U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

McGuff Compounding Pharmacy Services, Inc. 11/13/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

November 13, 2015

WL# 6-16

Ronald M. McGuff, President/CEO
McGuff Compounding Pharmacy Services
2921 West MacArthur Blvd., Suite 142
Santa Ana, CA 92704-7944

Dear Mr. McGuff:

From December 15, 2014, to December 31, 2014, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your facility, McGuff Compounding Pharmacy Services, located at 2921 West MacArthur Blvd., Suite 142, Santa Ana, CA. 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. FDA issued a Form FDA-483 to your firm on December 31, 2014. FDA acknowledges receipt of your firm's responses to the Form FDA 483, dated January 12, 2015, January 20, 2015, February 2, 2015, February 25, 2015, March 2, 2015, and April 28, 2015.

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 [21 U.S.C. § 353a] describes the conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FDCA: compliance with current good manufacturing practice (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 necessary to qualify 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.

Accordingly, the drugs you compound without valid prescriptions for individually identified patients are not entitled to 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

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) of the FDCA.

Misbranded Drug Products
You compound drug products for which you have not obtained valid prescriptions for individually-identified patients that 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, 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 and results in the drug being misbranded.

D. Corrective Actions

FDA acknowledges receipt of your response to the FDA Form 483 dated April 28, 2015, in which you indicate that your firm has completed its "[c]onversion to 100% Patient Prescription Orders," and "will no longer take orders for 'office use'."

If you continue to manufacture and distribute drug products without valid prescriptions for individually-identified patients, the manufacture of such drugs would be subject to FDA's drug CGMP regulations for Finished Pharmaceuticals, Title 21, *Code of Federal Regulations* (CFR), Parts 210 and 211, among other requirements described above.

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 the corrective actions cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your written notification should be addressed to:

Daniel Cline, Acting Director, Compliance Branch
FDA Los Angeles District Office
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

If you have questions regarding any issues in this letter, please contact Jessica Mu via email at Jessica.mu@fda.hhs.gov or by phone at 949-608-4477.

Sincerely,
/S/
LCDR Steven Porter, Acting Director
Los Angeles District

Cc:
Virginia Herold, Executive Officer
California State Board of Pharmacy
1625 N. Market Boulevard, Suite N-219
Sacramento, CA 95834

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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.

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