Cixi Zhixin Bird Clean-Care Product Co., Ltd. 1/6/17

Department of Health and Human Services

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

Via UPS **Warning Letter 320-17-16**
Return Receipt Requested

January 6, 2017

Mr. Rujun Sun, CEO
Ningbo Zhixin Bird Clean-Care Product Company, Ltd.
137 Bali Road, Zhangqi Town
Cixi City, Zhejiang 315313
China

Dear Mr. Rujun Sun:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility Ningbo Zhixin Bird Clean-Care Product Company, Ltd. (also known as Cixi Zhixin Bird Clean-Care Product Company, Ltd.), at 137 Bali Road, Zhangqi Town, Cixi City, Zhejiang, from May 3 to 6, 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).

We reviewed your May 20, 2016, response in detail.

Your response was inadequate. Although you committed to establishing written procedures for quality unit responsibilities, stability studies, and process and cleaning validation, your response lacked details overall. You did not include a retrospective review of CGMP deficiencies on the quality of your products already distributed to the United States.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. Your firm's quality control unit failed to review and approve all drug product production and control records, including those for packaging and labeling, to determine compliance with all established, approved written procedures before a batch is released or distributed (21 CFR 211.192).

Your firm's Quality Control Unit (QCU) failed to review and approve drug product production and control records. For example, your QCU did not identify discrepancies between your batch production records and your product labeling for the type and concentration of active ingredient in your **(b)(4)** gel and lotion products.

2. 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)).

Your firm did not perform assay tests for every batch of finished product prior to release. For example, our investigator reviewed your product release testing results and found that your QCU did not perform the assay test to verify product content of **(b)(4)** in your **(b)(4)** (**(b)(4)** oz) product.

3. Your firm failed to establish and follow an adequate 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)).

You did not retain any samples to test and evaluate product stability and had no data to support the **(b)(4)** shelf life claim of your products.

4. Your firm failed to establish and follow adequate written procedures designed to assure batch uniformity and integrity of drug products that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch (21 CFR 211.110(a)).

Your firm failed to perform process validation for **(b)(4)**gel, spray, and lotion destined for the U.S. market.

CGMP consultant recommended

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 for ensuring ongoing CGMP compliance.

Conclusion

Violations 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 all your facilities.

FDA placed your firm on Import Alert 66-40 on November 22, 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 Ningbo Zhixin Bird Clean-Care Product Company, Ltd. (also known as Cixi Zhixin Bird Clean-Care Product Company, Ltd.), 137 Bali Road, Zhangqi Town, Cixi City, Zhejiang, 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:

Rokhsana Safaai-Jazi, 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 3008077936.

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