U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Xiamen Origin Biotech Co. Ltd. 7/19/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Warning Letter 320-16-22

Via UPS
Return Receipt Requested

July 19, 2016

Mr. Zhang Jian
Owner
Xiamen Origin Biotech Co., Ltd.
No. 7 Xiang Yue Road
Xiamen Torch, Xiamen
Fujian 361101
CHINA

Dear Mr. Zhang Jian:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facilities Xiamen Origin Biotech Co., Ltd. (Attix Xiamen Pharmaceutical Co., Ltd.) at Unit D504 Jian Ye Building, 96 Xiangxing Road and No. 7 Xiang Yue Road, Xiamen Torch, Xiamen, Fujian, from January 18-20, 2016.

This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We have not received a response from your firm for corrective actions to the deviations identified during the inspection. We acknowledge your June 14, 2016, correspondence regarding placement of your firm on Import Alert 66-40.

Our investigator observed specific deviations including, but not limited to, the following.

1. Failure to establish, document, and implement an effective system for managing quality.

Your firm had no written procedures for supplier qualification, relabeling operations, sampling, product release, document retention, or training. Your firm was unable to provide our investigator records for relabeling operations from before September 2014.

2. Failure to transfer all quality or regulatory information received from the API manufacturer to your customers.

You repeatedly falsified and omitted information on the certificates of analysis (CoA) you issued to your customers. For example, your firm fabricated the name of an employee, and you used that name as the false signatory authority on the CoA you sent to your customers. You also omitted the name and address of the original API manufacturer and did not include a copy of the original batch certificate. Finally, you included an "expiration date" on your CoA that exceeded the manufacturer's labeled expiration date, but you had no basis for the extended retest/expiry period.

Regulators and customers rely on CoA to provide accurate information regarding drug quality and pedigree. Omitting and falsifying information on CoA compromises supply chain accountability and traceability and may put consumers at risk.

3. Failure to keep buildings used in the manufacture of API in a clean condition.

During the inspection, the investigator recorded dirty warehousing spaces and observed a rodent in the room adjacent to the warehouse at your facility.

Access to information during inspection

During the inspection, your firm also made misleading or deceptive statements and delayed the investigator's access to accurate and truthful information. For example:

- During the inspection, an employee told the investigator that there were no drugs on site. The investigator observed a room adjacent to the conference room that was being used as a warehouse for relabeled drugs.
- The same employee told the investigator that your firm stopped relabeling drugs in January, 2015. However, during the inspection, the investigator reviewed an exported drugs list that showed that your firm distributed drugs after January 2015 and into January 2016.

When an owner, operator, or agent delays, denies, limits, or refuses an inspection, the drugs may be adulterated under section 501(j) of the FD&C Act.We recommend that you review FDA's guidance for industry *Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection* at: **http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM360484.pdf (http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM360484.pdf#_blank)**

Conclusion

Deviations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these deviations, for determining the causes, for preventing their recurrence, and for preventing other deviations in all your facilities.

After you receive this letter, you have 15 working days to respond to this office in writing. Specify what you have done since our inspection to correct your deviations and to prevent their recurrence.

Based upon the nature of the deviations we identified at your firm, we strongly recommend engaging a consultant qualified to evaluate your operations and assist your firm in meeting CGMP requirements. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.

If you cannot complete corrective actions within 15 working days, state your completion date and reasons for delay.

Because of the findings of the FDA inspection described in this letter, your firm's facilities were placed on Import Alert 66-40 on May 13, 2016.

Until you completely correct all deviations and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as an API manufacturer. Failure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at Xiamen Origin Biotech Co., Ltd. (Attix Xiamen Pharmaceutical Co., Ltd.) at Unit D504 Jian Ye Building, 96 Xiangxing Road and No. 7 Xiang Yue Road, Xiamen Torch, Xiamen, Fujian, into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

Send your reply to:

Lynnsey Renn, Ph.D.
Compliance Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4359
10903 New Hampshire Avenue
Silver Spring, MD 20993
USA

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov

Please identify your response with FEI 3010307355.

Sincerely,
/S/
Francis Godwin
Acting Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)