Prescription Lab Compounding Pharmacy 11/16/16

Los Angeles District
19701 Fairchild Road
Los Angeles, CA 92612

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

November 16, 2016

WL# 07-17

David A. Nicoletti, R.Ph., President
MFP Limited, dba Prescription Lab Compounding Pharmacy
6586 E. Grant Road
Tucson, AZ 85715

Dear Mr. Nicoletti:

Between August 31, 2015 and September 10, 2015, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your facility, MFP Limited, dba Prescription Lab Compounding Pharmacy, located at 6586 E. Grant Road, Tucson, AZ 85715.

During the inspection, the investigator observed a serious deficiency in your practices for producing sterile drug products, which puts patients at risk. Specifically, glass beakers used to mix non-sterile drug product solutions prior to the sterilization step are not protected from contamination after they are processed through the dry oven. They were observed stored on a rack, uncovered, in the ISO 8 room after depyrogenation. The investigator also noted that your firm produces domperidone drug products. Domperidone is not the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, nor is it a component of an FDA-approved human drug product, and it does not appear on a list developed

by the Secretary under section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a(b)(1)(A)(i)(III)].

FDA issued a Form FDA-483 to your firm on September 10, 2015. To date, your firm has not responded to the Form FDA 483.

Based on this inspection, it appears that you are producing drugs that violate the FDCA.

A. Compounded Drugs Under the FDCA

Section 503A of the FDCA [21 U.S.C. § 353a] describes the conditions under which certain compounded human drug products qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) requirements, section 501(a)(2)(B) of the FDCA [21 U.S.C. § 351(a)(2)(B)]; labeling with adequate directions for use, section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)]; and FDA approval prior to marketing section 505 of the FDCA [21 U.S.C. § 355].

One of the conditions that must be met for a compounded drug to qualify for the exemptions under section 503A is that bulk drug substances used to compound it must: (I) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (II) if such a monograph does not exist, be components of drugs approved by the Secretary; or (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appear on a list developed by the Secretary through regulation ("503A bulks list") (section 503A(b)(1)(A)(i)).

Compounded drug products containing domperidone are not eligible for the exemptions under section 503A of the FDCA, because domperidone is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved human drug, and it does not appear on the 503A bulks list . [1] Accordingly, the drug products that you compound using domperidone are not entitled to the exemptions in section 503A of the FDCA.

We remind you that there are a number of other conditions that must be satisfied to qualify for the exemptions in section 503A of the FDCA. [2]

B. Violations of the FDCA

The domperidone drug products that you manufacture and distribute are misbranded drugs in violation of section 502(f)(1) of the FDCA.

In addition, your drug products that are intended or expected to be sterile were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth, or whereby they may have been rendered injurious to health causing them to be adulterated within the meaning of section 501(a)(2)(A) [21 U.S.C. § 351(a)(2)(A)] of the FDCA.

Misbranded Drug Products

You compound domperidone 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 [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.

Adulterated Drug Products

Additionally, an FDA investigator noted that drug products in your facility that were 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. Specifically, the investigator observed that glass beakers used to mix non-sterile drug product solutions prior to the sterilization step are not protected from contamination after they are processed through the dry oven. They were observed stored on a rack, uncovered, in the ISO 8 room after depyrogenation.

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 adulterated.

C. Corrective Actions

To date, your firm has not responded to the Form FDA 483. Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether the drugs are compounded and distributed after receipt of a prescription for an identified individual patient.

FDA strongly recommends that your management immediately undertake a comprehensive assessment of your operations, including facility design, procedures, personnel, processes, materials, and systems. 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.

In addition, you should also correct the violation of section 502(f)(1) of the FDCA noted above.

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.

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 (15) 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. Your written notification should be addressed 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 any issues in this letter, please contact Ms. Mu via email at Jessica.Mu@fda.hhs.gov or by phone at (949) 608-4477.

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

Cc:
Virginia Herold (Via Email Only)
Executive Officer
California State Board of Pharmacy

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[1] On June 9, 2016, FDA issued a final guidance titled, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. This guidance describes FDA's interim regulatory policy for State-licensed pharmacies, Federal facilities, and licensed physicians that compound human drug products using bulk drug substances that do not otherwise meet the conditions of section 503A(b)(1)(A)(i) while the 503A bulks list is being developed. Specifically, the guidance sets out the conditions under which FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or

licensed physician for compounding a drug product using a bulk drug substance that is not the subject of an applicable USP or NF monograph or a component of an FDA-approved drug, until the substance is identified in a final rule as included or not included on the 503A bulks list. These conditions include that the substance may be eligible for inclusion on the 503A bulks list, was nominated with adequate support for FDA to evaluate it, and has not been identified by FDA as a substance that appears to present significant safety risks pending further evaluation. Domperidone was nominated for inclusion on the 503A bulks list. It has been identified as a substance that appears to present significant safety risks.

[2] For example, section 503A also addresses anticipatory compounding, which includes compounding (not distribution) before receipt of a valid prescription order for an individual patient. We are not addressing anticipatory compounding here.