The Wellness Pharmacy LLC 3/23/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive; Suite 101
Baltimore, MD 21215

WARNING LETTER

March 23, 2016

WL# 483891

Russell T. Lederhouse, Owner
The Wellness Pharmacy, LLC
2228 Papermill Road, Suite E
Winchester, VA 22601-3681

Dear Mr. Lederhouse:

From March 9, 2015, to March 12, 2015, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your facility, The Wellness Pharmacy, LLC, located at 2228 Papermill Road, Suite E, Winchester, Virginia. 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, the investigator observed an ISO 5 **(b)(4)** located in an unclassified room. The investigator also noted that your firm uses non-sterile gloves in the **(b)(4)** for the production of sterile products. In addition, the investigator noted that your firm used non-sterile wipes to clean the **(b)(4)**. Furthermore, the investigator noted that your firm failed to demonstrate through appropriate studies that your **(b)(4)** 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 March 12, 2015. FDA acknowledges your facility's response dated March 16, 2015 and your statement in your response that as of March 12, 2015, your firm "has hereby agreed to cease and desist compounding sterile products altogether."

Based on this inspection, it appears that you 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 qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practices (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 investigator noted 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.

In addition, 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.

B. Violations of the FDCA

The drug products 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) 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 investigator 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.

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 noted that the 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, the investigator observed an ISO 5 **(b)(4)** located in an unclassified room. The investigator also noted that your firm uses non-sterile gloves in the **(b)(4)** for the production of sterile products. In addition, the investigator noted that your firm used non-sterile wipes to clean the **(b)(4)**. Furthermore, the investigator noted that your firm failed to demonstrate through appropriate studies that your **(b)(4)** 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 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 an adequate system for maintaining equipment used to control the aseptic conditions (21 CFR 211.42(c)(10)(vi)).
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 establish an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions (21 CFR 211.42(c)(10)(v)).
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 an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

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 receipt of your response to the Form FDA 483 dated March 16, 2015, in which you state, as noted previously, that as of March 12, 2015, your firm "has hereby agreed to cease and desist compounding sterile products altogether."

If you decide to resume production of sterile drugs, FDA strongly recommends that your management 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 should correct all insanitary conditions at your firm before you resume sterile drug production.

In addition, if you 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 Parts 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 regarding safety, identity, strength, quality, and purity.

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.

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 (15) 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 refer to the Warning Letter Number above (483891). Please address your reply to Ernest F. Bizjak, Compliance Officer, at the address above.

If you have questions regarding the contents of this letter, please contact Mr. Bizjak by email at ernest.bizjak@fda.hhs.gov or by phone at 301-796-4081.

Sincerely,
/S/
Evelyn Bonnin
District Director
Baltimore District

CC:
Caroline D. Juran, R.Ph., Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Ste 300
Henrico, VA 23233