# 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.pdf.

**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 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