FDA U.S. FOOD & DRUG ADMINISTRATION
CDER Office of Compliance
Office of Manufacturing Quality

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

DATE: July 22, 2026

FROM: Nelson Rivera, Acting Supervisor
Group 3
Division of Drug Quality I (DDQI)
Office of Manufacturing Quality (OMQ)
Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER)

TO: CMS File – Work Activity **738133**
Jiangsu Hengrui Pharmaceuticals Co., Ltd. FEI # 3006689263

Cc: Carmelo Rosa, Director
CDER/OC/OMQ/DDQI

SUBJECT: Classification of Surveillance Inspection: VAI as Inspection Classification

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FDA inspected the drug manufacturing facility, Jiangsu Hengrui Pharmaceuticals Co., Ltd., FEI 3006689263, located at No. 22 Jinqiao Road, Dapu Industrial Park, Economic and Technological Development Zone, Lianyungang, Jiangsu, China, from April 7 to April 15, 2026. This facility manufactures sterile finished drug products and sterile active pharmaceutical ingredients (API).

The inspection type was a surveillance inspection to determine the firm's adherence to current good manufacturing practice (CGMP).

OMQ received the Establishment Inspection Report (EIR) on May 29, 2026 with an initial recommendation of potential official action indicated (pOAI) from the Office of Inspections and Investigations (OII) and assigned it to Erika V. Butler, Compliance Officer, on June 8, 2026.

OMQ held a pre-enforcement meeting on July 9, 2026. Attendees included: Erika Butler, Consumer Safety Officer; Nelson Rivera, Acting Supervisor;; Nick Lyons, Supervisor; Rick Friedman, Deputy Director of Manufacturing Quality; and Carmelo Rosa, Director of Division of Drug Quality I.

OMQ considered the possibility of drug shortages for medically necessary drugs. We consulted with CDER's Drug Shortages Staff (DSS) and DSS noted shortage concerns with the following drug product: (b) (4) Injection (b) (4)

Based on our review of the findings from the inspection, including the firm's responses, and a written commitment of proposed corrective actions, OMQ determined that the inspection classification is voluntary action indicated (VAI).

The firm provided written correspondence on July 11, 2026, which included:

- A commitment to conduct a comprehensive contamination hazards risk assessment by a qualified independent third-party.
- A commitment to establish a systematic plan to vigilantly assure adherence to appropriate aseptic practices, cleanroom behaviors, and written procedures.
- A commitment to conduct an independent third-party observation of the firm's aseptic operations followed by an independent third party audit a year later, after assessing the effectiveness of implemented CAPAs.

A regulatory meeting will be requested with the firm to provide additional information on the status and progress of their proposed commitments.

OMQ has removed the pOAI facility alert in the platform (Panorama) and has informed the Office of Quality Surveillance (OQS) and OII that we consider the facility acceptable for CGMP.

Documents related to this matter have been uploaded in CMS. If you have any questions regarding this letter, you may contact Erika V. Butler via email at Erika.butler@fda.hhs.gov.

Sincerely,

Nelson E. Rivera -S

Digitally signed by Nelson E. Rivera -S
Date: 2026.07.22 15:34:17 -04'00'

Nelson Rivera
Acting Supervisor
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