DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Atlanta District
60 8th Street, NE
Atlanta, GA 30309

April 28, 2016

VIA UPS

(16-ATL-U01)

Mr. Phanesh Koneri, CEO
Mr. Jonathan E. Sterling, Vice President of Quality & Regulatory Affairs
Exela Pharma
1245 Blowing Rock Boulevard
Lenoir, NC 28645

Dear Mr. Koneri and Mr. Sterling:

You registered with the U.S. Food and Drug Administration (FDA) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b][1] on June 6, 2014, January 5, 2015, and January 12, 2016. From November 17, 2014, to November 21, 2014, FDA investigators inspected your facility, Exela Pharma Sciences, LLC, located at 1325 William White Place, NE Lenoir, NC. During the inspection, the investigators observed that you failed to meet the conditions under section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain requirements under the FDCA. FDA issued a Form FDA 483 to your facility on November 21, 2014. FDA acknowledges receipt of your facility's response, dated December 15, 2014.

Based on this inspection, it appears your facility is producing drugs that violate the FDCA. You are receiving this Untitled Letter instead of a Warning Letter because FDA has decided in its discretion that your violations of the FDCA, which relate to labeling and product reporting, do not meet the threshold of regulatory significance for a Warning Letter at this time. Nevertheless, you should promptly correct the violations discussed below and as observed in the Form FDA 483. FDA may reconsider the regulatory significance of these violations based on its review of any new information that may become available concerning this facility.

[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

A. Compounded Drugs under the FDCA

The Drug Quality and Security Act (DQSA) was enacted on November 27, 2013. Title I of the DQSA, the Compounding Quality Act (CQA), added a new section 503B to the FDCA. Under section 503B(b), a compounder can register as an outsourcing facility with FDA. Drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility can qualify for exemptions from the drug approval requirements in section 505 of the FDCA [21 U.S.C. § 355(a)], the requirement in section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] that labeling bear adequate directions for use and the Drug Supply Chain Security Act requirements in section 582 of the FDCA [21 U.S.C. § 360eee-1] if the conditions in section 503B of the FDCA are met.

An outsourcing facility, which is defined in section 503B(d)(4) of the FDCA [21 U.S.C. § 353b(d)(4)], is a facility at one geographic location or address that — (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section. Outsourcing facilities must comply with other provisions of the FDCA, including section 501(a)(2)(B) [21 U.S.C. § 351(a)(2)(B)], regarding current good manufacturing practice (CGMP), and section 501(a)(2)(A) [21 U.S.C. § 351(a)(2)(A)], regarding insanitary conditions. Generally, CGMP requirements for the preparation of drug products are established in Title 21 of the Code of Federal Regulations (CFR) parts 210 and 211.

B. Violations of the FDCA

The FDA investigators observed that your facility failed to meet the conditions of section 503B. For example, during the inspection, FDA investigators noted that some of your facility's drug products do not include the following on the label: the address and phone number of the outsourcing facility; the statements, "This is a compounded drug," "Office Use Only," and "Not for resale"; and storage and handling instructions. Although that information was included on the containers of those products, Section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10) requires that information to be on the product label itself.

In addition, your facility failed to submit a report to FDA upon initial registration as an outsourcing facility in June 2014, identifying the drug products that you compounded during the previous 6-month period [Section 503B(b)(2) of the FDCA [21 U.S.C. §353b(b)(2)]].

Because your compounded drug products have not met all of the conditions in section 503B, they are not eligible for the exemptions under section 503B from the FDA approval requirements in section 505, the requirement under section 502(f)(1) that labeling bear adequate directions for use, and the Drug Supply Chain Security Act requirements described in section 582 of the FDCA.[2]

Specific violations are described below.

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[2] See, e.g., section 503B(a)(11) of the FDCA [21 U.S.C. § 353b(a)(11)].

Misbranded Drug Products

You compound drug products that are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(1) of the FDCA, and they are not exempt from the requirements of section 502(f)(1) of the FDCA (*see, e.g.,* 21 CFR 201.115). It is a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

Failure to Report Drugs

As noted above, your facility failed to submit a report to FDA upon initial registration as an outsourcing facility in June 2014, identifying the drug products that you compounded during the previous 6-month period. (Section 503B(b)(2) of the FDCA [21 U.S.C. § 353b(b)(2)]). The failure to report drugs by an entity that is registered with FDA in accordance with section 503B(b) is a prohibited act under section 301(ccc)(3) of the FDCA [21 U.S.C. § 331(ccc)(3)].

C. Corrective Actions

In your December 15, 2014, correspondence, you described certain corrective actions you took in response to the Form FDA 483 observations. Your proposed corrective actions may have adequately corrected the CGMP observations if implemented appropriately.. However, the labeling deficiencies described above should be corrected.

D. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty working days of receipt of this letter, you should notify this office in writing of the specific steps you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If the corrective actions cannot be completed within thirty working days, state the reason for the delay and the time frame within which the corrections will be completed. Please address your reply to Marie Mathews, Compliance Officer, at the address above.

If you have questions regarding the contents of this letter, please contact Ms. Mathews at 404-253-1279.

Sincerely,

Dawne M. Hines
Acting Atlanta District Director