

正本

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：中華民國藥品行銷暨管理協會

發文日期：中華民國106年5月31日

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速別：

密等及解密條件或保密期限：

附件：美國FDA Warning Letter 320-17-35影本1份

主旨：美國FDA發布印度原料藥廠「Sal Pharma」（廠址：1-7-171/2 Bakaram, Hyderabad, Andhra Pradesh 500020, India）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2月15日列為Import Alert 66-40藥廠，並於106年4月20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

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| 台灣藥品行銷暨管理協會 | |
| 收文日期: 106年6月2日 | |
| 本文件保留: <input type="checkbox"/> 1M. <input type="checkbox"/> 3M. <input type="checkbox"/> 6M | |
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| <input type="checkbox"/> 未定. <input checked="" type="checkbox"/> 永久 | |

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| <input type="checkbox"/> | 最急件 |
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| <input checked="" type="checkbox"/> | 普通件 |

Sal Pharma 4/20/17



10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS
Return Receipt Requested

Warning Letter 320-17-35

April 20, 2017

Mr. Solomon Amrutharajan
Owner
Sal Pharma
1-7-171/2 Bakaram
Hyderabad, Andhra Pradesh 500020
India

Dear Mr. Amrutharajan:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Sal Pharma, at 1-7-171/2 Bakaram, Hyderabad, Andhra Pradesh, from June 27 to July 1, 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 itraconazole and lansoprazole API are 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 July 12, 2016, response in detail.

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 names and addresses of the original manufacturers of your API on certificates of analysis (COA) you issued to your customers. You generated your COA by replacing the original manufacturers' information with your letterhead.

During our inspection, we found that two of your suppliers were not registered with the FDA as drug manufacturers at the time of inspection. However, you shipped API from these firms to the United States, and declared on importation documents and the COA that you provided to your customers that you were the manufacturer. Your failure to declare the original manufacturers on your importation documents and COA provided to your customers enabled the entry of unregistered firms' products into the United States.

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

2. Failure to relabel and hold API under appropriate CGMP controls.

During the inspection, you stated that you drive your car and pick up API from various suppliers, relabel API in your car with Sal Pharma's information, and then transport API to your clearing agent. You stated that you cannot confirm whether or not your clearing agent securely stores API in a temperature-controlled environment.

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

You stated in your response that you intended to suspend exports to the United States and would address FDA's observations prior to resuming exports to the United States. Your response is inadequate because you did not provide sufficient detail or evidence of corrective actions to bring your operations into compliance with CGMP prior to resuming distribution.

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.

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 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.p>)

Misbranding Violations

The itraconazole and lansoprazole API labels identify Sal Pharma but do not designate the firm's role. Since these API labels bear only Sal Pharma's name without further qualifications, the labels falsely represent that Sal Pharma is the sole drug manufacturer. (See 21 CFR 201.1(h)(2)). Therefore, the itraconazole and lansoprazole API are misbranded under section 502(a) of the FD&C Act because the labels are false and misleading.

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 Sal Pharma 1-7-171/2 Bakaram, Hyderabad, Andhra Pradesh, 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:

Hien K. Lieu
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 3003916387.

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