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, MD 20857 e-mail your response to: ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	04/8/2019 - 4/16/2019
	FEI NUMBER 3010606982

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Zhisheng Chen, CEO

FIRM NAME	STREET ADDRESS
Wuxi Biologics Co Ltd	108 Meiliang Road, Binhu District
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Wuxi, Jiangsu, P.R.C. 214092	Biotech API and sterile finished dose manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Quality system:

1. The responsibilities and procedures applicable to the quality control unit for material suppliers are not fully followed. Specifically,

(a) Section 4.3.12.2.C of SOP WX-SOP-00451-14 "GMP Material Supplier Management" states that, if the results of material supplier performance assessment is (b) (4) ≤Score<(b) (4) then the supplier is considered "Partially satisfactory, no supply until corrective actions in place". Material Supplier Performance Assessment Forms show that the following suppliers received a score between (b) (4) ≤Score<(b) (4) for the indicated assessment timeframes:

- (b) (4) 01/01/2017 – 12/31/2017 (Assessment Report signed off by QA unit on 03/30/2018); and 01/01/2018 – 12/31/2018 (Assessment Report signed off by QA unit on 03/29/2019)

- (b) (4) : 01/01/2018 – 12/31/2018 (Assessment Report signed off by QA unit on 03/29/2019)

Your firm continued to receive lots from the aforementioned vendors in the absence of formal closure of the corrective actions. You have filed at least 7 complaints associated with leaking disposable bags, including (b) (4) bags, at least one used in the production of (b) (4) drug substance, with (b) (4) in 2017 and 2018. (b) (4) is identified as a critical supplier. As of the date of this inspection, you have not identified a corrective action and you do not have a written risk assessment or written risk mitigation strategy for the continued use of this supplier.

Add Continuation Page

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		Christopher T. Middendorf, Investigator Mekonnen Lemma Dechassa, Investigator Ramesh Potla, Investigator	04/16/2019

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Obs 1 continued
(b) The Material Supplier Complaint Sheet QA-RMM-001-D-08 requires that QA perform an effectiveness confirmation (b) (4) after closure of the complaint. The QA unit failed to meet the requirement for the following:

• Complaint EFS-18-020 was closed on 07/26/2018, and the effectiveness check was performed by QA 8 months later on 04/02/2019.

• Complaint EFS-18-021 was closed on 07/26/2018, and the effectiveness check was performed by QA 8 months later on 04/12/2019.

• Complaint EFS-18-023 was closed on 07/26/2018, and the effectiveness check was performed by QA 8 months later on 04/12/2019.

• Complaint EFS-18-002 was closed on 08/06/2018, and the effectiveness check was performed by QA 8 months later on 04/12/2019.

2. Corrective actions are not taken when data from critical quality attributes indicate a trend towards out of specification.

Specifically, the (b) (4) release data show a consistent decrease in the osmolality attribute for (b) (4) finished drug product lots manufactured between 2015 and 2019. The osmolality data for the most recent drug product lots are towards the lower end of release specification. You have not opened an investigation of the trend data to identify the root cause for the decrease in osmolality and you have not identified any corrective or preventative actions to reduce the possibility for potential out-of-specifications (OOS) for osmolality attribute in future batches.

Add Continuation Page

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Laboratory system:

3. The amount of samples sufficient to perform all tests, except for endotoxin and sterility, in duplicate, are not retained.

Specifically, for each lot of (b) (4) commercial drug product, your firm failed to retain sufficient reserve samples consisting of at least twice the quantity necessary for all the tests required to determine whether the active ingredient meets its established specifications, except for sterility and pyrogen testing. Your firm currently retains (b) (4) vials from each (b) (4) drug product lot whereas at least (b) (4) vials are required to perform all tests, except for endotoxin and sterility, in duplicate.

4. All information to ensure method accuracy, reproducibility, and reliability, is not included in analytical method evaluation to ensure validated QC analytical methods continue to operate in a state of control on a routine basis.

Specifically, during our inspection of QC labs on April 12, 2019, we observed there was a system suitability failure for CEX-HPLC analytical method while performing the release testing for (b) (4) DS lots (b) (4) and (b) (4) on December 06, 2018. The results were invalidated in the QC record WX-AMP-00038-08-I and the samples were re-analyzed, by CEX-HPLC method on December 08, 2018. QC management failed to record this system suitability failure as part of their evaluation of analytical method performance.

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