquiry concerning the possibility of the Administration issuing an executive order to expedite the approval of cancer drugs.

First, to proceed with drafting an executive order, related to the approval of cancer drugs, we would direct FDA to begin the process. In drafting such a proposed executive order, several FDA offices would be involved, including the Office of Regulatory affairs, the Office of the General Counsel and the Office of the Commissioner. The process would entail a review of all existing legislative and regulatory authorities governing the drug approval process in light of any such executive order. Additionally, we would want to solicit comments from offices within the Office of the Secretary, to ensure departmental clearance, prior to forwarding it to your office.

Second, based on preliminary discussions with FDA, as well as the information contained in the attached "Fact Sheet On the Development of Cancer Drugs", it is our belief that FDA and the Department are currently doing everything possible to ensure early access to investigational new drugs by cancer patients and that FDA's system for expediting the review and approval of anticancer drugs is working well.

Third, because FDA's current drug review and approval procedures focus on <u>all</u> drugs for serious and life-threatening illnesses, FDA has not promulgated regulations specific to one disease. It is our belief that such attention to one specific disease could alienate patients and their families that have other serious and life-threatening diseases and conditions.

Also, in response to your second inquiry, the information contained in the previous memorandums on this subject is public information.

Please feel free to contact me if you need additonal information.

Attachment

FACT SHEET ON THE DEVELOPMENT OF CANCER DRUGS

The Department's National Cancer Institute (NCI) is the largest sponsor of research with anticancer agents.

The development of anticancer agents is a long and complex process. NCI's Developmental Therapeutics and Cancer Therapy Evaluation Programs have a comprehensive development path to take new drugs from discovery through product-approval-directed clinical trials. The process can be used by academic, government and industrial organizations.

Currently, the NCI has more than 175 agents in various phases of clinical testing and a significant number in preclinical development as well. The NCI funds an extensive clinical trials network which includes cooperative groups, new drug development contractors, and individual investigators at cancer centers and university hospitals. Altogether, this includes more than 8000 investigators at approximately 1400 institutions.

The Food and Drug Administration (FDA) has a variety of mechanisms for ensuring early access to investigational new drugs by cancer patients.

FDA works with manufacturers to make promising investigational drugs for serious and life-threatening diseases, such as cancer, more widely available while the applications are being reviewed. FDA encourages expanded access through a number of mechanisms.

> One method is the "open-label" protocol, in which a manufacturer openly provides the medication to patients in a drug trial, without blinding its identity. Individual physicians also can conduct open label trials with one or more patients, provided that they can obtain the drug from the manufacturer. Generally, controlled clinical trials are already underway if this method is available.
>
> Another method is for a patient's physician to request an emergency investigational new drug application from FDA. Individual physicians can make the request if they have received permission from the drug company, if the patient's condition is life-threatening, and if the physician submits the necessary documentation after receiving the drug. As the name of the method implies, this mechanism is used in emergencies.
>
> Under a "single patient" investigational new drug application, FDA has permitted manufacturers to provide investigational drugs to doctors for use in individual patients who do not qualify for investigational trial enrollment but might be helped by the treatment.

The Treatment Investigational New Drug program allows promising investigational new drugs to be made available under special conditions prior to marketing approval. Since this program began, patients have had early access to eleven new cancer drugs under this program.

FDA expedites the review and approval of anticancer drugs.

- **Anticancer drugs, except for those that appear to be therapeutically similar to already marketed drugs, are considered a "priority" and are regularly reviewed faster than "standard" drugs.**

  Under the Prescription Drug User Fee Act, FDA is currently reviewing and acting on cancer drug applications within a year or less of submission. As of FY 1997, these priority drugs will have Prescription Drug User Fee Act goal action times of 6 months.

  "Priority" review is given to those anticancer drugs that appear to represent a therapeutic advance by

  (1) providing effective treatment or diagnosis for a disease not adequately treated or diagnosed by any marketed drug;

  (2) providing improved treatment through greater effectiveness or safety; or

  (3) have a modest, but real, advantage over available marketed drugs (e.g., greater patient convenience; elimination of annoying adverse reactions; useful in a specific subpopulation of patients with the disease (for example, children or the elderly); etc.

