WARNING LETTER

Empower Clinic Services, LLC

MARCS-CMS 516718 — MAY 25, 2017

Recipient:

Empower Clinic Services, LLC

United States

Issuing Office:

Dallas District Office

United States

U.S. FOOD & DRUG ADMINISTRATION

Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 900
Dallas, Texas 75204

May 25, 2017

CMS Case # 516718

WARNING LETTER

VIA UPS EXPRESS

Arta Shaun Noorian, Owner
Empower Clinic Services, LLC dba Empower Pharmacy
5980 W Sam Houston Parkway N, Suite 300
Houston, Texas 77041

Dear Mr. Noorian:

From November 9, 2015, to November 25, 2015, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Empower Clinic Services, LLC, dba Empower Pharmacy, located at 12123 Jones Rd., Houston, Texas 77070-5208. 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. Specifically, the investigators noted that you did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced. 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 November 25, 2015. FDA acknowledges receipt of your facility's response, dated December 18, 2015. Based on this inspection, it appears that you are producing drug products that violate the FDCA.

FDA further acknowledges that Empower Clinic Services, LLC registered a facility located at 5980 West Sam Houston Pkwy North, Suite 300, Houston, Texas 77041, as a 503B outsourcing facility on July 16, 2016, after the November 9, 2015 to November 25, 2015 inspection.

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 practices (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 of the FDCA. 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 of the FDCA 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 [21 U.S.C. § 351(a)(2)(A)]. For example, the investigators observed the transfer of partially stoppered vials filled with **(b)(4)** drug products from an ISO 5 hood to a **(b)(4)** located within an ISO 7 area, thereby exposing those sterile drug products to environmental conditions that do not meet ISO 5 standards.

Furthermore, the manufacture of the ineligible drug products is subject to FDA's CGMP regulations, Title 21, Code of Federal Regulations (CFR), parts 210 and 211. The FDA investigators observed significant CGMP violations at your facility, causing the ineligible drugs products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA [21 U.S.C. § 351(a)(2)(B)]. The violations included, 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 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)).

3. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing area (21 CFR 211.42(c)(10)(iv)).

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

5. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], 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 [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 adulterated.

Unapproved New Drug Products

You do not have any FDA-approved applications on file for the ineligible drug products that you compounded.[2] Under sections 505(a) and 301(d) of the FDCA [21 U.S.C. § 355(a) and § 331(d)], 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. Marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

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. The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA. It is also 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 misbranded.

D. Corrective Actions

We have reviewed your firm's response to the Form FDA 483. In that response you stated that you "performed smoke studies on December 7, 2015, demonstrating the air flow pattern of air supply **(b)(4)** of ISO 5 hood to the **(b)(4)**" and "no particulate count was found inside the **(b)(4)** once the **(b)(4)** was located directly in front of the ISO 5 hood where vials are introduced." We cannot fully evaluate whether the corrective actions taken were sufficient because your response did not include the supporting documentation, such as a video of the smoke studies done while the vials were being transferred from the ISO 5 area into the **(b)(4)**.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether the drug products you compound meet the conditions of 503A, including the condition on receipt of a valid prescription for an identified-individual patient prior to compounding and distributing drug products.

Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations. Before doing so, you must comply with the requirements of section 505 and 502(f)(1) and fully implement corrections that meet the minimum requirements of the CGMP regulations.

FDA strongly recommends that your management first undertake a comprehensive assessment of 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.

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 written notification should refer to the Warning Letter Number above (**CMS Case # 516718**).

Please address your reply to John W. Diehl, Acting Director, Compliance Branch at the FDA address provided on the first page of this letter. In addition, please submit a signed copy of your response on your firm's letterhead to john.diehl@fda.hhs.gov (https://wayback.archive-it.org/7993/20201219000611/mailto:john.diehl@fda.hhs.gov) (https://wayback.archive-it.org/7993/20201219000611mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer).

If you have questions regarding the contents of this letter, please contact John W. Diehl at (214) 253-5288.

Sincerely,
/S/
Monica R. Maxwell
Acting Program Division Director
Office of Pharmaceutical Quality Operations, Division II

CC:

Gay Dodson, RPh, Executive Director
Texas State Board of Pharmacy
William P. Hobby Building
Tower 3, Suite 600
333 Guadalupe Street
Austin, Texas 78701

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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.
[2] The specific products made by your firm are drugs within the meaning of section 201(g) of the Act, [21 U.S.C. § 321(g)] 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) [21 U.S.C. 321(p)] of the FDCA because they are not generally recognized as safe and effective for their labeled uses.

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