American Specialty Pharmacy 6/28/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District Office
4040 North Central Expressway
Suite 300
Dallas, Texas 75204

June 28, 2016

2016-DAL-WL-27

WARNING LETTER

UPS OVERNIGHT

Abdul Hameed, Owner
American Specialty Pharmacy, Inc.
2743 W. 15th Street, Suite B
Plano, Texas 75075-7525

Dear Mr. Hameed:

From December 9, 2014, to December 19, 2014, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, American Specialty Pharmacy, located at 2743 W. 15th Street, Plano, Texas 75075-7525. This inspection was conducted after receipt of a complaint about **(b)(6)**. During the 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. The investigators also noted that your firm produces domperidone products. Domperidone is not the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, nor is it a component of an FDA-approved human drug product, and it does not appear on a list developed by the Secretary of the Department of Health and Human Services (the Secretary) under section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a(b)(1)(A)(i)(III)]. In addition, the investigators observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, our investigators observed a technician performing aseptic processing of a sterile drug product with exposed facial skin. Our investigators also observed a technician placing his head under the ISO 5 hood,

above the work surface, while processing a sterile drug product. In addition, investigators noted that your firm was reusing mop covers to clean the production areas. Furthermore, your firm failed to demonstrate through appropriate studies that the hoods are able to provide adequate protection of the ISO 5 area in which sterile products are being produced. Therefore, your products may be produced in an environment that poses a significant contamination risk.

FDA issued a FDA-483 to your firm on December 19, 2014. FDA acknowledges your action on December 12, 2014, to voluntarily recall Hydroxocobalamin Injection Solution 1mg/mL (lot #10082014@10). FDA also acknowledges your response to the FDA-483 dated January 6, 2015.

Based on this inspection, it appears that you have produced drugs that violate the 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 investigators observed that your firm does not receive valid prescriptions for individually-identified patients for a portion of the drug products you produce.

In addition, compounded drug products containing domperidone are not eligible for the exemptions under section 503A of the FDCA because domperidone is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved human drug, and does not appear on a list of bulk drug substances that may be used for compounding developed by the Secretary under section 503A of the FDCA.

Accordingly, the drugs you compound without valid prescriptions for individually identified patients, and any drug products you compound using domperidone, 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.[1]

B. Violations of the FDCA

Because the drug products you manufacture and distribute without valid prescriptions for individually-identified patients and the domperidone drug products that you manufacture and distribute 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 [21 U.S.C. §§ 355(a) and 352(f)(1)], 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 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 [21 U.S.C. § 351(a)(2)(B)].

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 or the domperidone products you produce.**[2]** Under sections 505(a) and 301(d) of the FDCA [21 U.S.C. §§ 355(a) 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. Your marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

Misbranded Drug Products

You compound domperidone products and drug products for which you have not obtained valid prescriptions for individually-identified patients, which 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 [21 U.S.C. § 352(f)(1)], 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 U.S.C, § 331(a)].

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.

Adulterated Drug Products

Additionally, FDA investigators noted that drug products that are 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, our investigators observed a technician performing aseptic processing of a sterile drug product with exposed facial skin. Our investigators also observed that a technician placed his head under the ISO 5 hood, above the work surface, while processing a sterile drug product. In addition, investigators noted that your firm was reusing mop covers to clean the production areas. Furthermore, your firm failed to demonstrate through appropriate studies that

the hoods are able to provide adequate protection of the ISO 5 area in which sterile drugs are being produced. Therefore, your products may be produced in an environment that poses a significant contamination risk.

The 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 [21 U.S.C. § 351(a)(2)(B)]. 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 monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

3. Your firm failed to reject drug product failing to meet established specifications (21 CFR 211.165(f)).

4. 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)).

5. Your firm failed to clean and, where indicated by the nature of the drug, sterilize and process containers and closures to remove pyrogenic properties to assure they are suitable for their intended use (21 CFR 211.94(c)).

6. Your firm does not 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)).

7. 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)).

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.

C. Corrective Actions

FDA acknowledges your action on December 12, 2014, to voluntarily recall Hydroxocobalamin Injection Solution 1mg/mL (lot #10082014@10). FDA further acknowledges your response to the FDA-483, dated January 6, 2015, in which Mr. James E. Hooks, Pharmacist, Sterile Division, stated that your firm was “voluntarily closing down [your] sterile lab (clean room)” effective January 9, 2015, and

“discontinuing preparation and mixing of all sterile drugs.” You should correct all insanitary conditions at your firm before you resume sterile drug production.

If you decide to resume production of sterile drugs at the 2743 W. 15th Street, Plano, Texas facility, 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 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 210 and 211), among other requirements described above, and, 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 sections 505(a) and 502(f)(1) of the FDCA [21 U.S.C. §§ 355(a) and 352(f)(1)].

FDA acknowledges that American Specialty Pharmacy, Inc., registered its facility located at 2414 Babcock Road #106, San Antonio, TX, 78229 with FDA as an outsourcing facility under section 503B of the FDCA [21 U.S.C. § 353b] on November 20, 2015.

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 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 (2016-DAL-WL-27). Please address your reply to John W. Diehl, Compliance Officer, at the address above.

If you have questions regarding the content of this letter, please contact Mr. Diehl at 214-253-5288.

Sincerely,
/S/
Amy Barringer
Acting Director, Dallas District

CC:

Gay Dodson, RPh, Executive Director
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Tom Brinck, Manager
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Texas Department of State Health Services
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Austin, Texas 78714

James E. Hooks, Pharmacist, Sterile Division
American Specialty Pharmacy
2743 West 15th Street
Plano, Texas 75075

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[1] For example, section 503A of the FDCA [21 U.S.C. § 353a] 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 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.