Kolmar Korea Co. Ltd. 5/18/18

U.S. FOOD & DRUG ADMINISTRATION

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS
Return Receipt Requested

Warning Letter 320-18-53

May 18, 2018

Mr. Dong-Hwan Yoon
President and CEO
Kolmar Korea Co. Ltd.
245 Sandan-gil
Jeonui-Myeon, Sejong-si
Republic of Korea (South)

Dear Mr. Yoon:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Kolmar Korea Co. Ltd., at 245 Sandan-gil, Jeonui-Myeon, Sejong-si, from September 25 to 28, 2017.

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 October 27, 2017, 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 thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

Your firm failed to thoroughly investigate out-of-specification (OOS) assay test results for your over-the-counter **(b)(4)** cream, lots **(b)(4)**, **(b)(4)**, and **(b)(4)**. You retested the samples and invalidated the OOS results without any scientific justification. You released these lots into the U.S. market in September 2017.

In your response, you stated that your analysts failed to follow your *OOS checklist* procedures. You committed to revising the applicable procedures and retraining analysts.
Your response is inadequate because you did not extend the scope of your investigation to include a retrospective evaluation of all OOS results that were invalidated without scientific justification. You did not determine the root cause for the original OOS results or explain why your analysts failed to follow your procedure.

In response to this letter, provide a summary report on the retrospective review of all invalidated OOS results obtained for products distributed to the U.S. market. If your investigation reveals that you released drug products that did not meet specifications, indicate the corrective actions you have taken or will take, such as notifying customers or recalling products.

For more information about handling failing, OOS, out-of-trend, or other unexpected results, and documenting investigations, see FDA's guidance document, *Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production,* at **https://www.fda.gov/downloads/drugs/guidances/ucm070287.pdf (https://www.fda.gov/downloads/drugs/guidances/ucm070287.pdf)**.

2. Your firm failed to follow written procedures applicable to the quality control unit (21 CFR 211.22(d)).

Your firm failed to ensure that your employees followed your written procedure, *Document Control SOP KO-3 Rev. 9*, requiring quality unit approval prior to discarding documents and records. Our investigator observed documents and records, including batch production records, certificates of analysis, and laboratory worksheets, that were torn and discarded without documented quality unit approval.

In your response, you acknowledged that your personnel were inadequately trained in CGMP-compliant document control practices and procedures. Your firm's response identified plans to address the issues mentioned above by discontinuing poor CGMP practices, revising procedures, and providing employee training. Your response is inadequate because you did not address the effectiveness of your training program, and specific measures you will take to ensure that your employees follow written procedures.

In response to this letter, provide:

- A detailed plan for evaluating the effectiveness of your training program.
- A complete assessment of documentation systems used throughout your manufacturing and laboratory operations to determine where documentation practices are insufficient. Include a detailed CAPA plan that comprehensively remediates documentation practices, and ensures you retain complete and accurate records.

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.

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 refusing admission of articles manufactured at Kolmar Korea Co., 245 Sandan-gil, Jeonui-Myeon, Sejong-si, 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 (mailto:CDER-OC-OMQ-Communications@fda.hhs.gov)** or mail your reply to:

Runa Musib, Ph.D.
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 3004033751.

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

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