- **FDA has special procedures ("Subpart E") designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely debilitating illnesses, such as cancer, especially where no satisfactory alternative therapy exists.**

  Subpart E of 21 CFR 312 describes FDA's special procedures through which FDA exercises the broadest flexibility in applying the statutory standards, while preserving appropriate guarantees for safety and effectiveness. These procedures reflect recognition that (1) physicians and patients are generally willing to accept greater risks or side effects from products that treat life-threatening and severely-debilitating

illnesses, than they would accept from products that treat less serious illnesses; and (2) the benefits of the drug need to be evaluated in light of the severity of disease being treated.

- **Anticancer drugs may receive "accelerated approval" under FDA's regulations.**

FDA's "accelerated approval" program permits accelerated approval of drugs that promise significant benefit over existing therapy for serious or life-threatening illnesses such as cancer. This program incorporates several novel elements aimed at making sure that rapid review and approval of drugs is balanced by safeguards to protect both the public health and the integrity of the regulatory process.

Accelerated review can be used in two special circumstances: when approval is based on evidence of effectiveness on a "surrogate endpoint," an early indication that a drug is likely to have clinical benefit, and when FDA determines that safe use of a product depends on restricting its distribution or use. As a condition of approval, FDA can require the manufacturer to carry out post marketing studies to confirm that the drug does in fact provide a clinical benefit.

Two anticancer drugs have been reviewed under this program. Zinecard, was approved during this Administration and another, Doxil, is currently undergoing accelerated review.

FDA's system for expediting the review and approval of anticancer drugs is working well.

Since January 1992, FDA has received a total of 22 new drug applications/supplements for drugs to treat cancer: 5 in 1992, 5 in 1993, 9 in 1994, and 3 so far this year. Of these, 5 were approved, 3 received "approvable" letters, 5 received not approvable letters, and 9 are pending action. Of the 13 actions to date, 12 were within the required timetable. Of the 9 still pending, none is overdue, and action is expected soon on some of these.

Since January 1993, 6 new cancer drugs were approved and 4 merited "approvable letters." (An approvable letter tells a company that a drug is ready for approval as soon as a few final labeling details are worked out.) In addition, 3 drugs that were previously approved for cancer received approval for another

cancer indication through "supplemental" applications, e.g., tamoxifen was originally approved for female breast cancer and had a supplement approved for male breast cancer. There were also 5 applications approved for drugs to treat cancer-related illnesses such as anemia associated with cancer chemotherapy.

The attached charts show the 19 applications or supplemental applications for cancer or cancer-related illnesses that have been approved or that have received approvable letters since January 1993. They include applications submitted both prior to, and after, the enactment of the Prescription Drug User Fee Act.

In conclusion, FDA recognizes that drugs for serious and life-threatening illness, including cancer, require expedited review and approval.

FDA's expedited review and approval procedures focus on drugs for serious and life-threatening illness. The agency has not promulgated regulations specific to one disease, in recognition that this could alienate families of individuals, and individuals, with other serious and life-threatening diseases and conditions.

Attachments

Prepared by: FDA 9/6/95

NEW DRUG APPLICATIONS (NDAs) APPROVED FOR CANCER

Product	Date of NDA Submission	Date of NDA Approval***	Indication
Leustatin (cladribine)	12/31/91	02/26/93	Treatment of hairy cell leukemia.
Metastron (strontium chloride, SR-89)	10/02/92	06/18/93	Palliation of pain from bone metastases.
Navelbine (vinorelbine tartrate)	08/27/93	12/23/94	Single agent or in combination for the treatment of unresectable/advanced non-small cell lung cancer.
Oncaspar* (pegaspargase)	01/15/91	02/01/94	Treatment of patients with acute lymphoblastic leukemia who are hypersensitive to native asparaginase.
Octreoscan (indium IN-111 pentetreotide kit)	10/23/92	06/02/94	A scintigraphic agent for the detection and localization of primary or metastatic neuroendocrine tumors.
Thioplex (thiotepa)	02/14/90	12/22/94	Anti-neoplastic.
Daunoxome (liposomal daunorubicin)	01/06/95	Approvable Letter Issued on 07/10/95**	Treatment of advanced HIV-related Kaposi's sarcoma in patients who have failed conventional chemotherapy.
Photofrin (porfimer sodium)	04/13/94	Approvable Letter Issued on 07/10/95**	Reduction of obstruction and palliation of dysphagia in patients with completely or partially obstructing esophageal cancer.
Vesanoid (tretinoin)	07/28/94	Approvable Letter Issued on 07/27/95**	Induction of remission in acute promyelocytic leukemia.
Doxil (liposomal doxorubicin)	09/07/94	Approvable Letter to Issue on 09/07/95**	Kaposi's sarcoma after chemotherapy failure.

