HHCS Pharmacy, Inc., dba Freedom Pharmacy 5/14/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration

Florida District

555 Winderley Place, Suite 200

Maitland, Florida 32751

Telephone: 407-475-4700

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VIA UPS NEXT DAY AIR

w/ DELIVERY CONFIRMATION

WARNING LETTER

FLA-15-26

May 14, 2015

N. Lois Adams, CRPh, MBA

President/CEO

HHCS Pharmacy, Inc., dba Freedom Pharmacy

3901 E. Colonial Drive

Orlando, FL 32803-4602

Dear Ms. Adams:

From July 14, 2014, to July 28, 2014, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, HHCS Pharmacy, Inc., dba Freedom Pharmacy, located at 3901 E. Colonial Drive, Orlando, FL 32803-4602. During this 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. In addition, the investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, the investigators observed the ceiling tiles in the ISO 7 and ISO 8 areas to be unsealed. The investigators found your firm does not monitor air pressure differentials in the ISO 7 and ISO 8 areas throughout the day, only infrequently performs environmental monitoring in ISO 5 areas, and infrequently performs personnel monitoring of operators involved in the aseptic production of sterile drugs. In addition, your firm failed to utilize a sporicidal cleaning agent to disinfect the ISO 5 laminar airflow workstations. Also, your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 areas in which sterile products are processed. Therefore, your products may be produced in an environment that poses a significant contamination risk. A Form FDA483 was issued to your firm on July 28, 2014. We acknowledge receipt of your firm's responses to the Form FDA 483, dated August 14 and 15, 2014.

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 are entitled to exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP), 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. Accordingly, the drugs you compound without valid prescriptions for individually identified patients are not entitled to 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 section 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 those drugs is subject to FDA's Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals, Title 21, *Code of Federal Regulations* (CFR), Parts 210 and 211. FDA investigators observed significant CGMP violations at your facility, causing your drug product(s) to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA [21 U.S.C. § 351(a)(2)(B)].

Misbranded Drug Products

Because the drug products for which you have not obtained valid prescriptions for individually-identified patients are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written for them 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.

Adulteration Charges

Additionally, FDA investigators observed that your sterile drug products 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, the investigators observed the ceiling tiles in the ISO 7 and ISO 8 areas to be unsealed. The investigators found your firm does not monitor air pressure differentials in the ISO 7 and ISO 8 areas throughout the day and only infrequently performs environmental monitoring in ISO 5 areas and infrequently performs personnel monitoring of operators involved in the aseptic production of sterile drugs. In

addition, your firm failed to utilize a sporicidal cleaning agent to disinfect the ISO 5 laminar airflow workstations. Also, your firm failed to demonstrate through appropriate studies that your hoods are able to provide adequate protection of the ISO 5 areas 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 observed 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 perform operations within specifically defined areas of adequate size and to have separate or defined areas or such other control systems necessary to prevent contamination or mix-ups in aseptic processing areas (21 CFR 211.42(c)(10)).

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 of the components used to make the drug and results in the drug being adulterated.

C. Corrective Actions

We have reviewed your firm's planned corrective actions, as documented in your August 15, 2014 response to the Form FDA-483 Inspectional Observations issued at the close of the inspection, and determined that they do not meet the minimum requirements of 21 CFR 210 and 211 and are inadequate to correct the observed insanitary conditions at your facility. For example, while you state you have replaced the ceiling tiles that were observed to be cracked, water damaged or porous in the ISO 8 area, you have stated in your response to the FDA form 483 that you do not intend to seal the ceiling area because to do so would render the HEPA filters inaccessible. HEPA filters should be accessible without disrupting the ceiling tiles.

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 your response, you state that you "do not manufacture or process drug products per our 503A permit." However, as discussed above, your firm has manufactured and distributed drugs without valid prescriptions for individually-identified patients. These drug products do not qualify for the exemptions under section 503A and the manufacture of such drugs is subject to FDA's finished drug product CGMP regulations, 21 CFR parts 210 and 211.

In addition, you should also correct the violations 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 and 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 the corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be completed. Your written notification should be addressed to: Andrea Norwood, Compliance Officer , FDA Florida District Office, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, FL 32751. If you have questions regarding any issues in this letter, please contact Ms. Norwood via email at **andrea.norwood@fda.hhs.gov** or by phone at 407-475-4724.

Sincerely,

/S/

Susan M. Turcovski

Director, Florida District

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[1]The CQA contains a number of other provisions, including new exemptions and requirements for compounders seeking to operate as outsourcing facilities. A discussion of the CQA and the agency's plans to implement the new law may be found at **http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Pharmacy** Compounding/default.htm