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

VIA SIGNATURE CONFIRMED DELIVERY

October 1, 2020

Gregory A. Maag, Owner
Maag Prescription Center LLC
dba Maag Prescription and Medical Supply
333 West Center Street
Pocatello, ID 83204-3243

Dear Mr. Maag:

From September 19, 2018, to September 28, 2018, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Maag Prescription Center LLC dba Maag Prescription and Medical Supply, located at 333 West Center Street, Pocatello, Idaho 83204-3243.

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 FDCA. In addition, the investigator noted deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on September 28, 2018. FDA acknowledges receipt of your facility's response, dated October 7, 2018, as well as your subsequent correspondence. 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 practice (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.

[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.

Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road, Irvine, CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417
www.fda.gov

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 noted that 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 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

Adulterated Drug Products

The FDA investigator noted that 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. For example, the investigator observed that:

1. Your firm failed to confirm the quality of (b) (4) was suitable for its intended use in the production of non-sterile drug products. In addition, non-pharmaceutical grade components, including (b) (4) , were used in the production of non-sterile drug products.

2. Hazardous drugs were produced without providing adequate containment, segregation, or cleaning of work surfaces and utensils to prevent cross-contamination.

3. An operator touched their bare wrist with a spatula and continued to use the same spatula to mix product without cleaning or replacing the spatula.

4. Spatulas used in non-sterile drug production had cracked wooden handles and were discolored. In addition, the screws connecting the wooden handle to the spatula appeared to be rusted.

On May 23, 2018, FDA received a report regarding adverse events reportedly experienced by a patient who was hospitalized after ingesting "Urinary Antiseptic Capsules" (Hyoscyamine, Methenamine, and Methylene Blue) produced by your firm.

During the inspection, FDA collected and subsequently analyzed samples labeled as "Urinary Antiseptic Capsules." FDA analysis determined that the capsules contained on average approximately 83.9% of the labeled concentration of Hyoscyamine and 72.9% of the labeled concentration of Methylene Blue, which is below the label claim. Under section 501(c) of the FDCA [21 U.S.C. § 351(c)], a drug is adulterated if it does not purport to be or is not represented as a drug the name of which is recognized in an official compendium and its strength differs from, or its quality or purity falls below, that which it purports or is represented to possess. The strength of the Hyoscyamine and Methylene Blue differed from the labeled amount the product was purported to possess, causing it to be adulterated under section 501(c) of the FDCA.

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.[2] 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 responses to the Form FDA 483. Regarding your responses related to the insanitary conditions, we cannot fully evaluate the adequacy of the following corrective actions described in your responses because you did not include sufficient information or supporting documentation:

1. You stated that you are using "(b) (4) " and have obtained "(b) (4) (b) (4)," however you did not provide supporting documentation, such as training material, training logs, purchase orders, invoices, or updated copies of your SOPs.

2. You stated that your firm is using (b) (4) for cleaning of work surfaces and shared equipment to prevent cross-contamination, and that gowning, eye protection, and face masks will be cleaned and replaced "during production of compounded hazardous and non-hazardous compounds to prevent cross-contamination." However, you did not provide supporting documentation,

[2] 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).

such as training material, training logs, purchase orders, invoices, or updated copies of your SOPs.

3. In your response, you stated that your firm purchased new spatulas and that spatulas will be replaced “if any spatula touches bare skin.” However, you did not provide supporting documentation such as training materials, training logs, purchase orders, invoices, or updated copies of your SOPs.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A, including the condition on receipt of a prescription for an identified individual patient prior to compounding and distributing drug products.

In addition, regarding issues related to the conditions of section 503A of the FDCA, we acknowledge your statement that “prescriptions compounded for office stock is discontinued.”

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

Send your electronic reply to ORAPharm4_responses@fda.hhs.gov or mail your reply to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road
Irvine, CA 92612-2506

Please identify your response with unique identifier **586881**

If you have questions regarding any issues in this letter, please contact Ms. Maria P. Kelly-Doggett, Compliance Officer via email to maria.kelly-doggett@fda.hhs.gov or by phone at (425) 302-0427 and reference unique identifier **586881**.

Sincerely,

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP: mpk