Ausmetics Daily Chemicals (Guangzhou)

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS
Return Receipt Requested

Warning Letter 320-17-21

January 31, 2017

Mr. Jacky Lau
General Manager
Ausmetics Daily Chemicals (Guangzhou) Co., Ltd.
NO. 1 Jinxiu Rd., Economic and Technical Development District
Guangzhou, Guangdong 510730
China

Dear Mr. Lau:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Ausmetics Daily Chemicals (Guangzhou) Co., Ltd. at NO. 1 Jinxiu Road, Economic and Technical Development District, Guangzhou, Guangdong from July 25–29, 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 August 12, 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 failed to perform, 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, and for each batch of drug product required to be free of objectionable microorganisms, appropriate laboratory testing, as necessary (21 CFR 211.165(a) and (b)).

You failed to sufficiently test batches for conformance to specifications. For example, out of approximately **(b)(4)** total batches of **(b)(4)** released in 2015, you tested only three batches for identity and strength, and two batches for microbiological quality.

2. Your firm failed to ensure that its drug product bore an expiration date that was supported by appropriate stability testing (21 CFR 211.137(a)).

For example, many of your drug products have expiration dates of **(b)(4)** without any supporting stability studies.

3. Your firm failed to ensure the identity of components sourced from various suppliers, including your active ingredients (21 CFR 211.84(d)(1) and (2)).

For example, you accepted and used active raw materials in your drug products based only on their appearance and odor.

4. Your firm failed to prepare batch production and control records with complete information relating to the production and control of each batch of drug product produced (21 CFR 211.188)).

For example, your batch record for **(b)(4)** Gel product lot **(b)(4)** did not define and document process parameters to assure that the in-process materials and the finished drug product meets predetermined quality requirements.

Further, you did not demonstrate that manufacturing processes were designed and controlled to ensure reproducible product quality.

In your September 28, 2016, correspondence, you state that you “have withdrawn and discontinued any manufacture of Pharmaceutical products,” and “ceased the export to the US,” and therefore do not plan to remediate the violations.

CGMP Consultant Recommended

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. Your use of a consultant 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 December 20, 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 Ausmetics Daily Chemicals (Guangzhou) Co., Ltd., Guangzhou, 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:

Chhaya Shetty, Compliance 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 3005063169.

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