The Wellness Center Pharmacy, Inc., dba Designer Drugs 8/5/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200 – Suite 500
Nashville, TN 37217

Telephone: (615) 366-7801
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August 5, 2016

WARNING LETTER No. 2016-NOL-11

UNITED PARCEL SERVICE
Delivery Signature Requested

Randal J. Davis, President
The Wellness Center Pharmacy, Inc., dba Designer Drugs
7304 Jarnigan Road
Chattanooga, Tennessee 37421-3042

Dear Mr. Davis:

From May 18-20, 22, 28, 2015, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your facility, The Wellness Center Pharmacy, Inc., dba Designer Drugs, located at 7304 Jarnigan Road, Chattanooga, Tennessee. This inspection was conducted after receipt of a MedWatch report involving a patient who reportedly experienced an adverse event after being implanted with hormone replacement pellets produced by your firm.

During the inspection, the investigator noted you did not receive valid prescriptions for individually-identified patients for all of the drug products you were producing. The investigator also noted that your firm produced 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 (the Act) [21 *United States Code* (USC) 353a(b)(1)(A)(i)(III)]. In addition, the investigator observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, our

investigator observed environmental sampling taken immediately after cleaning, which could potentially bias the results. In addition, your firm did not use sterile wipes or have an adequate contact time for your sporicidal agent used to disinfect the aseptic processing area. Your firm used non-pharmaceutical grade nitrogen gas in the production of sterile drug products. Furthermore, your firm failed to demonstrate through appropriate studies that your hood is able to provide adequate protection in the ISO 5 area in which sterile products are being produced. 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 May 28, 2015. FDA acknowledges receipt of your firm's response to the Form FDA 483, dated June 17, 2015. Based on this inspection, it appears that you are producing drugs which violate the Act.

A. Compounded Drugs under the Act

Section 503A of the Act [21 USC 353a] describes the conditions under which certain compounded human drug products may qualify for exemptions from three Sections of the Act: compliance with current good manufacturing practice (CGMP) requirements, Section 501(a)(2)(B) of the Act [21 USC 351(a)(2)(B)]; labeling with adequate directions for use, Section 502(f)(1) of the Act [21 USC 352(f)(1)]; and FDA approval prior to marketing, Section 505 of the Act [21 USC 355]. Receipt of valid prescriptions for individually-identified patients is one of the conditions that must be met to quality for the exemptions under Section 503A of the Act.

During the FDA inspection, the investigator observed 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 of the Act 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) of the Act].

During the FDA inspection, the investigator observed your firm produces drug products containing domperidone. Compounded drug products containing domperidone are not eligible for the exemptions provided by subsection (a) of Section 503A of the Act 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 of bulk drug substances that may be used for compounding developed by the Secretary.[1]

Accordingly, drug products you compound without valid prescriptions for individually-identified patients and drug products you compound using domperidone are not entitled to the exemptions in Section 503A of the Act.

In addition, we remind you there are a number of other conditions which must be satisfied to qualify for the exemptions in Section 503A of the Act.[2]

B. Violations of the Act

The drug products you manufacture and distribute without valid prescriptions for individually-identified patients and the domperidone drug products you manufacture are misbranded drugs in violation of Sections 502(f)(1) of the Act. In addition, 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) of the Act [21 USC 351(a)(2)(A)of the Act].

Misbranded Drug Products

The drug products you compound without obtaining valid prescriptions for individually-identified patients and the domperidone drug products you manufacture are intended for conditions which 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, product labeling fails to bear adequate directions for their intended uses, causing them to be misbranded under Section 502(f)(1) of the Act, and they are not exempt from the requirements of Section 502(f)(1) of the Act [21 *Code of Federal Regulations* (CFR) 201.115].

It is a Prohibited Act under Section 301(k) of the Act [21 USC 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 investigator observed your 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 Act. For example, our investigator observed environmental sampling taken immediately after cleaning, which could potentially bias the results. In addition, your firm did not use sterile wipes or have an adequate contact time for your sporicidal agent used to disinfect the aseptic processing area. Your firm used non-pharmaceutical grade nitrogen gas in the production of sterile drug products. Furthermore, your firm failed to demonstrate through appropriate studies that your hood is able to provide adequate protection in the ISO 5 area in which sterile products are being produced.

It is a Prohibited Act under Section 301(k) of the Act 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

We have reviewed your firm's planned corrective actions, as documented in your June 17, 2015, response to the Form FDA 483 inspectional observations issued at the close of the inspection. Regarding insanitary conditions, several of your proposed corrective actions appear adequate. However, some of the corrective actions described in your response are inadequate to correct the insanitary conditions noted at your facility. For example, in your response to the observation that you use non-sterile wipes in the aseptic processing area, you indicated that you have ordered a wipe that, although not sterile, is laundered and packaged in a clean room. The item purchased is specified to be for use in ISO 5-6 environments. The use of non-sterile wipes increases the potential for contamination to be introduced into the aseptic processing area and is an insanitary condition. In addition, in your response you believe no corrective action is needed to address the observation regarding the sporicidal agent you use in the aseptic processing area is inadequate. Neither your response nor your policy supports the effectiveness of the agent at sporicidal disinfection when used at the concentration and for the contact time in your policy. Also, the documentation provided in your response does not establish smoke studies were performed under dynamic conditions during your latest certification.

Please be aware that Section 501(a)(2)(A) of the Act concerning insanitary conditions applies regardless of whether the drugs are compounded and distributed after receipt of a valid prescription for an identified-individual patient.

FDA strongly recommends 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 processing expertise could be useful in conducting this comprehensive evaluation.

In addition, your response indicated your firm ceased compounding and distributing products without a prescription for an individually identified patient on May 15, 2015 (*i.e.,* 3 days prior to FDA's initiation of the inspection of your facility on May 18, 2015). We also note you informed the investigator during the inspection you have ceased compounding and distributing products containing domperidone.

If you were to resume manufacture and distribution of drug products without valid prescriptions for individually-identified patients or of drug products containing domperidone, the manufacture of such drugs would be subject to FDA's drug CGMP regulations (21 CFR 210 and 211), among other requirements. Before resuming such operations, you should fully implement corrections which meet the minimum requirements of 21 CFR 211 in order to provide assurance the drug products produced by your firm conform to basic standards regarding safety, identity, strength, quality, and purity. Such drug products would also be subject to the requirement to be labeled with adequate directions for use in Section 502(f)(1) of the Act, among other requirements of the Act.

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.

In addition, we note your firm used a multiple purpose, household glue as a component within one of your topical drug products. We are concerned with this practice and request documentation that this component is appropriate for use within a topical drug product.

Within 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 the reference number listed above and 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 Act, 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.

If you have questions regarding any issues in this letter, please contact Compliance Officer Kari Batey via email at Kari.Batey@fda.hhs.gov or by phone at 615-366-7808. Please address your reply to Kari L. Batey, Compliance Officer, at the address above.

Sincerely,
/S/
Ruth P. Dixon
District Director
New Orleans District

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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 bulks 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 and licensed physicians that compound human drug products using bulk drug substances that do not otherwise meet the conditions of 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 pharmacist, 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 bulks list. These conditions include that the substance may be eligible for inclusion on the 503A bulks list, was nominated with sufficient supporting information for FDA to evaluate it, and that it 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.