Village Pharmacy 10/30/17

Division of Pharmaceutical
Quality Operations I
10 Waterview Blvd, 3rd Floor
Parsippany, NJ 07054
Telephone: (973) 331-4900
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AMENDED WARNING LETTER
17-NWJ-10

October 30, 2017
VIA UPS NEXT DAY AIR
Ann Ervin, Owner
Village Pharmacy
1280 Yardville-Allentown Road
Allentown, New Jersey 08501-1830
Dear Ms. Ervin:

From June 14, 2016, to June 22, 2016, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Village Pharmacy, located at 1280 Yardville-Allentown Road, Allentown, New Jersey 08501-1830. During the inspection, the investigators noted that drug products you produced, such as Hydroxyzine Pamoate 25 mg/ml Suspension, 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 failed to meet the conditions of section 503A of the FDCA, and in addition, the investigators noted serious deficiencies in your practices for producing non-sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on June 22, 2016. FDA acknowledges receipt of your facility's response dated June 30, 2016. Based on this inspection, 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 inspection, the FDA investigators noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigators noted that 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 requirement under sections 505, 502(f)(1) and 501(a)(2)(B) 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

Adulterated Drug Products

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 investigators 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 establish and follow an adequate written testing program designed to assess the stability characteristics of drug products and to use results of such stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)).
2. Your firm does not have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)).
3. 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)).

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 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, 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 reviewed your firm’s response to the Form FDA 483. We acknowledge your statement that your firm “will immediately cease compounding non-patient specific compounded prescriptions.” We note that in 2014 you compounded and distributed domperidone 20 mg capsules. Drug products compounded using domperidone are not eligible for the exemptions provided by section 503A of the FDCA. Our review of your records indicates that you have not compounded domperidone products since that time.

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 502(f)(1) and fully implement corrections that meet the minimum requirements of the 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 the 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-NWJ-10]). Please address your reply to: CDR Liatte Krueger, Compliance Officer, U.S. FDA, 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054. If you have questions regarding the contents of this letter, please contact CDR Krueger via email at liatte.krueger@fda.hhs.gov or by phone at (973) 331-4933.

Sincerely,

/S/

Diana Amador-Toro

District Director/OPQ Division 1

New Jersey District Office

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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.