DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
ORA OPQO HQ, Room 2032 12420 Parklawn Drive Rockville, Maryland 20857 ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	04/09/2018 to 04/13/2018
	FEI NUMBER 3006689263

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Sumei Jiang, Executive Vice President

FIRM NAME	STREET ADDRESS
Jiangsu Hengrui Medicine Co., LTD.	No. 22 Jinqiao Road, Dapu Industrial Park
CITY, STATE AND ZIP CODE Lianyugang, Jiangsu, China 222002	TYPE OF ESTABLISHMENT INSPECTED API and Sterile Drug Manufacturer

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) (WE) OBSERVED:

MATERIAL SYSTEM

OBSERVATION 1

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm has not performed an assessment to evaluate your practice of (b) (4) samples for raw material release testing to ensure the (b) (4) sample is representative of the lot received and capable of detecting variations in attributes being tested. For example, procedure QC-007, Sampling Procedure for Raw Materials, Excipients and Packaging Materials, Revision T, Effective Date: 2018.03.27, allows for up to (b) (4) samples collected from (b) (4) for testing.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 2

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically, there is a lack of assurance that electronic data generated in Workshop (b) (4) is protected from deletion and retained. For example, access is not restricted for the online environmental data (e.g., non-viable, viable,

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		Qin Xu, Investigator Jonathan W. Chapman, Investigator	04/13/2018

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temperature, humidity, differential pressure) collected in Workshop (b) (4) by the Particle Measuring System (PMS) and Enterprise Building Integrator (EBI) system. On 04/09/2018, I witnessed a control room operator access the original electronic data for both systems stored on the C:Drive and observed the operator had deletion privileges.

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