U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

November 22, 2017

CMS Case # 524736

UPS Overnight

Ernesto F. Garza-Gongora II, Owner
Stone Oak Pharmacy LP
18866 Stone Oak Parkway, Suite 101
San Antonio, Texas 78258-4181

Dear Mr. Garza-Gongora:

From November 28, 2016, to December 6, 2016, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Stone Oak Pharmacy LP, located at 18866 Stone Oak Parkway, Suite 101, San Antonio, TX 78258-4181. During the inspection, the investigator 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 Act.

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.

In addition, for a compounded drug product to qualify for the exemptions under Section 503A, bulk drug substances used to compound it must: (I) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (II) if such a monograph does not exist, be components of drugs approved by the Secretary; or, (III) if such a monograph does not exist and the drug substance is not a

[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.

component of a drug approved by the Secretary, appear on a list developed by the Secretary through regulations ("503A bulks list")(Section 503A(b)(1)(A)(i) of the FDCA).

B. Failure to Meet the Conditions of Section 503A

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

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

2. Your firm compounded drug products using acidophilus lactobacillus, melatonin, and (b) (4) ((b) (4)). Drug products compounded using acidophilus lactobacillus, melatonin, and (b) (4) (b) (4)) are not eligible for the exemptions provided by Section 503A(a), because these bulk drug substances are not subjects of applicable USP or NF monographs, are not components of FDA-approved human drugs, and do not appear on the 503A bulks list.[2]

Therefore, you compounded drug products that do 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. In the remainder of this letter, we refer to your drug products that do not qualify for exemptions under Section 503A as the "ineligible drug products". Specific violations are described below.

C. Violations of the FDCA

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

[2] On June 9, 2016, FDA issued a final guidance titled, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. This guidance describes FDA's interim regulatory policy for State-licensed pharmacies, Federal facilities, and licensed physicians that compound human drug products using bulk drug substances that do not otherwise meet the conditions of Section 503A(b)(1)(A)(i) while the 503A bulks list is being developed. Specifically, the guidance sets out the conditions under which FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician for compounding a drug product using a bulk drug substance that is not the subject of an applicable USP or NF monograph or a component of an FDA-approved drug, until the substance is identified in a final rule as included or not included on the 503A bulks list. These conditions include that the substance may be eligible for inclusion on the 503A bulks list, was nominated with adequate support for FDA to evaluate it, and has not been identified by FDA as a substance that appears to present significant safety risks pending further evaluation. Grape seed oil was nominated for inclusion on the 503A bulks list; however, it was not nominated with adequate support for FDA to evaluate the substances. For additional information, see the guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf.

adequate directions for their intended uses.[3] 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

Regarding issues related to the conditions of Section 503A of the FDCA, the following corrective action appears adequate: During the inspection close-out discussion with the FDA investigator, you stated that your firm would stop production of acidophilus lactobacillus and melatonin immediately.

As explained above, receipt of valid prescriptions for individually-identified patients is a condition of Section 503A, which your firm failed to meet for a portion of the drug products you produced. Additionally, as noted above, drug products compounded using (b) (4) ((b) (4)) are not eligible for the exemptions provided by Section 503A of the FDCA because (b) (4) ((b) (4)) 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 the 503A bulks list.

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.

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.

Within thirty (30) 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 the corrective actions within thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

[3] Your ineligible drug products are not exempted from the requirements of Section 502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR 201.115).

Your written response should be sent to Shawn E. Larson, Acting Compliance Officer, U.S. Food and Drug Administration, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204. Your written notification should refer to the **CMS Case # 524736**. In addition, please submit a signed copy of your response to Shawn.Larson@fda.hhs.gov. If you have questions regarding the contents of this letter, please contact Mr. Larson by phone at (214) 253-5216.

Sincerely,

Vincent M. Williams -S

Digitally signed by Vincent M. Williams -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300092435, cn=Vincent M. Williams -S
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