*Biologic

**Final details such as labeling and manufacturing and control issues have not been worked out.

***The date of approval includes time required by applicant to adequately respond to agency's requests for information.

(Prepared by Terry Martin:09/01/95)

NEW DRUG APPLICATIONS (NDAs) APPROVED FOR CANCER-RELATED ILLNESSES

Product	Date of NDA Submission	Date of NDA Approval	Indication
Kytril Injection (granisetron hydrochloride)	12/17/91	12/29/93	Prevention of nausea and vomiting associated with initial and repeat courses of Metogenic cancer therapy.
Epogen* (epotin alfa)	07/22/91	04/01/93	Anemia associated with cancer chemotherapy.
Zofran (ondansetron HcL dihyrate)	10/01/93	01/31/95	Prevention of nausea and vomiting associated with cancer chemotherapy and for the prevention of postoperative nausea and vomiting.
Kytril Tablets (granisetron hydrochloride)	12/17/92	03/16/95	Prevention of nausea and vomiting associated with initial and repeat courses of Metogenic cancer therapy.
Zinecard (dexrazoxane)	08/05/94	05/26/95	Prevention of cardiomyopathy associated with doxorubicin administration.

*Biologic

(Prepared by Terry Martin:08/18/95)

SUPPLEMENTS APPROVED FOR CANCER

Product	Date Supplement Submitted	Date Supplement Approved	Indication
Nolvadex (tamoxifen citrate)	05/26/92	04/01/93	Treatment of male breast cancer.
Nipent (pentostatin)	11/12/92	09/29/93	Treatment of hairy cell leukemia.
Taxol (paclitaxel)	07/02/93	04/13/94	Treatment of breast cancer.
Zoladex	08/31/94	Approvable Letter Issued on 08/31/95	Treatment of breast cancer.

(Prepared by Terry Martin:09/01/95)

NEW DRUG APPLICATIONS (NDAs) APPROVED FOR CANCER

Product	Date of NDA Submission	Date of NDA Approval	Indication
Leustatin (cladribine)	12/31/91	**02/26/93**	Treatment of hairy cell leukemia.
Navelbine (vinorelbine tartrate)	08/23/93	**12/23/94**	Single agent or in combination for the treatment of unresectable/advanced non-small cell lung cancer.
Oncaspar* (pegaspargase)	01/15/91	**02/01/94**	Treatment of patients with acute lymphoblastic leukemia who are hypersensitive to native asparaginase.
Zinecard (dexrazoxane)	12/12/94	**05/26/95**	Prevention of cardiomyopathy associated with doxorubicin administration.
Daunoxome (liposomal daunorubicin)	01/06/95	**Approvable Letter Issued on 07/10/95****	Treatment of advanced HIV-related Kaposi's sarcoma in patients who have failed conventional chemotherapy.
Photofrin (porfimer sodium)	04/13/94	**Approvable Letter Issued on 07/13/95****	Reduction of obstruction and palliation of dysphagia in patients with completely or partially obstructing esophageal cancer.

Biologic

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Zofran (ondansetron [illegible] dihyrate)	10/01/93	01/31/95	Prevention of nausea and vomiting associated with cancer chemotherapy and for the prevention of postoperative nausea and vomiting.
Kytril Tablets (granisetron hydrochloride)	12/17/92	03/16/95	Prevention of nausea and vomiting associated with initial and repeat courses of Metogenic cancer therapy.

*Biologic

THE WHITE HOUSE

WASHINGTON

AUGUST 24, 1995

MEMORANDUM FOR HAROLD ICKES

FROM: **LEEANN INADOMI**

SUBJECT: **CANCER DRUGS**

Per your request, attached is additional information from HHS/FDA on cancer drugs approved in Western European countries between January 1993 - January 1995. Please let me know if you have any additional questions.

Thank you.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

August 24, 1995

MEMORANDUM FOR LEEANN INADOMI

Attached is the information on European approvals of anticancer drugs since 1993 from FDA's data base. They have sent us two charts:

- The first is taken from a set of "approval" dates submitted by regulatory authorities in the UK and Germany.
- The second table identifies three anticancer drugs first marketed in the world and in western Europe in 1995. No information is given on dates of approval.

The combined tables show 11 drugs approved or marketed between January 1993 and 1995. Of these 11, three are for cancer related indications. Germany and the UK have drug regulatory systems somewhat comparable to that in the US and have data available. FDA could not obtain information from other western European countries.

