U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Concept Products Limited 7/26/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

Warning Letter: 320-16-23

Via UPS
Return Receipt Requested

July 26, 2016

Mr. John Zhao
General Manager
Concept Products Limited
No. 33, The Third Branch Saida Road
Xiqing Economic Development Area
Tianjin, 300385
China

Dear Mr. Zhao:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Concept Products Limited, No. 33, The Third Branch Saida Road, Xiqing Economic Development Area, Tianjin, from August 3-5, 2015.

This warning letter reviews significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 CFR, parts 210 and 211.

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products 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 have reviewed your August 20, 2015, response in detail.

Our investigator observed specific CGMP violations including, but not limited to, the following.

1. Your firm does not have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient,

prior to release (21 CFR 211.165(a)).

2. Your firm failed to withhold from use each lot of components, drug product containers, and closures until the lot had been sampled, tested, or examined, as appropriate, and released for use by the quality control unit (21 CFR 211.84(a)).

3. Your firm failed to establish and follow a written testing program designed to assess the stability characteristics of drug products and to use results of such stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)).

4. Your firm failed to establish written procedures for production and process controls, including validation protocols and reports, designed to assure that your firm's drug products have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

5. Your firm failed to establish and follow written procedures for cleaning and maintenance of equipment used in the manufacturing, processing, packaging or holding of a drug product (21 CFR 211.67(b)).

In your response of August 5, 2015, you acknowledged the significance of the CGMP observations and said you "**(b) (4)**." You did not commit to any corrective actions regarding the CGMP violations observed on the inspection.

Conclusion

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations for determining the causes, for preventing their recurrence, and for preventing other violations in your facility.

If your firm resumes manufacturing drugs for the United States market, we strongly recommend engaging a consultant, qualified as set forth in 21 CFR 211.34, to assist your firm in meeting CGMP requirements. Using a consultant does not relieve your firm's obligation to comply with CGMP. Notify this office, in writing, of the specific steps that you have taken to correct violations and prevent recurrence. Provide supporting documentation. If your firm cannot complete corrective actions, state the reasons and the date by which your firm will have completed the corrections.

Until you completely correct all violations and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug product manufacturer. Failure to correct these violations may also result in FDA refusing admission of articles manufactured at Concept Product Limited No. 33, the Third Branch Saida Road, Xiqing Economic Development Area, Tianjin, 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).

Send your reply to:

Loan Chin
Pharmacist
U.S. Food and Drug Administration
White Oak Building 51, Room 4359
10903 New Hampshire Avenue
Silver Spring, MD 20993
USA

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov.

Please identify your response with FEI 3006594435.

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

More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)