Inspections, Compliance, Enforcement, and Criminal Investigations

Home Intensive Care Pharmacy, Inc. 1/22/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District
4040 North Central Expressway
Suite 300
Dallas, TX 75204-3158

January 22, 2014

Ref. 2014-DAL-WL-02

WARNING LETTER

John R. Carson, President and CEO
Home Intensive Care Pharmacy, LLC
7220 Louis Pasteur Drive, Suite 168
San Antonio, TX 78229

Dear Mr. Carson:

From February 25 to March 1, 2013, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility known as Home Intensive Care Pharmacy, Inc., located at 7220 Louis Pasteur Drive, Suite 168, San Antonio, TX 78229. During the inspection, the investigators noted that you were not receiving valid prescriptions for individually-identified patients for a portion of drug products you were producing. In addition, the investigators observed significant deficiencies regarding the poor aseptic processing area design and unacceptable aseptic practices, which place sterile products at considerable risk of microbial contamination. For example, our inspection found that your firm's "ISO 5" workbenches are constructed from particleboard with a laminated surface. The laminated surface is porous and difficult to clean, and can harbor contamination. In addition, we observed a technician wearing a non-sterile laboratory coat and resting his elbows on the bench top of the "ISO 5" workbench with exposed skin from his forearm while performing aseptic processing of an intrathecal medication. These observations and others were noted on a Form FDA 483 issued on March 1, 2013.

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 exempts compounded drugs from several key statutory requirements if certain conditions are met, including receipt of valid prescriptions for individually-identified patients prior to distribution of compounded drugs.[1] During the FDA inspection, investigators observed that your firm does not receive valid prescriptions for individually-identified patients for a portion of the drug products you produce. Based on this factor alone, those drugs were not entitled to the statutory exemptions for compounded drugs described in section 503A of the FDCA.[2]

Since FDA inspected your facility, Congress enacted and the President signed into law the Compounding Quality Act (CQA)[3], which amended FDCA section 503A by eliminating the advertising restrictions that had been the basis for conflicting judicial decisions. The CQA otherwise left section 503A intact, and so clarified that the remainder of section 503A, including the requirement of valid prescriptions for individually-identified patients, is applicable in every federal judicial circuit. Accordingly, the drugs you compound without valid prescriptions for individually-identified patients are not entitled to the exemptions in section 503A.[4]

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.[5]

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) [21 U.S.C. § 352(f)(1)] of the FDCA. In addition, your sterile drug products are 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. As such, all sterile products you manufacture are 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 drugs without valid prescriptions for individually-identified patients, the manufacture of those drugs is also 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 such 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 [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 C.F.R. § 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 of the components used to make the drug and results in the drug being misbranded.

Adulteration Charges

Additionally, FDA investigators noted 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 [21 U.S.C. § 351(a)(2)(A)]. The conditions include that your firm's "ISO 5" workbenches are constructed from particleboard with a laminated surface. The laminated surface is porous and difficult to clean, and can harbor contamination. In addition, we observed a technician wearing a non-sterile laboratory coat and resting his elbows on the bench top of the "ISO 5" workbench with exposed skin from his forearm while performing aseptic processing of an intrathecal medication.

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:

CGMP violations

1. Your firm failed to ensure that manufacturing personnel wear clothing appropriate to protect drug products from contamination [21 CFR 211.28(a)].

2. Your firm failed to establish an adequate system for maintaining equipment used to control the aseptic conditions [21 CFR 211.42(c)(10)(vi)].

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 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)].

5. Your firm failed to establish an adequate system for cleaning and disinfecting the room and equipment to product aseptic conditions [21 CFR 211.42(c)(10)(v)].

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

C. 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. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

In your response to the Form FDA 483, your firm indicates plans to address our inspectional findings with corrective actions. Your firm's planned corrections do not meet the minimum requirements of 21 CFR part 211, and there is no assurance that the drug product(s) produced by your firm without valid prescriptions for individually-identified patients conform to the basic quality standards that ensure safety, identity, strength, quality, and purity. FDA strongly recommends that your management undertake a comprehensive assessment of your manufacturing operations, including facility design, procedures, personnel, processes, materials, and systems. In particular, this review should assess the acceptability of your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise could be useful in conducting this comprehensive evaluation.

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 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 implemented. Your notification should be addressed to:

Rose Ashley, Compliance Officer
FDA Dallas District Office
U.S. Food and Drug Administration
4040 North Central Expressway
Suite 300
Dallas, TX 75204-3158

If you have questions regarding any issues in this letter, please contact Mrs. Ashley at 210-308-1407.

Sincerely,
/S/
Reynaldo R. Rodriguez, Jr.
Dallas District Director

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[1] In your response to the 483, you stated that your firm's produced drugs fell within the exercise of enforcement discretion set forth in Compliance Policy Guide 460.200 on Pharmacy Compounding (CPG) (2002). While there were conflicting judicial decisions regarding the applicability of section 503A at the time FDA inspected your facility, your firm resided in the Fifth Circuit where section 503A of the FDCA applied. *Compare Western States Med. Ctr. v. Shalala*, 238 F.3d 1090 (9th Cir. 2001); *with Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383 (5th Cir. 2008). Even if the CPG applied, your firm would not have qualified for the exercise of enforcement discretion set forth in the CPG because it did not receive valid prescriptions for individually-identified patients for a portion of the drug products it produces. We also note that the CPG has been withdrawn in light of new legislation. See below.
[2] *See* 21 U.S.C. § 353a(a) (granting compounded drugs statutory exemptions if, among other things, "the drug product is compounded for an identified individual patient based on the . . . receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient . . . .").
[3]Drug Quality and Security Act, Public Law 113-54, 127 Stat. 587 (Nov. 27, 2013).
[4]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/PharmacyCompounding/default.htm.
[5] 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.

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