Of note is that 6 of the 11 drugs were first marketed in the United States. To summarize for comparison with U.S. data from the paper we sent to you on Tuesday, between January 1993 and 1995, 4 new anticancer drugs were approved, 2 merited "approval letters" and 4 new drugs were approved to treat cancer related conditions for a total of 10 new drugs.

Mary Beth Donahue

New Cancer drugs approved in UK and Germany January 1993 - April 1995

NEW CANCER DRUG NAME	1ST MKT	1st MKT YEAR WORLDWIDE	USA APP DATE	UK APP DATE	GER APP DATE	TREATMENT
FLUDARABINE	USA	91	04/18/91	11/21/94		Cancer
LENOGRASTIM (G-CSF)	JPN	91		11/29/93	Oct-93	Related
SARGRAMOSTIM (GM-CSF)	USA	91	03/05/91	09/27/93		Related
PENTOSTATIN	USA	92	10/11/91	01/25/93	Jun-93	Cancer
CLADRIBINE	USA	93	02/26/93	10/13/94		Cancer
FORMESTANE	GBR	93		1993	May-94	Cancer
PACLITAXEL (TAXOL)	USA	93	12/29/92	11/18/93	Nov-93	Cancer
PEGASPARGASE	USA	94	02/01/94		Nov-94	Cancer

Based on Drugs new to the world market 1990-94

Cancer drugs new to the world market in 1995

NEW CANCER DRUG NAME	1ST CTY	MKT YR	INDICATION
AMIFOSTINE (ETHYOL)	GER	95	CHEMOTHERAPY PROTECTANT
17-1A MAB (PANOREX)	GER	95	COLORECTAL CANCER
BICALUTAMIDE	UK	95	PROSTATE CANCER

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THE WHITE HOUSE

WASHINGTON

AUGUST 22, 1995

MEMORANDUM FOR HAROLD ICKES

FROM: **LEEANN INADOMI**

SUBJECT: **CANCER DRUGS**

Attached is a copy of a memorandum prepared by HHS in response to questions the President raised relating to the approval of new cancer drugs.

Please let me know if you have any additional questions.

8/23 - Lee - Can HHS provide us with the number of similar drugs that were approved by ~~Eu~~ Western European countries in the same time period -

cc: Jennifer O'Connor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

August 22, 1995

MEMORANDUM TO HAROLD ICKES

FROM: Kevin Thurm KT MD

SUBJECT: Cancer Drugs

This is in response to your inquiry about the number of cancer drugs that FDA has approved since January 1993. The President read a newspaper account that stated there had been only two and expressed concern.

I am pleased to report that that number is incorrect. FDA has provided the attached charts showing the cancer drugs approved since January 1993. There have been four new cancer drugs approved and two that merited "approvable letters" last month. (An approvable letter tells a company that a drug is ready for approval as soon as a few final labeling details are worked out.) In addition, three drugs that were previously approved for cancer received approval for another cancer indication through "supplemental" applications, e.g., tamoxifen was originally approved for female breast cancer and had a supplement approved for male breast cancer. There were also four applications approved for drugs to treat cancer-related illnesses such as anemia associated with cancer chemotherapy.

Under the Prescription Drug User Fee Act, FDA is currently reviewing and acting on cancer drug applications within a year or less of submission. FDA has received a total of 22 new drug applications/supplements for drugs to treat cancer since January 1, 1992--5 in 1992, 5 in 1993, 9 in 1994, and 3 so far this year. Of these, 5 were approved, 3 received approvable letters, 5 received not approvable letters, and 9 are pending action. Of the 13 actions to date, 12 were within the required timetable. Of the 9 still pending, none is overdue, and action is expected soon on some of these.

Two of the drugs have been reviewed under the accelerated approval program for speeding the approval of drugs that promise significant benefit over existing therapy for serious or life-threatening illnesses. This program incorporates several novel elements aimed at making sure that rapid review and approval of drugs is balanced by safeguards to protect both the public health

and the integrity of the regulatory process. Accelerated review can be used in two special circumstances: when approval is based on evidence of effectiveness on a "surrogate endpoint," an early indication that a drug is likely to have clinical benefit, and when FDA determines that safe use of a product depends on restricting its distribution or use. As a condition of approval, FDA can require the manufacturer to carry out post marketing studies to confirm that the drug does in fact provide a clinical benefit. The only cancer drug to be approved via the accelerated approval mechanism, Zinecard, was approved during this Administration and another, Doxil, is currently undergoing accelerated review.

