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# Spoonamore Drug Co Inc 12/18/15

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**Department of Health and Human Services**

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
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**VIA UPS**

**WARNING LETTER**
**CIN-16-455964-04**

December 18, 2015

Steven D. Williams, President
Spoonamore Drug Co. Inc., dba
Louisville Pharmacy and Custom Script
4014 Dutchmans Lane, Suite II
Louisville, KY 40207

Dear Mr. Williams:

From January 13, 2015, to February 3, 2015, a Food and Drug Administration (FDA) investigator conducted an inspection of your facility located at 4014 Dutchmans Lane, Suite 11, Louisville, Kentucky. During the inspection, the investigator noted that you were not receiving valid prescriptions for individually-identified patients for a portion of the drug products you were producing. In addition, the investigator observed serious deficiencies in your practices for producing sterile drug products, which put patients at risk. For example, your firm did not use a sporicidal agent as part of the disinfection program for the clean room and the ISO 5 area. In addition, the investigator found that your firm failed to monitor the pressure differential between the ISO 7 cleanroom and ISO 8 anteroom. Therefore, your products may be produced in an environment that poses a significant contamination risk.

FDA issued a Form FDA 483 to your facility on February 3, 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 investigator 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.[1]

The FDA investigator observed that your firm had produced domperidone products as recently as November 2014, but was not producing domperidone products at the time of the inspection. We acknowledge your statement to the investigator during the inspection that your firm has ceased all domperidone production. Compounded drug products containing domperidone are not eligible for the exemptions under section 503A of the FDCA because domperidone 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 a list of bulk drug substances that may be used for compounding developed by the Secretary.

### B. Violations of the FDCA

Because the drug products that you manufacture and distribute without valid prescriptions for individually-identified patients are not the subject of approved applications, they are unapproved new drugs and misbranded drugs in violation of sections 505(a) and 502(f)(1) of the FDCA, respectively. In addition, your drug products that are intended or expected to be sterile were 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, causing them to be adulterated within the meaning of section 501(a)(2)(A) of the FDCA [21 U.S.C. § 351(a)(2)(A)]. Furthermore, because you manufacture and distribute drugs without valid prescriptions for individually-identified patients, the manufacture of those drugs is subject to FDA's Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations (CFR), Parts 210 and 211. The FDA investigator 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.

### Unapproved New Drug Products

You do not have any FDA-approved applications on file for the drug products for which you have not obtained valid prescriptions for individually-identified patients.**2** Under sections 301(d) and 505(a) of the FDCA [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. Your marketing of these products, or other applicable products, without an approved application violates these provisions 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)(l) of the FDCA (see, e.g., 21 CFR § 201.115). The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA [21 U.S.C. § 331(a)]. It is also 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.

### Adulterated Drug Products

The FDA investigator noted that drug products in your facility that were intended or expected to be sterile 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, your firm did not use a sporicidal agent as part of the disinfection program for the clean room and the ISO 5 area. In addition, the investigators found that your firm failed to monitor the pressure differential between the ISO 7 cleanroom and ISO 8 anteroom. Therefore, your products may be produced in an environment that poses a significant contamination risk.

The FDA investigator also observed 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 establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).
2. 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)).
3. Your firm failed to ensure that manufacturing personnel wear clothing appropriate to protect drug product from contamination (21 CFR 211.28(a)).
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 does not have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product (21 CFR 211.167(a)).
6. Your firm does not have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product (21 CFR 211.165(a)).
7. Your firm failed to establish and follow an adequate 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)).

Under section 301(a) of the FDCA, the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, 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 adulterated.

## C. Corrective Actions

FDA has not received a written response from your firm to the Form 483. 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.

In addition, you should implement corrective actions to address the violations of FDCA sections 501(a)(2)(A), 502(f)(l), and 505(a), noted above.

### D. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of the 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 assure 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. FDA may re-inspect to ensure that your firm complies with all requirements of federal law and FDA regulations.

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 within which you will complete the correction. Your written notification should refer to the Warning Letter Number CIN-16-455964-04. Please address your reply to:

Stephen J. Rabe
Compliance Officer
U.S. Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097

If you have questions regarding the contents of this letter, please contact Mr. Rabe at 513-679-2700 (extension 2163).

Sincerely,
/S/
Steven B. Barber
District Director

Cinncinnati District

cc:
Rupa Murthy, MS, PharmD
Spoonamore Drug Co. Inc., dba
Louisville Pharmacy and Custom Script
4014 Dutchmans Lane, Suite 11
Louisville, Kentucky 40207

B. Steven Hart, Executive Director
Kentucky State Board of Pharmacy
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort, Kentucky 40601

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[1] The Compounding Quality Act (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/def

[2] The specific products made by your firm are drugs within the meaning of section 201(g) of the Act, [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases. Further, they are "new drugs" within the meaning of section 201(p) of the FDCA [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for their labeled uses.

**More in 2015**

Page Last Updated: 01/07/2016
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