Aztex Enterprises Ltd. 10/20/17

10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS
Return Receipt Requested

Warning Letter: 320-18-03

October 20, 2017

Mr. Grant Gillard
President
Aztex Enterprises Ltd.
5155 Fairview Street
Burlington, Ontario
L7L 0J8 Canada

Dear Mr. Gillard:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Aztex Enterprises Ltd. at 5155 Fairview Street, Burlington, Ontario, Canada, from June 12 to June 13, 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 July 12, 2017 response in detail.

Your response is inadequate. Although you committed to addressing the observations we identified, your response lacks detail. You also did not perform adequate evaluations of your suppliers.

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

1. Your firm failed to establish an adequate quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products (21 CFR 211.22(a)).

You firm has not established a formal quality unit, nor has your firm established written procedures describing responsibilities of the quality unit. Additionally, your firm has not established written procedures for labeling operations and complaint handling for over-the-counter (OTC) drug products you ship to the United States. Your firm has also failed to establish written procedures to properly qualify your suppliers.

Purchase of drugs from a manufacturer on FDA Import Alert 66-40

We reviewed a list of your suppliers, which includes **(b)(4)** has been listed on FDA Import Alert 66-40, *Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs*, since **(b)(4)**. Import Alert 66-40 can be found on the FDA public website: **https://www.accessdata.fda.gov/cms_ia/importalert_189.html (https://www.accessdata.fda.gov/cms_ia/importalert_189.html)**. As indicated on Import Alert 66-40, drugs manufactured at **(b)(4)** are subject to refusal of admission to the United States because they do not conform to CGMP. Because you used adulterated materials that you purchased from a firm on Import Alert 66-40, **(b)(4)**, the drugs you manufacture also are adulterated under the FD&C Act.

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 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 October 19, 2017.

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 Aztex Enterprises Ltd. at 5155 Fairview Street, Burlington, Ontario, 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:

Kevin Maguire
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 3003516782.

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

More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)