DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4225, Silver Spring, MD 20993-0002 Phone: (301) 796-3334. Fax: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	03/26/2018 to 04/03/2018
	FEI NUMBER 3010625707

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Yongqun (Eric) Tang, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd.	28 Xuefu Road, Nanjing High and New Technology Development Zone
CITY, STATE, ZIP CODE, COUNTRY Nanjing, Jiang-Su Province, China 210061	TYPE ESTABLISHMENT INSPECTED 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, WE OBSERVED:

Production System

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

Specifically, the procedure to requalify the cleanrooms and (b) (4) periods of (b) (4) is inadequate.

a. The firm routinely (b) (4) operations including the air supply to the cleanrooms and (b) (4) For example, there was a (b) (4) between (b) (4) to (b) (4) and a (b) (4) between (b) (4) to (b) (4) to (b) (4) . However, there is no defined procedure to requalify the HEPA filters (b) (4) a (b) (4) period.

b. Cleaning activities defined for (b) (4) periods are not supported by any data. For example, according to SOP SMP-PR-1010, version 01, effective date 24 March 2015 titled "Clean area and (b) (4) back again (b) (4) the air conditioning system outage management discipline", if the HVAC system is (b) (4) or (b) (4) to (b) (4) no additional cleaning is required as long as the differential pressure between the rooms is restored and environmental monitoring is in place in the production area. For (b) (4) periods between (b) (4) to (b) (4) or greater than (b) (4) , the required cleaning activities are not clearly specified or supported by data.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Darren Brown, Investigator Rose Xu, Reviewer Djamila Harouaka, Investigator	DATE ISSUED 04/03/2018

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OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

a. Your firm failed to incubate environmental monitoring plates at 20-25 °C between July 2015 and March 2018. This includes environmental monitoring plates from media fills including lot (b) (4) manufactured on 20 May 2016 and lot (b) (4) manufactured on 26 January 2018.

b. Your firm did not establish appropriate microbial limits for active air sampling, and passive air sampling in the Grade C areas used for drug product manufacturing including (b) (4) injection.

c. Your firm did not establish appropriate specifications for the leak testing performed for the HEPA filter in the (b) (4) (b) (4) Your current acceptance criterion for leak testing of these HEPA filters is set at (b) (4) %.

d. Your firm does not have a scientific rationale to support the selection and identification of (b) (4) colony from environmental monitoring plates containing large numbers of colonies.

OBSERVATION 3

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, your firm failed to establish a sampling plan for the validation of the production of (b) (4) (b) (4) injection at the commercial scale.

Materials System

OBSERVATION 4

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Certificates of testing of containers and closures are accepted in lieu of testing without establishing the reliability of the supplier's test results through appropriate validation of test results at appropriate intervals.

Specifically, your firm failed to perform testing as part of your supplier qualification for the microbial limits and endotoxin levels for glass vials (material no. 303010) used to package (b) (4) injection. Your firm also failed to perform testing as part of your supplier qualification for microbial limits for (b) (4) stoppers (material no. 304003) used to package (b) (4) injection.

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