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：中華民國藥品行銷暨管理協會

發文日期：中華民國106年3月24日
發文字號：FDA風字第1061101869號
速別：
密等及解密條件或保密期限：
附件：美國FDA Warning Letter 320-17-27影本1份

主旨：美國FDA發布中國原料藥廠「Lumis Global Pharmaceuticals Co. Ltd.」（廠址：Unit 305 Huishang Mansion Building A2 Wudayuan Road Donghu New Technology Development ZoneWuhan, Hubei, 430073 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，並於106年3月2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

中華民國藥品行銷暨管理協會
收文日期:106年 3月27日
本文件保留:□1M,□3M,□6M
□1Y,□3Y,□5Y
□未定,□永久

□最急件
□急　件
☑普通件

Lumis Global Pharmaceuticals Co. Ltd. 3/2/17

U.S. FOOD & DRUG
ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS
Return Receipt Requested

Warning Letter 320-17-27

March 2, 2017

Ms. Jocelyn (Jun) Ning
Owner
Lumis Global Pharmaceuticals Co. Ltd.
Unit 305 Huishang Mansion Building A
2 Wudayuan Road Donghu New Technology Development Zone
Wuhan, Hubei, 430073
China

Dear Ms. Ning:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Lumis Global Pharmaceuticals Co. Ltd. at Unit 305 Huishang Mansion Building A, 2 Wudayuan Road Donghu New Technology Development Zone, Wuhan, from September 26 to 28, 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).

In addition, your gabapentin API is misbranded under sections 502(a) and 502(b)(1) of the FD&C Act, 21 U.S.C. 352(a) and 352(b)(1).
We reviewed your November 9, 2016, response in detail. We note your response addressed some FDA observations, but did not address the issues noted below.

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

CGMP Deviations

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 manufacturers 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 manufacturers, replacing the manufacturers' 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 control the API repackaging, relabeling, and holding operations in order to avoid mix ups and loss of API identity.

Our FDA investigator documented unlabeled material in your "released for shipping" area. You told the investigator that this material was not to be released to customers, but was in fact intended for destruction.

To avoid mix-ups between materials that can and cannot be released, or between different API, you must repackage, relabel, and hold API under appropriate CGMP controls.

3. Failure of your quality unit to exercise its responsibility to ensure the API relabeled at your facility are in compliance with CGMP.

Your relabeling operation was not documented adequately. You did not document the time and date of relabeling operations, nor the employee who conducted relabeling operations for API you distributed. You did not sign and date records at the same time the activites were performed.

Misbranding Violations

The gabapentin API labels bear the statement "Manufactured under cGMP conditions by: Lumis Global Pharmaceuticals Co., Ltd." This statement is misleading because it indicates that the manufacturer of the API is Lumis Global Pharmaceuticals Co., Ltd. instead of **(b)(4)**. Therefore, the gabapentin APIs is misbranded under section 502(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) in that the API labeling is misleading.

In addition, section 502(b)(1) of the FD&C Act requires a drug to contain the name and place of business of the manufacturer, packer, or distributor of the drug. The label of Lumis' API product is misbranded under section 502(b)(1) because it misidentifies Lumis, which is a distributor or packer, as the manufacturer. As evidenced by the certificates of analysis, **(b)(4)** is the manufacturer of the gabapentin API, not Lumis Global Pharmaceuticals Co. Ltd.

Shipping drugs from a manufacturer on FDA Import Alert 66-66

(b)(4), one of your suppliers, has been on Import Alert 66-66 since **(b)(4)**, specifically for their **(b)(4)** USP API. However, you shipped **(b)(4)** USP API manufactured by this firm to the United States in February 2015 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 obligation to comply with CGMP. Your firm's executive 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.

Your response

In response to this letter:

- Provide written procedures for transferring quality and regulatory information, including the information you send to your customers.
- Provide a plan to establish, document, and implement an effective system for managing quality. Include written procedures for CGMP-related activities and the roles of personnel responsible for oversight.

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.

FDA placed your firm on Import Alert 66-40 on February 15, 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 Lumis Global Pharmaceuticals Co. Ltd. at Unit 305 Huishang Mansion Building A, 2 Wudayuan Road Donghu New Technology Development Zone, Wuhan, 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:

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Interdisciplinary Scientist
U.S. Food and Drug Administration
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