DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	3/31/2025-4/4/2025
	FEI NUMBER 3011603969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lu Yun, Vice President

FIRM NAME	STREET ADDRESS
Jiangsu Hengrui Pharmaceuticals Co., Ltd.	567-3 Huaguoshan Avenue, 3rd Floor, Economic and Technological Development Zone
CITY, STATE, ZIP CODE, COUNTRY Lianyungang, Jiangsu, 222069 China	TYPE ESTABLISHMENT INSPECTED Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Written procedures are not established for evaluations done at least annually and including provisions for a review of investigations conducted for each drug product.

Specifically,

Your firm's annual product review is not sufficient in trending to decrease Visible Particulates in Sterile (b) (4) Injection.

Your firm released the following batches of Sterile (b) (4) njection to the Unites States:

Product
Sterile (b) (4) Injection, USP, (b) (4) mg Batch #: (b) (4) Manufacture Date (b) (4) Expiration Date: (b) (4)
Sterile (b) (4) Injection, USP, (b) Batch #: (b) (4) Manufacture Date: (b) (4) Expiration Date: (b) (4)

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sara H Gabel, Investigator	Sara H Gabel Investigator Signed By: 2003025353 Date Signed: 04-04-2025 14:36:13	4/4/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	3/31/2025-4/4/2025
	FEI NUMBER 3011603969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Lu Yun, Vice President

FIRM NAME	STREET ADDRESS
Jiangsu Hengrui Pharmaceuticals Co., Ltd.	567-3 Huaguoshan Avenue, 3rd Floor, Economic and Technological Development Zone
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lianyungang, Jiangsu, 222069 China	Laboratory

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sara H Gabel, Investigator	Sara H Gabel Investigator Signed By: 2003025353 Date Signed: 04-04-2025 14:36:13	4/4/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."