Dorneyville Pharmacy 2/7/17

Philadelphia District Office
U.S. Customs House, Room 900
200 Chestnut Street
Philadelphia, PA 19106

Telephone: (215) 597-4390
FAX: (215) 597-8212

WARNING LETTER
17-PHI-05

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 7, 2017

Thomas Silvonek, Owner
Dorneyville Pharmacy
3330 Hamilton Blvd.
Allentown, PA 18103-4537

Dear Mr. Silvonek:

From December 9, 2015 to January 7, 2016, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Dorneyville Pharmacy, located at 3330 Hamilton Blvd., Allentown, PA 18103-4537. This inspection was conducted to follow up on a report concerning a product labeled as deoxycholic acid sodium 1% injection solution that was produced by your firm. During the inspection, the investigator noted that drug products you produced failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA. In addition, the investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on January 7, 2016. Based on this inspection, it appears that you are producing drug products that violate the FDCA.

A. Compounded Drugs Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].[1] Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A.

B. Failure to Meet the Conditions of Section 503A

During the inspection, the FDA investigator noted that drug products produced by your firm failed to meet the conditions of section 503A. Specifically, the investigator noted that your firm does not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

Therefore, you compounded drug products that do not meet the conditions of section 503A and are not eligible for the exemptions in that section from the FDA approval requirement of section 505 of the FDCA, the requirement under section 502(f)(1) of the FDCA that labeling bear adequate directions for use, and the requirement of compliance with CGMP under section 501(a)(2)(B) of the FDCA. In the remainder of this letter, we refer to your drug products that do not qualify for exemptions under section 503A as the "ineligible drug products."

Specific violations are described below.

C. Violations of the FDCA

Adulterated Drug Products

As noted above, FDA's inspection was conducted to follow up on a report of a product labeled as deoxycholic acid sodium 1% injection solution that was produced by your firm. FDA analysis of a sample of this product found that it contained 80.4% of the labeled concentration of deoxycholic acid, which is below the label claim. Under section 501(c) of the FDCA [21 U.S.C. § 351(c)], a drug is deemed to be adulterated if it is unrecognized in an official compendium and its strength differs from, or its quality or purity falls below, that which it purports or is represented to possess. Deoxycholic acid sodium injection solution is not recognized in an official compendium, and the strength of your deoxycholic acid sodium injection solution differed from the labeled amount of deoxycholic acid sodium the product was purported to possess, causing it to be adulterated under section 501(c) of the FDCA.

The FDA investigator noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed that sterilized items wrapped in aluminum foil were stored in your anteroom without an established hold time to ensure that these items remain sterile. Our investigator also noted that operators applied a hand sanitizer, which is not labeled as sterile, to their sterile gloves prior to aseptic processing. In addition, your firm did not depyrogenate the rubber stoppers used for finished sterile drug products.

Furthermore, the manufacture of the ineligible drug products is subject to FDA's CGMP regulations, Title 21, Code of Federal Regulations (CFR), parts 210 and 211. The FDA investigator observed significant CGMP violations at your facility, causing the ineligible drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations included, for example:

1. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity,

strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a)).

2. Your firm failed to ensure that manufacturing personnel wear clothing appropriate to protect drug product from contamination (21 CFR 211.28(a)).

3. Your firm failed to clean and, where indicated by the nature of the drug, sterilize and process container closures to remove pyrogenic properties to assure they are suitable for their intended use (21 CFR 211.94(c)).

4. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

5. Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).

6. Your firm does not have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product (21 CFR 211.167(a)).

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 of the components used to make the drug and results in the drug being adulterated.

Misbranded Drug Products

The ineligible drug products you compounded are intended for conditions 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.**[2]** Accordingly, these ineligible drug products are misbranded under section 502(f)(1) of the FDCA.

Further, under section 502(a) of the FDCA [21 U.S.C. § 352(a)], a drug product is misbranded if its labeling is false or misleading in any particular. As noted above, FDA analysis showed that your deoxycholic acid solution contained less than the labeled concentration of deoxycholic acid. Because the labeling of this drug product was false, it was misbranded under section 502(a) of the FDCA.

It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] 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.

D. Corrective Actions

We did not receive a response from your firm to the Form FDA 483 issued at the close of the inspection. As a result, we have not been able to evaluate the adequacy of any corrective actions you may have taken in response to the Form FDA 483.

Please be aware that section501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A, including, the condition on receipt of a prescription for an identified individual patient prior to compounding and distributing drug products. In addition, sections 501(c) and 502(a) of the FDCA apply regardless of whether drug products you compound meet the conditions of section 503A.

Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations. Before doing so, you must

comply with the requirements of section 505 and 502(f)(1) and fully implement corrections that meet the minimum requirements of the CGMP regulations.

FDA strongly recommends that your management immediately undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug processing expertise should assist you in conducting this comprehensive evaluation.

E. 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 and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that 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 you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Your written notification should refer to the Warning Letter Number above (17-PHI-05). Please address your reply to:

Yvette Johnson, Compliance Officer
Philadelphia District Office
U.S. Customs House, Room 900
200 Chestnut Street
Philadelphia, PA 19106

If you have questions regarding any issues in this letter, please contact Ms. Johnson via email at Yvette.Johnson@fda.hhs.gov or by phone at 215-717-3077.

Sincerely,
/S/
Anne E. Johnson
District Director
Philadelphia District

---

[1] We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in section 503A of the FDCA.
[2] Your ineligible drug products are not exempted from the requirements of section 502(f)(1) of the FDCA by regulations issued by the FDA (*see*, *e.g.*, 21 CFR 201.115).

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