Carlton's Dunwoody Pharmacy Corp 8/20/17

U.S. FOOD & DRUG ADMINISTRATION

Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204

August 20, 2017
CMS Case # 512043

WARNING LETTER

VIA UPS EXPRESS
Marvin O. McCord, Owner
Carlton's Dunwoody Pharmacy Corporation
5484 Chamblee Dunwoody Rd.
Dunwoody, Georgia 30338
Dear Mr. McCord:
From January 5, 2016 to January 13, 2016, U.S. Food and Drug Administration (FDA) investigators inspected your facility, Carlton's Dunwoody Pharmacy Corp., located at 5484 Chamblee Dunwoody Rd., Dunwoody, Georgia 30338-4133. During the inspection, the investigators noted that drug products you produced failed to meet the conditions of Section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA. Specifically, the investigators noted that you did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.
FDA issued a Form FDA 483 to your firm on January 13, 2016. FDA acknowledges receipt of your facility's response to the Form FDA 483, dated January 21, 2016. Based on this inspection, it appears that you produced drug products that violate the FDCA.

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three Sections of the FDCA: compliance with current good manufacturing practices (CGMP) (Section 501(a)(2)(B)); labeling with adequate directions for use (Section 502(f)(1)); and FDA approval prior to marketing (Section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].***1*** Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under Section 503A.

B. Failure to Meet the Conditions of Section 503A

During the inspection, FDA investigators noted that drug products produced by your firm failed to meet the conditions of Section 503A. For example, the investigators

noted your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

Therefore, you compounded drug products (collectively the “ineligible drug products”) that did not meet the conditions of Section 503A and are not eligible for the exemptions in that Section from the FDA approval requirement of Section 505 of the FDCA, the requirement under Section 502(f)(1) of the FDCA that labeling bear adequate directions for use, and the requirement of compliance with CGMP under Section 501(a)(2)(B) of the FDCA.

Specific violations are described below.

C. Violations of the FDCA

Adulterated Drug Products

The manufacture of the ineligible drug products is subject to FDA’s CGMP regulations, Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. The FDA investigators observed significant CGMP violations at your facility, causing the ineligible drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the FDCA. The violations included, for example:

1. Your firm failed to establish and follow a 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)).
2. Your firm’s quality control unit failed to approve or reject all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product (21 CFR 211.22(c)).
3. Your firm failed to prepare batch production and control records with complete information relating to the production and control of each batch of drug product produced (21 CFR 211.188).
4. Your firm used instruments, apparatus, gauges, and/or recording devices that did not meet established specifications (21 CFR 211.160(b)(4)).

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.

Misbranded Drug Products

The ineligible drug products you compounded are intended for conditions 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, and they are not exempt from the requirements of Section 502(f)(1) of the FDCA (see, e.g., 21 CFR 201.115). Accordingly, these ineligible drug products are misbranded under Section 502(f)(1) of the FDCA. 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 misbranded.

D. Corrective Actions

We have reviewed your firm’s January 21, 2016, response to the Form FDA 483 observations. You have not addressed whether or not you will discontinue compounding and distributing drugs without valid prescriptions for individually-identified patients.

Should you continue to compound and distribute drug products that do not meet the conditions of Section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products

with adequate directions for use, and the drug CGMP regulations. Before doing so, you must comply with the requirements of Section 502(f)(1) and fully implement corrections that meet the minimum requirements of the CGMP regulations.1F2

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. See Section 501 of the FDCA. If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that drugs you produce are neither adulterated nor misbranded. [See 21 CFR 210.1(b), 21 CFR 200.10(b)].

E. 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 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 you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction. Your written notification should refer to the Warning Letter Number above (CMS Case # 512043).

Please address your reply to Mark W. Rivero, Compliance Officer, Compliance Branch at the FDA address provided on the first page of this letter. In addition, please submit a signed copy of your response to mark.rivero@fda.hhs.gov.

If you have questions regarding the contents of this letter, please contact Mark W. Rivero at (504) 450-3735.

Sincerely,

/S/

Monica R. Maxwell
Acting Program Division Director
Office of Pharmaceutical Quality Operations, Division II

Cc: Chris Jones, President
Georgia Board of Pharmacy
2 Peachtree Street, NW 6th Floor
Atlanta, GA 30303
and
C. Richard Allen, Director
Georgia Drugs and Narcotics Agency

254 Washington Street SW - Suite G2000
Atlanta, Georgia 30334

_____

1 We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in Section 503A of the FDCA.
2 In this letter we do not address whether your proposed corrective actions would resolve the CGMP violations noted above.