檔　　號：
保存年限：

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2月13日
發文字號：FDA風字第1061100879號
速別：普通件
密等及解密條件或保密期限：
附件：原料藥廠違反GMP警訊乙份(A21020000I106110087900-1.pdf)

主旨：美國FDA發布中國原料藥廠「Suzhou Pharmaceutical Technology Co., Ltd」（廠址：#3 Tongjing Commercial Plaza, Room 920 Jifeng Road, Suzhou, Jiangsu Province, 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，判定嚴重違反CGMP，並於106年1月6日正式發布Warning Letter（詳如附件）。

二、鑑於旨揭原料藥之製造品質無法符合GMP之要求，可能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：2017-02-14 08:52:02

Suzhou Pharmaceutical Technology Co.,Ltd 1/6/17

Department of Health and Human Services

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

Via UPS
Return Receipt Requested

Warning Letter 320-17-14

January 6, 2017

Mr. Michael Lu
Sales Manager
Suzhou Pharmaceutical Technology Co., Ltd
#3 Tongjing Commercial Plaza, Room 920
Jifeng Road
Suzhou, Jiangsu Province, 215007
China

Dear Mr. Lu:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Suzhou Pharmaceutical Technology Co., Ltd at #3 Tongjing Commercial Plaza, Room 920, Jifeng Road, Suzhou, from June 6 to 8, 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 reviewed your August 1, 2016, response in detail.

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

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

You omitted the name and address of the original API manufacturer on the certificates of analysis (CoA) you issued to your customers, and did not include copies of the original batch certificate.

For multiple API, you generated CoA by copying and pasting analytical results from the original API manufacturer, replacing the manufacturer's information with your letterhead, then issuing these CoA to your customers. You omitted critical information including the original manufacturers' names and addresses and the names, addresses, and telephone numbers of laboratories that performed the testing.

Customers and regulators rely on CoA for information about the quality and sourcing of drugs and their components. Omitting information from CoA compromises supply-chain accountability and traceability, and may put consumers at risk.

2. Failure to have a quality unit responsible for reviewing and approving all appropriate quality-related documents, including Certificates of Analysis.

Your firm has no Quality Unit. During the inspection, you provided no written documents describing the roles and responsibilities of a Quality Unit. You had no written procedures for quality activities.

Your salespeople signed your CoA under the title "QC Director." Without performing tests, your salespeople also signed under "Tested By." Your response states your salespeople will no longer sign under these headings on CoA. Your response is inadequate because you did not provide sufficient detail of your corrective actions, nor address the validity of CoA issued previously.

3. Failure to have facilities suitable for the storage of all materials under appropriate conditions.

During the inspection, your facility's room temperature was warm and humid, requiring you to open the windows in an attempt to lower the temperature. You had no temperature and humidity control system. Storage conditions are not documented for API that may be stored up to **(b)(4)** on site.

API stored on site included **(b)(4)**. United States Pharmacopeia (USP) monograph defined **(b)(4)** storage conditions as 25° centigrade with excursions permitted between 15° and 30° centigrade.

Repackaging, relabeling and holding of API must be performed under appropriate CGMP controls to avoid loss of API purity.

Shipping drugs from manufacturer on FDA Import Alert 66-40

One of your suppliers, **(b)(4)**, was on Import Alert 66-40 from March 2014 to July 2016. However, you shipped **(b)(4)** API manufactured by this firm in May 2015 to the United States, and declared that you were the manufacturer on importation documents.

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 assist your firm in meeting CGMP requirements. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.

Additional 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
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073497.p
(http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073497.

In response to this letter, provide the following:

- written procedures for the transfer of quality and regulatory information to your customers, including specific details of the information you will transfer
- a plan to establish, document, and implement an effective system for managing quality, including written procedures for CGMP related activities and the personnel responsible for oversight
- corrective actions for establishing and maintaining adequate storage conditions

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 deviations.

FDA placed your firm on Import Alert 66-40 on October 17, 2016.

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 Suzhou Pharmaceutical Technology Co., Ltd, at #3 Tongjing Commercial Plaza, Room 920, Jifeng Road, Suzhou 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:

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

Please identify your response with FEI 3010679196.

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

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