Green Hills Health and Wellness Pharmacy Inc 6/4/15

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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June 4, 2015
WARNING LETTER NO. 2015-NOL-10

UNITED PARCEL SERVICE
Delivery Signature Requested

Mark F. Binkley, D.Ph., Co-Owner
Green Hills Health and Wellness Pharmacy, Inc.
dba Health and Wellness Compounding Pharmacy
329 21st Avenue North, Suite 3
Nashville, Tennessee 37203-1839

Dear Dr. Binkley:

From October 14 to October 22, 2014, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, Green Hills Health and Wellness Pharmacy, Inc. (dba Health and Wellness Compounding Pharmacy), located at 329 21st Avenue North, Suite 3, Nashville, Tennessee. During the inspection, the investigators noted 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 some cleaning and disinfecting agents used for your aseptic processing areas are not sterile. Therefore, your products may be produced in an environment that poses a significant contamination risk. FDA issued a Form FDA 483, Inspectional Observations (FDA 483) to your firm on October 22, 2014. FDA acknowledges receipt of your firm's response dated November 11, 2014, to the FDA 483.

Based on this inspection, it appears 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 *United States Code* 353a] describes the conditions under which certain compounded human drug products are entitled to exemption from three Sections of the FDCA: compliance with current good manufacturing practices (CGMP), Section 501(a)(2)(B) of the FDCA [21 USC 351(a)(2)(B)]; labeling with adequate directions for use, Section 502(f)(1) of the FDCA [21 USC 352(f)(1)]; and FDA approval prior to marketing, Section 505 of the FDCA [21 USC 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 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 there are a number of other conditions which must be satisfied to qualify for the exemptions in Section 503A of the FDCA. [1]

B. Violations of the FDCA

Because the drug products you manufacture and distribute without valid prescriptions for individually-identified patients are not the subject of approved applications, they are unapproved new drugs and misbranded drugs in violation of Sections 505(a) and 502(f)(1) of the FDCA, respectively. 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 rendered injurious to health causing them to be adulterated within the meaning of Section 501(a)(2)(A) of the FDCA [21 USC 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. FDA investigators 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.

Unapproved New Drug Products

You do not have any FDA approved applications on file for the drug products for which you have not obtained valid prescriptions for individually-identified patients. [2] Under Sections 301(d) and 505(a) of the FDCA [21 USC 331(d) and 355(a)], 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. Your marketing of these products, or other applicable products, without an approved application violates these provisions 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). The introduction or delivery for introduction into interstate commerce of these products therefore violates Section 301(a) of the FDCA [21 USC 331(a)]. It is also a prohibited act under Section 301(k) of the FDCA [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

FDA investigators noted 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 investigators noted some cleaning and disinfecting agents used for your aseptic processing areas are not sterile. Therefore, your products may be produced in an environment that poses a significant contamination risk.

FDA investigators 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 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)].

5. 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)].

Under Section 301(a) of the FDCA, 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 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 November 11, 2014 response to the FDA 483 issued at the close of the inspection and determined that they are inadequate to correct the observed insanitary conditions at your facility. It is not clear if the sterile sporicidal pre-soaked towel you will require to clean the ISO 5 area will be a non-particle shedding/lint free material. In addition, it is unclear if you will continue to use self-sterilizing disinfectant outside the ISO 5 area.

We also acknowledge that in this response, you state that your firm "now requires a patient-specific prescription for all sterile and non-sterile compounded medications." 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. Should you continue to manufacture and distribute 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 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. You should also correct the violations of FDCA Sections 505(a) and 502(f)(1).

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 manufacturing expertise could be useful in conducting this comprehensive evaluation.

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.

Within 15 working days of receipt of this letter, please notify this office in writing of the specific steps 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 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 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your written notification should refer to the Warning Letter Number above (Warning Letter No. 2015-NOL-10). Please address your reply to Rebecca Asente, Compliance Officer, at the address above.

If you have questions regarding the contents of this letter, please contact Compliance Officer Asente via (504) 832-1290 extension 1104.

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

cc: Reginald "Reggie" Dilliard
Executive Director
Tennessee State Board of Pharmacy
665 Mainstream Drive
Nashville, TN 37243

[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.

[2] The specific products made by your firm are drugs within the meaning of section 201(g) of the FDCA [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases. Further, they are “new drugs” within the meaning of section 201(p) of the FDCA [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses.