JD & SN Inc., dba Moses Lake Professional Pharmacy 10/14/16

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
Seattle District
22215 261h Avenue SE,
Suite 210
Bothell, WA 98021

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 17-01

Shawn W. Needham, R.Ph., President
JD & SN Inc., dba Moses Lake Professional Pharmacy
1555 Pilgrim St.
Moses Lake, Washington 98837-4623

WARNING LETTER

Dear Mr. Needham:

Between July 13, 2015, and July 21, 2015, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, JD & SN Inc., dba Moses Lake Professional Pharmacy, located at 1555 Pilgrim St., Moses Lake, Washington. During the inspection, the investigators noted that you were not receiving valid prescriptions for individually-identified patients for a portion of the drug products you were producing. Investigators 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]. In addition, the investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, investigators observed a **(b)(4)** solution produced by your firm was stored in a vial that is punctured multiple times throughout

the assigned expiry period and contained free floating particulate matter. Also, your firm used non-sterile wipes, non-sterile disinfectants and failed to use a sporicidal agent as part of the disinfection program for the cleanroom and ISO 5 area. In addition, your firm failed to demonstrate through appropriate studies that the hood is able to provide adequate protection 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.

FDA issued a Form FDA 483 to your firm on July 21, 2015. FDA acknowledges receipt of your firm's response to the Form FDA 483, dated August 10, 2015. FDA acknowledges your action on July 24, 2015, and on August 7, 2015, to voluntarily recall compounded sterile drug products within expiry and to cease production of compounded sterile preparations until further notice.

Based on this inspection, it appears that you are producing drugs that violate the Federal Food, Drug, and Cosmetic Act (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]. Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A of the FDCA. During the FDA inspection, the investigators observed that your firm does not receive valid prescriptions for individually-identified patients for a portion of the drug products you produce.

Another condition that must be met for a compounded drug to qualify for the exemptions under section 503A is that it is compounded from bulk drug substances that: (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, are 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, that appear on a list developed by the Secretary through regulation (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 does not appear on a list developed by the Secretary.[1] Accordingly, the drugs you compound without valid prescriptions for individually-identified patients and any drug products you compound using domperidone are not entitled to the exemptions in section 503A.

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

Because the domperidone drug products that you manufacture and distribute are not the subject of approved applications, they are unapproved new drugs in violation of section 505(a) of the FDCA. Further, the domperidone drug products and the drug products that you manufacture and distribute without valid prescriptions for individually-identified patients are misbranded drugs in violation of section 502(f)(1) of the FDCA.

In addition, drug products that are intended or expected to be sterile drug products 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) of the FDCA [21 U.S.C. § 351(a)(2)(A)].

Furthermore, because you manufacture and distribute a portion of your drugs without valid prescriptions for individually-identified patients, the manufacture of those drugs is subject to FDA's CGMP regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. The FDA investigators observed significant CGMP violations at your facility, causing your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA .

Unapproved New Drug Products

You do not have any FDA approved applications on file for the domperidone drug products that you manufacture and distribute.[3] Under sections 301(d) [21 U.S.C. § 331(d)] and 505(a) of the FDCA, a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. Your marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

Misbranded Drug Products

You compound drug products, for which you have not obtained valid prescriptions for individually-identified patients and 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).

The introduction or delivery for introduction into interstate commerce of the domperidone products therefore violates section 301(a) of the FDCA [21 U.S.C. § 331(a)]. Further, 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, the FDA investigators observed 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.

For example, investigators observed a **(b)(4)** solution produced by your firm was stored in a vial that is punctured multiple times throughout the assigned expiry period and contained free floating particulate matter. Also, your firm used non-sterile wipes, non-sterile disinfectants and failed to use a sporicidal agent as part of the disinfection program for the cleanroom and ISO 5 area. In addition, your firm failed to demonstrate through appropriate studies that the hood is able to provide adequate protection 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.

The FDA investigators also noted CGMP violations at your facility, causing the drug products for which you have not obtained valid prescriptions for individually-identified patients to be adulterated under section 501(a)(2)(B) of the FDCA. The violations include, for example:

1. Your firm failed to establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions [21 CFR 211.42(c)(10)(v)].

2. 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)].

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

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 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)].

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)].

Under section 301(a) of the FDCA, the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, 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

FDA acknowledges your action on July 24, 2015, and on August 7, 2015, to voluntarily recall compounded sterile drug products within expiry and to cease production of compounded sterile preparations until further notice. FDA further acknowledges receipt of your response to the Form FDA 483 dated August 10, 2015, in which you stated your firm has "elected to cease all further sterile compounding…."

If you decide to resume production of sterile drugs, before resuming such operations, 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, if you were to continue to manufacture and distribute drug products without valid prescriptions for individually-identified patients, the manufacture of such drugs would be subject to FDA's drug CGMP regulations (21 CFR 210 and 211), and before doing so, you should fully implement corrections that meet the minimum requirements of 21 CFR Part 211, in order to provide assurance that the drug products produced by your firm conform to the basic quality standards regarding safety, identity, strength, quality, and purity. As indicated above, such drug products would also be subject to new drug approval requirements in section 505 and the requirement to be labeled with adequate directions for use in section 502(f)(1), among other requirements of the FDCA. Please also 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 valid prescription for an identified-individual patient.

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. *See* section 501 of the FDCA, as amended by the Food and Drug Administration Safety and Innovation Act (Pub.L. 112-144, Title VII, section 711). If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that your compounded drug products are neither adulterated nor misbranded. *See* 21 CFR 210.1(b), 21 CFR 200.10(b).

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.

If you decide to resume sterile operations, 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 if you have taken any specific steps to correct violations, or you may inform us that you do not intend to resume production of sterile drugs. If you intend to resume production of sterile drugs in the future, 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. In addition to taking appropriate corrective actions, you should notify this office prior to resuming production of any sterile drugs in the future. Your written notification should be addressed to:

Jessica L. Kocian, Compliance Officer
Seattle District Office
22215 26th Avenue SE, Suite 210
Bothell, WA 98021-4425

If you have questions regarding any issues in this letter, please contact Jessica Kocian by phone at 425-302-0444.

Sincerely,
/S/
Miriam R. Burbach
District Director

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[1] Domperidone was nominated for inclusion on the list of bulk drug substances that can be used in compounding that must be developed through regulation pursuant to section 503A(b)(i)(A)(i)(III) of the FDCA (503A bulk drug substances list). 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 regulatory policy for licensed pharmacists in State-licensed pharmacies and Federal facilities and for 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 bulk drug substances 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 being included or not included on the 503A bulk drug substances list. These conditions include that the substance may be eligible for inclusion on the 503A bulk drug substances list, was nominated with sufficient supporting information 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 has been identified as a substance that appears to present significant safety risks. For additional information, see the guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf.

[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.

[3] The specific products made by your firm are drugs within the meaning of section 201(g) [21 U.S.C. § 321(g)] of the FDCA because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases and/or because they are intended to affect the structure or any function of the body. Further, they are “new drugs” within the meaning of section 201(p) of the FDCA [21 U.S.C. §321(p)] because they are not generally recognized as safe and effective for their labeled uses.