Precision Pharmacy Center, LLC 11/15/16

Los Angeles District
19701 Fairchild Road
Los Angeles, CA 92612

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

November 15, 2016

WL# 6-17

Ms. Amy L. Summers, Pharmacist-In-Charge
Precision Pharmacy Center, LLC, dba Heritage Compounding Pharmacy
2903 Saturn Street, Suite A
Brea, CA 92821-6259

Dear Ms. Summers:

From March 25, 2015, to April 1, 2015, and again from June 3, 2016, to June 10, 2016, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Precision Pharmacy Center, LLC, dba Heritage Compounding Pharmacy, located at 2903 Saturn Street, Suite A, Brea, CA. During the inspection, the investigators 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. Specifically, the investigators noted that you did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

FDA issued a Form FDA 483 to your firm on April 1, 2015, and again on June 10, 2016. FDA acknowledges receipt of your facility's responses, received on April 17, 2015, and dated June 13, 2016. Based on these inspections, it appears that you produced drug products that violate the FDCA.

A. Compounded Drug Products 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 inspections, the FDA investigators noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigators noted your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

Therefore, you compounded drug products (collectively the "ineligible 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.

Specific violations are described below.

C. Violations of the FDCA

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, and they are not exempt from the requirements of section 502(f)(1) of the FDCA (*see*, *e.g.*, 21 CFR 201.115). Accordingly, these ineligible drug products are misbranded under section 502(f)(1) of the FDCA. 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.

D. Corrective Actions

We have reviewed your firm's responses to the Forms FDA 483. We acknowledge your statement in your June 13, 2016, response that "[a]s a 503A facility, Heritage Compounding Pharmacy never makes 'batches' of any sterile products rather we make patient-specific prescriptions." This response is not adequate because it does not address your intention with respect to non-sterile drug products that you compound. During FDA's inspections of your facility, we noted that you distributed non-sterile drug products without first receiving valid prescriptions for identified individual patients. Section 503A of the FDCA requires that ***all*** compounding of

drugs, whether sterile or non-sterile, be based on the receipt of a valid prescription for an identified individual patient (section 503A(a) of the FDCA).

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.

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, including 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 (WL 6-17). Please address your reply to:

Kelly D. Sheppard, Director
Compliance Branch
U.S. Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, California 92612-2445

If you have questions regarding the contents of this letter, please contact Ms. Mariza Jafary, Compliance Officer at Mariza.Jafary@fda.hhs.gov phone at 949-608-2977.

Sincerely,
/S/
CDR Steven E. Porter, Jr.
Los Angeles District Director

Cc:

Ms. Cheryl A. Estep and Mr. Paul G. Kagan, Co-Owners
Precision Pharmacy Center, LLC, dba Heritage Compounding Pharmacy
2903 Saturn Street, Suite A
Brea, CA 92821-6259

Virginia Harold, Executive Officer
California State Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834

---

[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.