FDA also works with manufacturers to make promising investigational drugs for serious and life-threatening diseases such as cancer more widely available while the applications are being reviewed. FDA reviewers are always aware of the development of potentially important new drugs and when sufficient evidence of effectiveness and safety become available, FDA encourages expanded access through a number of mechanisms. Under "compassionate use," FDA has permitted manufacturers to provide investigational drugs to doctors for use in individual patients who do not qualify for investigational trial enrollment but might be helped by the treatment. The Treatment Investigational New Drug program allows promising investigational new drugs to be made available under special conditions prior to marketing approval. Patients have had early access to eleven cancer drugs under this program.

The development of anticancer agents is a long and complex process. A very important component of cancer drug development in this country is this Department's National Cancer Institute (NCI). The Developmental Therapeutics and Cancer Therapy Evaluation Programs of the NCI have a comprehensive development path to take new drugs from discovery through product-approval-directed clinical trials. The process can be used by academic, government and industrial organizations. NCI remains the largest sponsor of research with anticancer agents. Currently the NCI has more than 175 agents in various phases of clinical testing and a significant number in preclinical development as well. The NCI funds an extensive clinical trials network which includes cooperative groups, new drugs development contractors, and individual investigators at cancer centers and university hospitals. Altogether, this includes more than 8000 investigators at approximately 1400 institutions.

I hope this information is useful. Please let me know if you have any further questions.

Attachments

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*Biologic

THE WHITE HOUSE

WASHINGTON

AUGUST 22, 1995

MEMORANDUM FOR HAROLD ICKES

FROM: **LEEANN INADOMI**

SUBJECT: **CANCER DRUGS**

Attached is a copy of a memorandum prepared by HHS in response to questions the President raised relating to the approval of new cancer drugs.

Please let me know if you have any additional questions.

8/23 - Lee - Can HHS provide us with the number of similar drugs that were approved by ~~E~~ Western European countries in the same time period -

cc: Jennifer O'Connor

8/26 -

John - Fay Kevin's underlying memo to Dick Flores w/ a cover memo from me -

Don't pay LeeAnn Inadomi's memo to Flores -

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

August 22, 1995

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I hope this information is useful. Please let me know if you have any further questions.

Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES
Chief of Staff
Washington D.C. 20201

FACSIMILE

DATE 8/22/95

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

LeeAnn Inadomi
Cabinet Affairs

456-7461

Jennifer —
Let me know if this isn't what you want.
I think it's fine.
Q.

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Kevin Thurm
Chief of Staff
DHHS

690-6133

RECIPIENT'S FAX NUMBER: ( ) 456-6704

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 6

COMMENTS:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

August 22, 1995

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Two of the drugs have been reviewed under the accelerated approval program for speeding the approval of drugs that promise significant benefit over existing therapy for serious or life-threatening illnesses. This program incorporates several novel elements aimed at making sure that rapid review and approval of drugs is balanced by safeguards to protect both the public health

and the integrity of the regulatory process. Accelerated review can be used in two special circumstances: when approval is based on evidence of effectiveness on a "surrogate endpoint," an early indication that a drug is likely to have clinical benefit, and when FDA determines that safe use of a product depends on restricting its distribution or use. As a condition of approval, FDA can require the manufacturer to carry out post marketing studies to confirm that the drug does in fact provide a clinical benefit. The only cancer drug to be approved via the accelerated approval mechanism, Zinecard, was approved during this Administration and another, Doxil, is currently undergoing accelerated review.

FDA also works with manufacturers to make promising investigational drugs for serious and life-threatening diseases such as cancer more widely available while the applications are being reviewed. FDA reviewers are always aware of the development of potentially important new drugs and when sufficient evidence of effectiveness and safety become available, FDA encourages expanded access through a number of mechanisms. Under "compassionate use," FDA has permitted manufacturers to provide investigational drugs to doctors for use in individual patients who do not qualify for investigational trial enrollment but might be helped by the treatment. The Treatment Investigational New Drug program allows promising investigational new drugs to be made available under special conditions prior to marketing approval. Patients have had early access to eleven cancer drugs under this program.

