Wellcare Rx Investments LLC dba Denson's Specialty Pharmacy 9/30/16

Chicago District Office
550 W. Jackson Blvd., 15th Floor
Chicago, IL 60661
Telephone: (312) 353-5863
Fax: (312) 596-4187

September 30, 2016

WARNING LETTER

CHI-14-16

VIA UPS NEXT DAY
SIGNATURE REQUIRED

Mr. Inayat Patel, Registered Agent and Co-owner
Mr. Koshy Mathew, Co-owner
Ms. Mariam Meah, Co-owner
Ms. Nuzhuth Siddiqui, Co-owner
Wellcare Rx Investments LLC dba Denson's Specialty Pharmacy
200 E. Willow Ave.
Wheaton, IL 60187-5463

Dear Messrs. Patel and Mathew and Mses. Meah and Siddiqui:

From August 12, 2015, to November 19, 2015, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your facility, Wellcare Rx Investments LLC dba Denson's Specialty Pharmacy, located at 200 E Willow Ave., Wheaton, IL 60187-5463.

During the inspection, the investigator noted that you were not receiving valid prescriptions for individually-identified patients for a portion of the drug products you were producing. In addition, the investigator observed serious deficiencies in your practices for producing sterile

drug products, which put patients at risk. For example, our investigator noted that your facility is not adequately designed for sterile drug production. Specifically, your laminar airflow hood, where aseptic production occurs, is located in an unclassified room that does not contain any HEPA filtration. The investigator also noted within this room a laminate-covered wood ledge and two wooden carts, which may harbor contamination, and are located in close proximity to the ISO 5 area. In addition, the investigator observed poor aseptic practices, such as an operator opening packages of sterile items outside of the laminar airflow hood, thus exposing those sterile items to unclassified room air, as well as an operator transferring items into the laminar airflow hood without being disinfected. Furthermore, your firm failed to demonstrate through appropriate studies that your 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 November 19, 2015. An amended Form FDA 483 was issued to your firm on January 6, 2016. FDA acknowledges receipt of your facility's response to the Form FDA 483 dated December 7, 2015, your decision to cease sterile compounding on October 7, 2015, and your action on December 9, 2015, to voluntarily recall all sterile drug products within expiry.

Based on this inspection, it appears that you have produced 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 may 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 necessary to qualify for the exemptions under section 503A.

During the FDA inspection, the investigator observed that your firm does not receive valid prescriptions for individually-identified patients for a portion of the drug products you produce.

Accordingly, the drugs you compound without valid prescriptions for individually identified patients are not entitled to the exemptions in section 503A.

In addition, we remind you that there are other conditions that must be satisfied to qualify for the exemptions in section 503A of the FDCA.[1]

B. Violations of the FDCA

The drug products that you manufacture and distribute without valid prescriptions for individually-identified patients are misbranded drugs in violation of 502(f)(1) of the FDCA. 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) [21 U.S.C. § 351(a)(2)(A)] of the FDCA. Furthermore, because you manufacture and distribute a portion of your drugs without valid prescriptions for individually-identified patients, the manufacture of such drugs is also subject to FDA's CGMP regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. The FDA investigator observed significant CGMP

violations at your facility, causing such drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA.

Misbranded Drug Products

You compound drug products for which you have not obtained valid prescriptions for individually-identified patients 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, the FDA investigator observed that drug products that are 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 investigator noted that your facility is not adequately designed for sterile drug production. Specifically, your laminar airflow hood, where aseptic production occurs, is located in an unclassified room that does not contain any HEPA filtration. The investigator also noted within this room a laminate-covered wood ledge and two wooden carts, which may harbor contamination, and are located in close proximity to the ISO 5 area. In addition, the investigator observed poor aseptic practices, such as an operator opening packages of sterile items outside of the laminar airflow hood, thus exposing those sterile items to unclassified room air, as well as an operator transferring items into the laminar airflow hood without being disinfected. Furthermore, your firm failed to demonstrate through appropriate studies that your hood is able to provide adequate protection of the ISO 5 area in which sterile products are processed.

The FDA investigator 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 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)).
2. 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)).
3. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).
4. Your firm failed to ensure that manufacturing personnel wear clothing appropriate to protect drug product from contamination (21 CFR 211.28(a)).
5. Your firm failed to establish and follow a 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(k) of the FDCA, it is a prohibited 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 acknowledge your action on October 7, 2015, to permanently discontinue sterile drug production and your action on December 9, 2015, to voluntarily recall all sterile drug products within expiry. FDA further acknowledges receipt of your response to the Form FDA 483 inspectional observations, dated December 7, 2015.

If you decide to resume production of sterile drugs, 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.

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. You must correct all insanitary conditions at your firm.

If you were to continue to manufacture and dispense 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), among other requirements described above, 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 that ensure safety, identity, strength, quality, and purity.

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 and FDA regulations.

If you decide to resume sterile operations, you should take prompt action to correct the violations cited in this letter relating to sterile compounding. 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. 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 15 working days prior to resuming production of any sterile drugs in the future. Your written notification should be addressed to:

Russell Riley, Compliance Officer
FDA Chicago District Office

U.S. Food and Drug Administration
550 W. Jackson Blvd., Suite 1500
Chicago, IL 60661

Refer to the Unique Identification Number (CMS# 506635) when replying. If you have questions regarding any issues in this letter, please contact Mr. Riley via email at russell.riley@fda.hhs.gov or by phone at (312) 596-4219.

Sincerely,
/S/
William R. Weissinger
District Director

---

[1]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.