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

Guangzhou Haishi Biological Technology Co., Ltd. 6/22/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Warning Letter: 320-16-20

Via UPS
Return Receipt Requested

June 22, 2016

Mr. Shihai Zou
General Manager
Guangzhou Haishi Biological Technology Co., Ltd.
1/F, 2/F, Bldg.1, No.3, Songyuan Rd.
New Industrial Zone, No.11 She, Xiamao
Guangzhou, Guangdong 510450
China

Dear Mr. Zou:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Guangzhou Haishi Biological Technology Co., Ltd. at 1/F, 2/F, Bldg. 1, No. 3, Songyuan Road, New Industrial Zone, No. 11 She, Xiamao, Guangzhou, Guangdong, from July 20-24, 2015.

This warning letter summarizes 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 (FD&C) Act, 21 U.S.C. 351(a)(2)(B).

We reviewed your firm's August 14, 2015, response in detail and acknowledge receipt of your subsequent response.

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

1. Your firm failed to test finished batches of your drug products for the identity and strength of active ingredients (21 CFR 211.165(a)).

2. Your firm failed to conduct at least one specific identity test on a component when relying on that component supplier's analysis (21 CFR 211.84(d)(2)).

3. Your firm failed to establish adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

Despite these violations and others cited on the July 24, 2015, Form FDA 483, your quality unit released multiple batches of drug products for distribution.

In your firm's response of August 14, 2015, you state that you will purchase analytical instruments and standards to conduct incoming material testing and finished product testing. However, your response is inadequate as you did not commit to testing every batch of finished product prior to release. Furthermore, you did not include a risk assessment for all your drug products within expiry that have been distributed to the United States.

Based upon the nature of the violations we identified at your firm, we strongly recommend engaging a consultant, qualified as set forth in 21 CFR 211.34, to 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.

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.

After you receive this letter, you have 15 working days to respond to this office in writing. Specify what you have done since our inspection to correct your violations and to prevent their recurrence.

If you cannot complete corrective actions within 15 working days, state your completion date and reasons for delay.

Because of the findings of the FDA inspection described in this letter, your firm was placed on Import Alert 66-40 on March 14, 2016.

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 continuing to refuse admission of articles manufactured at Guangzhou Haishi Biological Technology Co., Ltd. located at 1/F, 2/F, Bldg. 1 No. 3, Songyuan Road, New Industrial Zone, No. 11 She, Xiamao, Guangzhou, Guangdong, 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:

Runa Musib, Ph.D.
Interdisciplinary Scientist
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 3010166847.

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

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