Ballard Plaza Pharmacy I, Inc. 8/1/17

Division of Pharmaceutical
Quality Operations IV
19701 Fairchild Road
Los Angeles, CA 92612

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

August 1,
2017 **CMS#**
507776

William G. Ewing, Shareholder and Pharmacist-in-charge
Ballard Plaza Pharmacy I, Inc.
1801 N.W. Market Street, Suite 104
Seattle, Washington 98107-3909

Dear Mr. Ewing:

From April 25, 2016, to May 17, 2016, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Ballard Plaza Pharmacy I, Inc., located at 1801 N.W. Market Street, Suite 104, Seattle, Washington 98107-3909. 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. In addition, the investigators 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 May 17, 2016. FDA acknowledges receipt of your facility's response, dated June 2, 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 practice (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, 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

Adulterated Drug Products

The FDA investigators 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:

- Our investigators observed a piece of partially detached wood paneling from the underside of your ISO 5 Laminar Flow Hood (LFH). Wooden material is difficult to clean and may harbor contamination.
- Our investigators observed poor aseptic practices, including an operator with the elbows of **(b)(6), (b)(7)(C)** non-sterile disposable lab coat resting in direct contact with the work surface of the ISO 5 LFH while performing aseptic operations.
- Your firm used non-sterile wipes to wipe down the ISO 5 LFH and other aseptic processing areas.
- Our investigators found that your firm failed to demonstrate, through appropriate studies, that your hoods are able to provide adequate of the ISO 5 area in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk.

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 any human or animal 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 any human or animal 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

In your response to the Form FDA 483 inspectional observations, dated June 2, 2016, you described certain corrective actions you took to address the observations. Although some of your proposed corrective actions that address the identified insanitary conditions appear to be adequate, certain corrective actions cannot be fully evaluated as your firm did not provide supporting documentation. For example, your response indicates that your firm intends to replace your current LFH, which has exposed wood, with a "compounding aseptic **(b)(4)**" and perform smoke studies under dynamic conditions within the ISO 5 area. However, you did not submit documentation to support these changes. In addition, your response does not include any interim actions that your firm put in place prior to implementation of corrective actions. Furthermore, you stated that your firm will revise current procedures to require the use of sterile wipes to disinfect the aseptic processing area; however, such procedures were not provided in your response.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A. For more information on compounding, please see FDA's website, at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, materials, and systems for human and animal drugs. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise could be useful 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, 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 firm's response should be sent to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
United States Food and Drug Administration
19701 Fairchild
Irvine, California 92612

If you have questions regarding the contents of this letter, please contact Ms. Maria P. Kelly-Doggett, Compliance Officer via email at maria.kelly-doggett@fda.hhs.gov or by phone at (425) 302-0427 and reference unique identifier **507776**.

Sincerely,
/S/
CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

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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.