Inspections, Compliance, Enforcement, and Criminal Investigations

Oakdell Pharmacy, Inc 5/27/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3128

May 27, 2014

2014-DAL-WL-04

WARNING LETTER

UPS OVERNIGHT

John R. Carson, President and CEO
Oakdell Pharmacy, Inc.
7220 Louis Pasteur Drive, Suite 176
San Antonio, TX 78229

Dear Mr. Carson:

From February 25 to March 1, 2013, U.S. Food and Drug Administration (FDA) investigators conducted inspections of your facility known as Oakdell Pharmacy, Inc., located at 7220 Louis Pasteur Drive, Suite 176, San Antonio, TX 78229. FDA conducted a limited follow up inspection from January 6 to January 14, 2014, focusing on whether you were obtaining prescriptions for your compounded products and whether you were engaging in interstate distribution. During the inspections, 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 serious deficiencies in your practices for producing sterile drug products, which put patients at risk. 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, with exposed skin (forehead and neck), and resting his elbows on the bench top of the "ISO 5" workbench while performing aseptic processing of ophthalmic drops. These observations and others were noted on a Form FDA 483 issued on March 1, 2013. No 483 was issued at the end of the follow-up inspection in January 2014.

Based on these inspections, 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 inspections, 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 first 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.

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, 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 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. Examples of these 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, with exposed skin (forehead and neck), and resting his elbows on the bench top of the "ISO 5" workbench while performing aseptic processing of ophthalmic drops.

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 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 produce aseptic conditions [21 CFR 211.42(c)(10)(v)].

6. Your firm failed to ensure that its drug product bore an expiration date that was supported by appropriate stability testing (21 CFR 211.137(a)).

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

C. Corrective Actions

In your April 11, 2013 response the Form FDA 483, you reference your purported compliance with United States Pharmacopeia (USP)-National Formulary (NF) General Chapter <797> Pharmaceutical Compounding-- Sterile Preparations. As noted above, your firm has manufactured and distributed a portion of drugs without valid prescriptions for individually-identified patients, and the manufacture of such drugs is subject to FDA's drug CGMP regulations (21 CFR Parts 210 and 211). In addition, 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 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 should fully implement corrections that meet the minimum requirements of 21 CFR Part 211 in order to provide assurance that the drug product(s) 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 FDCA section 502(f)(1) 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 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.

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 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. 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 our office at 210-308-1407.

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

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[1] While there were conflicting judicial decisions regarding the applicability of section 503A at the time FDA first 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).
[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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