Ko Da Pharmaceutical Co Ltd 5/27/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

Via UPS
Return Receipt Requested

Warning Letter 320-16-16

May 27, 2016

Mr. Chao-Hsiang Chen
General Manager
KO DA Pharmaceutical Co.
No. 20-1, Gongye 3rd Rd., Pingzhen Dist.
Taoyuan City, Taiwan 324

Dear Mr. Chen:

The U.S. Food and Drug Administration (FDA) inspected your pharmaceutical manufacturing facility, KO DA Pharmaceutical Co. at No. 20-1, Gongye 3rd Rd., Pingzhen Dist., Taoyuan City, Taiwan, from May 25-27, 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 product is 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 firm's May 28, 2015 response in detail.

Our investigator observed specific violations, including, but not limited to, the following:

1. Your firm's quality control unit failed to approve or reject all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product (21 CFR 211.22(c)).

2. Your firm failed to establish adequate written procedures for production and process controls, including validation protocols and reports, designed to assure that the drug products your firm manufactures have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

3. Your firm failed to withhold from use each lot of components, drug product containers, and closures until the lot had been sampled, tested, or examined, as appropriate, and released for use by the quality control unit (21 CFR 211.84(a)).

4. Your firm failed to establish and follow written procedures for the preparation of master production and control records designed to assure uniformity from batch to batch (21 CFR 211.186(a)).

In your response of May 28, 2015, you acknowledged significant violations of CGMP regulations and "decided to stop manufacturing and distributing the product named **(b)(4)** to the United States market." You did not commit to any corrective actions regarding the CGMP violations observed on the inspection.

Conclusion

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, determining the causes, for preventing their recurrence, and preventing other violations.

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. Using a consultant does not relieve your firm's obligation to comply with CGMP. Notify this office, in writing, of the specific steps that you have taken to correct violations and prevent recurrence. Provide supporting documentation. If your firm cannot complete corrective actions, state the reasons and the date by which your firm will have completed the corrections.

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 refusing admission of articles manufactured at KO DA Pharmaceutical Co., Ltd., No. 20-1, Gongye 3rd Road, Pingzhen District, Taoyuan City, Taiwan 324, 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:

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

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov

Please identify your response with FEI 3001878625.

Sincerely,