The development of anticancer agents is a long and complex process. A very important component of cancer drug development in this country is this Department's National Cancer Institute (NCI). The Developmental Therapeutics and Cancer Therapy Evaluation Programs of the NCI have a comprehensive development path to take new drugs from discovery through product-approval-directed clinical trials. The process can be used by academic, government and industrial organizations. NCI remains the largest sponsor of research with anticancer agents. Currently the NCI has more than 175 agents in various phases of clinical testing and a significant number in preclinical development as well. The NCI funds an extensive clinical trials network which includes cooperative groups, new drugs development contractors, and individual investigators at cancer centers and university hospitals. Altogether, this includes more than 8000 investigators at approximately 1400 institutions.

I hope this information is useful. Please let me know if you have any further questions.

Attachments

NEW DRUG APPLICATIONS (NDAs) APPROVED FOR CANCER

Product	Date of NDA Submission	Date of NDA Approval	Indication
Leustatin (cladribine)	12/31/91	**02/26/93**	Treatment of hairy cell leukemia.
Navelbine (vinorelbine tartrate)	08/23/93	**12/23/94**	Single agent or in combination for the treatment of unresectable/advanced non-small cell lung cancer.
Oncaspar* (pegaspargase)	01/15/91	**02/01/94**	Treatment of patients with acute lymphoblastic leukemia who are hypersensitive to native asparaginase.
Zinecard (dexrazoxane)	12/12/94	**05/26/95**	Prevention of cardiomyopathy associated with doxorubicin administration.
Daunoxome (liposomal daunorubicin)	01/06/95	**Approvable Letter Issued on 07/10/95****	Treatment of advanced HIV-related Kaposi's sarcoma in patients who have failed conventional chemotherapy.
Photofrin (porfimer sodium)	04/13/94	**Approvable Letter Issued on 07/13/95****	Reduction of obstruction and palliation of dysphagia in patients with completely or partially obstructing esophageal cancer.

*Biologic

**Final details such as labeling have not been worked out.

SUPPLEMENTS APPROVED FOR CANCER

Product	Date Supplement Submitted	Date Supplement Approved	Indication
Nolvadex (tamoxifen citrate)	05/26/92	04/01/93	Treatment of male breast cancer.
Nipent (pentostatin)	11/11/92	09/29/93	Treatment of hairy cell leukemia.
Taxol (paclitaxel)	07/01/93	04/13/94	Treatment of breast cancer.

NEW DRUG APPLICATIONS (NDAs) APPROVED FOR CANCER-RELATED ILLNESSES

Product	Date of NDA Submission	Date of NDA Approval	Indication
Kytril Injection (granisetron hydrochloride)	12/17/91	**12/19/95**	Prevention of nausea and vomiting associated with initial and repeat courses of Metogenic cancer therapy.
Epogen* (epotin alfa)	07/22/91	**04/01/93**	Anemia associated with cancer chemotherapy.
Zofran (ondansetron HcL dihyrate)	10/01/93	**01/31/95**	Prevention of nausea and vomiting associated with cancer chemotherapy and for the prevention of postoperative nausea and vomiting.
Kytril Tablets (granisetron hydrochloride)	12/17/92	**03/16/95**	Prevention of nausea and vomiting associated with initial and repeat courses of Metogenic cancer therapy.

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THE WHITE HOUSE

WASHINGTON

AUGUST 22, 1995

MEMORANDUM FOR HAROLD ICKES

FROM: **LEEANN INADOMI**

SUBJECT: **CANCER DRUGS**

Attached is a copy of a memorandum prepared by HHS in response to questions the President raised relating to the approval of new cancer drugs.

Please let me know if you have any additional questions.

cc: Jennifer O'Connor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

August 22, 1995

MEMORANDUM TO HAROLD ICKES

FROM: Kevin Thurm KT MD

SUBJECT: Cancer Drugs

This is in response to your inquiry about the number of cancer drugs that FDA has approved since January 1993. The President read a newspaper account that stated there had been only two and expressed concern.

I am pleased to report that that number is incorrect. FDA has provided the attached charts showing the cancer drugs approved since January 1993. There have been four new cancer drugs approved and two that merited "approvable letters" last month. (An approvable letter tells a company that a drug is ready for approval as soon as a few final labeling details are worked out.) In addition, three drugs that were previously approved for cancer received approval for another cancer indication through "supplemental" applications, e.g., tamoxifen was originally approved for female breast cancer and had a supplement approved for male breast cancer. There were also four applications approved for drugs to treat cancer-related illnesses such as anemia associated with cancer chemotherapy.

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