檔　　號：
保存年限：

正本

衛生福利部食品藥物管理署　函

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受文者：中華民國西藥代理商業同業公會

發文日期：中華民國106年5月31日
發文字號：FDA風字第1061103264號
速別：
密等及解密條件或保密期限：
附件：美國FDA Warning Letter 320-17-38影本1份

主旨：美國FDA發布中國原料藥廠「Changzhou Jintan Qianyao Pharmaceutical Raw Materials」（廠址：No. 678 Zhuangcheng, Baita Town,Jintan District, Changzhou City, China）Warning Letter乙案，詳如說明段，請轉知所屬會員知照。

說明：

一、美國衛生主管機關US Food and Drug Administration（FDA）查核旨揭原料藥廠，判定違反CGMP，於106年5月4日列為Import Alert 66-40藥廠，並於106年5月11日正式發布Warning Letter（詳如附件）。

二、鑑於旨揭原料藥之製造品質恐無法符合GMP之要求，可能導致對藥品製造品質帶來影響與危害，請轉知所屬會員釐清相關輸台製劑產品是否使用旨揭原料藥廠所生產原料藥，並應依風險管理原則辦理相關後續處置。

正本：中華民國西藥商業同業公會全國聯合會、中華民國西藥代理商業同業公會、台北市西藥代理商業同業公會、中華民國開發性製藥研究協會、中華民國藥品行銷暨管理協會

副本：

署長吳秀梅

Changzhou Jintan Qianyao Pharmaceutical Raw Materials 5/11/17

U.S. FOOD & DRUG ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS

Warning Letter 320-17-38

May 11, 2017

Mr. Zheng Goubin
General Manager
Changzhou Jintan Qianyao Pharmaceutical Raw Material Factory
No. 678 Zhuangcheng, Baita Town,
Jintan District, Changzhou City,
China 213200

Dear Mr. Goubin:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Changzhou Jintan Qianyao Pharmaceutical Raw Materials at No. 678 Zhuangcheng, Changzhou, Jintan, from February 13–17, 2017.

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 reviewed your March 2017 response in detail.

During our inspection, our investigator observed specific deviations including, but not limited to, the following.

1. Failure to implement a system for managing quality encompassing the organizational structure, procedures, processes and resources, as well as activities to ensure confidence that the API will meet its intended specifications for quality and purity. Failure to define and document all quality-related activities.

Before August 2016, your firm did not have any quality-related procedures in place even though you were manufacturing and shipping drugs to the United States. Although you had drafted some procedures by the time of our February 2017 inspection, you had not yet implemented any such procedures as of the date of our inspection.

2. Failure to have adequate written procedures for the receipt, identification, quarantine, storage, sampling, testing, handling, and approval or rejection of raw materials.

For example, when our investigator asked for a list of your critical raw materials and your sampling requirements, you told our investigator that you had no written procedures for testing and sampling incoming materials. Instead, you explained, your warehouse employees accounted for incoming raw material handling, sampling, and testing "in their heads."

3. Failure to have laboratory control records that include complete data derived from all laboratory tests conducted to ensure compliance with established specifications and standards.

For example, our investigator reviewed the audit trail from your assay testing for **(b)(4)** lot **(b)(4)**, and found that you tested the same sample set three times over several days without documentation or investigation. You reported only the result of the third and final test for purposes of completing your certificate of analysis and releasing this batch of API.

4. Failure to prepare adequate batch production records and record the activities at the time they are performed.

For example, our investigator found that your operator used process parameter values from previous batches of **(b)(4)** to complete new batch records when she was too tired to immediately record the data and had forgotten the values.

API CGMP Guidance
FDA considers the expectations outlined in ICH Q7 in determining whether API are manufactured in conformance with CGMP. See FDA's guidance document, *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients,* for guidance regarding CGMP for the manufacture of API, at **https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm200364.htm (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)**.

CGMP consultant recommended
Based upon the nature of the deviations we identified at your firm, we strongly recommend engaging a consultant qualified to evaluate your operations, and to 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.

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 your facility.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at **drugshortages@fda.hhs.gov (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)**, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug

manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

FDA placed your firm on Import Alert 66-40 on May 4, 2017.

Until you correct all deviations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug manufacturer.

Failure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at Changzhou Jintan Qianyao Pharmaceutical Raw Materials at No. 678 Zhuangcheng, Changzhou, Jintan 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).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your deviations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to **CDER-OC-OMQ-Communications@fda.hhs.gov (mailto:CDER-OC-OMQ-Communications@fda.hhs.gov)** or mail your reply to:

Chhaya Shetty
Compliance Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4355
10903 New Hampshire Avenue
Silver Spring, MD 20993
USA

Please identify your response with FEI 3005587213.

Sincerely,
/S/
Thomas J. Cosgrove, J.D.
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)