U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Sichuan Pharmaceutical Co., Ltd. 9/9/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring MD 20993

Warning Letter

VIA UPS MAIL

WL: 320-11-019

September 09, 2011

Mr. Wang Gouping
General Manager
Sichuan Pharmaceutical Co., Ltd.
No. 189 Hualong Road
Pengzhou, Sichuan, China 611930

Dear Mr. Gouping:

During our June 23 to 29, 2010 inspection of your active pharmaceutical ingredient (API) manufacturing facility, Sichuan Pharmaceutical Co., Ltd. located at No. 189 Hualong Road, Pengzhou, Sichuan, China, an investigator from the Food and Drug Administration (FDA) identified significant deviations from Current Good Manufacturing Practice (CGMP) for the manufacture of APIs. These deviations cause your API(s) to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 351(a)(2)(B)] in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP.

We have reviewed your firm's response of August 05, 2010 and December 13, 2010, and note that it lacks sufficient corrective actions.
Specific deviations observed during the inspection include, but are not limited, to the following:

1. Failure to have appropriate procedures in place to prevent cross-contamination.

   From September 2008 to July 2009 your firm manufactured **(b)(4)** API in workshop **(b)(4)**, which is adjacent to workshops **(b)(4)** and **(b)(4)** where you manufactured **(b)(4)** API and **(b)(4)** injection, respectively. However, you failed to have adequate controls and monitoring program to prevent cross-contamination between these adjacent workshops.

In addition, your firm manufactures a **(b)(4)** API (**(b)(4)** (API) in a facility that was previously used to manufacture **(b)(4)** without conducting adequate decontamination, renovation, and activation of the facility. Your firm has failed to conduct adequate assessment of the cross-contamination risks.

Please note that analytical testing of a product for possible contamination with **(b)(4)** is not sufficient to ensure adequate conditions for **(b)(4)** manufacture. In your response to this letter include your plans for decontamination, renovation, and reactivation (if appropriate) of your facility including the decontamination agent, decontamination plans, analytical methodology for environmental and product testing, and the data obtained to support the effectiveness of the decontamination plan.

The deviations detailed in this letter are not intended to be an all-inclusive statement of deviations that exist at your facility. You are responsible for investigating and determining the causes of the deviations identified above and for preventing their recurrence and the occurrence of other deviations. If you wish to continue to ship APIs to the United States, it is the responsibility of your firm to ensure compliance with all U.S. standards for CGMP and all applicable U.S. laws and regulations.

Additionally, your firm is neither registered nor has it listed every API in commercial distribution in the United States with FDA, as required by 21 C.F.R. § 207.40 and section 510(i) of the Act [21 U.S.C. § 360(i)]. Information on how to register and list is available at the following internet website: http://www.fda.gov/cder/drls/registration_listing.htm [1]. You must complete the required registration and listing and provide evidence that you have fulfilled these requirements in your response to this letter.

Until all corrections have been completed and FDA has confirmed corrections of the deviations and your firm's compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as an API manufacturer. In addition, failure to correct these deviations may result in FDA refusing admission of articles manufactured at Sichuan Pharmaceutical Co., Ltd. located at No. 189 Hualong Road, Pengzhou, Sichuan, China into the United States. The articles are subject to refusal of admission pursuant to section 801(a)(3) of the Act [21 U.S.C. § 381(a)(3)] in that the methods and controls used in their manufacture do not appear to conform to Current Good Manufacturing Practice within the meaning of section 501(a)(2)(B) of the Act [21 U.S.C. § 351(a)(2)(B)].

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct deviations. Include an explanation of each step being taken to prevent the recurrence of deviations and copies of supporting documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the date by which you will have completed the correction.

Additionally, your response should state if you no longer manufacture or distribute **(b)(4)** API and provide the date(s) and reason(s) you ceased production. Please identify your response with FEI # 3002808073.

If you have questions or concerns regarding this letter, contact Milva E. Meléndez, Compliance Officer, at the below address and telephone number.

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Manufacturing and Product Quality
Division of International Drug Quality
White Oak, Building 51
10903 New Hampshire Ave
Silver Spring, MD 20993
Tel: (301) 796-0662
Fax: (301) 847-8741

Sincerely,

/Steven Lynn/
Steven Lynn
Director
Office of Manufacturing and Product Quality
Office of Compliance
Center for Drug Evaluation and Research

Links on this page:

1. http://www.fda.gov/cder/drls/registration_listing.htm