Zhejiang Bangli Medical Products Co., Ltd 1/26/17

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS
Return Receipt Requested

Warning Letter 320-17-20

January 26, 2017

Mr. Zheng Guo Li
General Manager
Zhejiang Bangli Medical Products Co., Ltd.
South of YueGui Road 118, Huachuan Block
Yongkang City, Zhejiang Province 321313
China

Dear Mr. Li:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Zhejiang Bangli Medical Products Co., Ltd. at South of YueGui Road 118, Huachuan Block, Yongkang City, from August 16 to 17, 2016.

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 Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

In addition, your firm limited our inspection. Under the FD&C Act, as amended by the Food and Drug Administration and Innovation Act (FDASIA), section 707, 21 U.S.C. 351(j), your drugs are adulterated in that they have been manufactured, processed, packed, or held in an establishment where the owner or operator has limited an inspection.

We reviewed your September 7, 2016, response in detail, and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigator observed specific 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)).

For example, you have not tested any of the **(b)(4)** patches you manufacture to determine the identity, purity, or potency of each active ingredient prior to release.

2. Your firm failed to test samples of each component for conformity with all appropriate written specifications for purity, strength, and quality (21 CFR 211.84(d)(2)).

For example, you have not tested incoming active pharmaceutical ingredients or other components you use in manufacturing **(b)(4)** patches to determine their identity, purity, and potency.

3. Your firm failed to establish and follow written procedures for cleaning and maintenance of equipment (21 CFR 211.67(b)).

For example, you did not have cleaning procedures for the manufacturing equipment you use to make **(b)(4)** patches. During the inspection, our investigator observed rust and unidentified **(b)(4)** residue on your **(b)(4)** and other manufacturing equipment.

4. Your firm failed to establish written procedures to prevent mix-ups and cross contamination by physical or spatial separation from operations on other drug products (21 CFR 211.130(a)).

For example, our investigator observed **(b)(4)** of unlabeled **(b)(4)** patches of different sizes and colors co-mingled on a table awaiting final packaging, which could lead to product mix-ups during packaging operations.

5. Your firm delayed, denied, or limited an inspection, or refused to permit the FDA inspection.

You limited FDA’s inspection because you refused to provide FDA with records related to suppliers of components and products that you repackage at your facility.

Although you provided the names of two of your suppliers, you refused to provide documentation to show the identities of components or products you obtained from these suppliers, or whether these suppliers performed appropriate release testing on the materials before you received them. Refusing to provide records requested by the FDA investigator that FDA has authority to inspect is considered limiting an inspection.

When an owner, operator, or agent delays, denies, limits, or refuses an inspection, the drugs may be deemed adulterated under section 501(j) of the FD&C Act. See FDA's guidance, *Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection*, available online at www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM360484.pdf.

FDA Sampling and Testing of your Products

FDA collected samples of your product during an inspection of a customer's facility. FDA tested samples of **(b)(4)** (**(b)(4)** ointment **(b)(4)**%). FDA laboratory analysis showed that they samples of your product were sub-potent for the labeled active ingredient, containing an average potency of 69.0% of the label claim.

Consultant Recommended

In your response to the Form FDA 483, you committed to **(b)(4)**. In addition, you committed to engaging a contract laboratory to test drug products distributed to the United States in 2016, and you provided some reports of test results. However, the reports you provided are inadequate because they omit critical information about the tests your contract laboratory performed, such as relevant drug product specifications, and details about the methods used.

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 help you meet CGMP requirements. Your use of consultants does not relieve your 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.

FDA placed your firm on Import Alert 66-40 on September 7, 2016, and Import Alert 99-32 on September 9, 2016.

Until you correct all violations 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 violations may also result in FDA continuing to refuse admission of articles manufactured at Zhejiang Bangli Medical Products Co., at South of YueGui Road 118, Huachuan Block, Yongkang City, 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 violations 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:

Karen D'Orazio
Consumer Safety 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 3007028032.

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