Walter's Pharmacy, Inc. 1/11/17

Philadelphia District Office
900 U.S. Customhouse
200 Chestnut Street
Philadelphia, PA 19106

Telephone: (215) 597-4390
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WARNING LETTER
17-PHI-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

January 11, 2017

Howard L. Anthony, Owner
Walter's Pharmacy
401 N. 17th Street
Allentown, PA 18104-5034

Dear Mr. Anthony:

From February 9, 2016, to March 1, 2016, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your facility, Walter's Pharmacy, located at 401 N. 17th Street, Allentown, PA 18104-5034.

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 observed that your firm produced drug products intended or expected to be sterile in an uncontrolled environment on the pharmacy counter. 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 1, 2016. FDA has not received your facility's response to the Form FDA 483 as of the date of this letter. However, FDA acknowledges your action on February 12, 2016, to voluntarily recall all sterile drug products within expiry and your decision to permanently discontinue production of drug products intended to be sterile.

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 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 of the FDCA, section 505 [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 did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produce.

Accordingly, the drugs compounded without valid prescriptions for individually-identified patients are ineligible for the exemptions in section 503A of the FDCA.

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

Because the drug products that 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 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 manufactured and distributed 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 the facility, causing such 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]** Your marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA. Under sections 301(d) and 505(a) of the FDCA [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced 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.

Misbranded Drug Products

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; therefore, adequate directions for use cannot be written so that a layman can use these products safely and 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**.[3]** It is also 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. The introduction or delivery for introduction into interstate commerce of these products, therefore, violates section 301(a) of the FDCA [21 U.S.C. § 331(a)].

Adulterated Drug Products

Additionally, the FDA investigator noted that 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 may have been rendered injurious to health, causing the drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, our investigator observed that your firm produced drug products intended or expected to be sterile in an uncontrolled environment on the pharmacy counter. Therefore, your products may have been 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 air supply filtered through high-efficiency particulate air filters under positive pressure in the aseptic processing areas (21 CFR 211.42(c)(10)(iii)).
2. Your firm failed to ensure that manufacturing personnel wear clothing appropriate to protect drug products from contamination (21 CFR 211.28(a)).
3. Your firm failed to establish and follow an adequate written testing program designed to assess the stability characteristics of drug products and to use the results of such stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)).
4. Your firm failed to test samples of each component of a drug product for conformity with all appropriate written specifications for purity, strength, and quality (21 CFR 211.84(d)(2)).

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

FDA issued a Form FDA 483, Inspectional Observations, to your firm on March 1, 2016. FDA has not received your facility's response to the Form FDA 483 as of the date of this letter. However, FDA acknowledges your action on February 12, 2016, to voluntarily recall all sterile drug products within expiry. We also acknowledge your decision to permanently discontinue sterile compounding operations and your commitment to cease compounding products that are not pursuant to a prescription for an individually-identified patient.

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. You must correct all insanitary conditions at your firm's facilities if you resume sterile operations. Furthermore, should you resume distribution of 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 that ensure safety, identity, strength, quality, and purity.

In addition, you should correct the violations of sections 502(f)(1) and 505(a) 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, 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 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 correction actions, you should notify this office fifteen working days prior to resuming production of any sterile drugs in the future.

Your written response should be sent to Ms. Yvette Johnson, Compliance Officer, U.S. Food and Drug Administration, 900 U.S. Customhouse, 200 Chestnut Street, Philadelphia, Pennsylvania 19106. If you have any questions about this letter, please contact Ms. Johnson at (215)717-3077 or e-mail at Yvette.Johnson@FDA.HHS.GOV.

Sincerely,
/S/
Anne E. Johnson
District Director
Philadelphia District Office

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[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 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) of the FDCA [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses.

[3] These products are not exempt from the requirements of section 502(f)(1) of the FDCA under section 503A or regulations issued by FDA (see, e.g., 21 CFR 201.115).