



VIA ELECTRONIC MAIL
READ/DELIVERY RECEIPT REQUESTED

December 5, 2025

Joseph Bagan, Chief Executive Officer
STAQ Pharma of Ohio, LLC
255 Phillipi Road
Columbus, OH 43228-1307

Dear Mr. Bagan:

You registered your facility with the U.S. Food and Drug Administration (FDA) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b]¹ on January 26, 2023, and most recently on November 19, 2024. From May 6, 2025, to May 16, 2025, FDA investigators inspected your facility, STAQ Pharma of Ohio, LLC located at 25 Phillipi Road, Columbus, OH 43228. During the inspection, the investigators noted that drug products you produced failed to meet the conditions of section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain provisions of the FDCA. In addition, the investigators noted deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk.

FDA issued a Form FDA 483 to your facility on May 16, 2025. FDA acknowledges receipt of your facility's responses, dated June 6, 2025, and August 15, 2025. Based on this inspection, it appears you produced drugs that violate the FDCA.

A. Compounded Drug Products under the FDCA

Under section 503B(b) of the FDCA, a compounder can register as an outsourcing facility with FDA. Drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility qualify for exemptions from the drug approval requirements in section 505 of the FDCA [21 U.S.C. § 355(a)], the requirement in section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] that labeling bear adequate directions for use and the Drug Supply Chain Security Act requirements in section 582 of the FDCA [21 U.S.C. § 360eee-1] if the conditions in section 503B of the FDCA are met.²

¹ See Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

² 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 503B of the FDCA.

An outsourcing facility, which is defined in section 503B(d)(4) of the FDCA [21 U.S.C. § 353b(d)(4)], is a facility at one geographic location or address that — (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section. Outsourcing facilities must comply with other applicable provisions of the FDCA, including section 501(a)(2)(B) [21 U.S.C. § 351(a)(2)(B)], regarding current good manufacturing practice (CGMP), and section 501(a)(2)(A) [21 U.S.C. § 351(a)(2)(A)], regarding insanitary conditions. Generally, CGMP requirements for the preparation of drug products are established in Title 21 of the Code of Federal Regulations (CFR) parts 210 and 211.

In addition, for a compounded drug product to qualify for the exemptions under section 503B, the labeling of the drug must include certain information (section 503B(a)(10) of the FDCA [21 U.S.C. §353b(a)(10)]).

B. Failure to Meet the Conditions of Section 503B

During the inspection, the FDA investigators noted that drug products produced by your facility failed to meet the conditions of section 503B. For example, the investigators noted that some of your facility's drug products, including Phenylephrine Hydrochloride 1000mcg/10mL, Succinylcholine Chloride 100 mg/5mL, and Succinylcholine Chloride 200mg/10 mL did not include the following on the label or container: a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

Because your compounded drug products have not met all of the conditions of section 503B, they are not eligible for the exemptions in that section from the FDA approval requirements of section 505, the requirement under section 502(f)(1) that labeling bear adequate directions for use, and the Drug Supply Chain Security Act requirements described in section 582 of the FDCA.

Specific violations are described below.

C. Violations of the FDCA

Adulterated Drug Products

FDA investigators noted CGMP violations at your facility, that caused your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations include, for example:

1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

2. Your firm failed to establish adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

Outsourcing facilities must comply with CGMP requirements under section 501(a)(2)(B) of the FDCA. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. FDA has issued a revised draft guidance, *Current Good Manufacturing Practice — Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act*. This draft guidance, when finalized, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], 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 [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

You compound drug products that 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 causing them to be misbranded under section 502(f)(1) of the FDCA.³ 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 facility's responses to the Form FDA 483.

Some of your corrective actions appear adequate; however, we are unable to fully evaluate some of your corrective actions due to lack of adequate supporting documentation:

1. In regard to your *Sampling Plan* SOP-0052, your revision lacks sufficient detail regarding reinspection parameters. While we acknowledge that you have established more stringent parameters for a secondary Acceptable Quality Limit (AQL) inspection,

³ Your compounded 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).

the current language requires clarity. The Standard Operating Procedure (SOP) states that reinspection is permissible, “if the inspection process is capable of detecting the defect,” but does not define what constitutes process capability. You provided risk assessment documents for syringes and amber glass vials that contain more specific language; however, it is not clear if your other SOPs capture the requirements for your reinspection parameters. Incorporating the specific language and criteria from your risk assessments into the *Sampling Plan* SOP-0052 and other relevant SOPs will ensure clarity and consistency throughout all your documents.

2. Your *SOP-0051 Quality Trending and Management Review* emphasizes management review processes rather than establishing robust trending protocols. The SOP allows Quality Assurance to determine the "type" of quality data to be trended without specifically ensuring that visual inspection defects will be systematically gathered, trended, and reviewed. Your firm committed to implement (b) (4) trending of visual inspection defect rates and AQL but have failed to provide evidence of trending data for review and evaluation. Additionally, recent batch records demonstrating the implementation of changes made to your SOPs and visual inspection program were not provided for review.
3. Regarding the qualification of your (b) (4) Manual Inspection Hoods (*OH-PRT-23-023-Add02-FR*), while installation and operational qualification data were provided, performance qualification documentation did not appear to be included as well as calibration reports for light meters MTR-103 and RLR-1010. It appears your SOP, document *OH-WI-0021 (R3) Use of the (b) (4) Manual Inspection Hood-OH* does not direct your operators to measure the light intensity of each hood prior to use. In addition, batch records demonstrating visual inspection of drug products in amber vials were not provided, including documentation of light intensity settings used during inspections. Finally, it is not clear if supplemental destructive testing is performed on your sterile drug products in amber vials.

Some of your corrective actions appear deficient:

1. Your firm’s response is deficient in addressing the failure to implement adequate controls for defect identification, rejection, and investigation. Specifically, your firm failed to investigate a defect identified during 100% visual inspection and AQL sampling in a timely manner. During the AQL inspection of Dexmedetomidine Hydrochloride 4 mcg/mL, Lot 42123092A, an orange particle was identified. While your response describes investigation of a similar particle at your sister facility, it appears no further evaluation was performed on the critical defect recovered at your Ohio location. Your firm generated a memorandum outlining details of the types of defects identified during production; however, the analytical reports corresponding to the findings were not provided for review.

2. Your firm's *Visual Inspection Procedure* SOP-0009 has become globalized to incorporate visual inspection practices from your facility as well as practices from your sister facility in Colorado. Your SOP-0009 outlines defects for each product family in Table 1; further information is needed in how your firm plans to document and capture each type of defect identified during the visual inspection process, as it is not clearly stated or outlined in your SOP.

In addition, we acknowledge your efforts to standardize visual inspection practices across both facilities through your company wide program; however, your response did not provide a rationale for combining the defects of your two facilities. Furthermore, it is unclear how you will ensure that quality issues can be properly identified, investigated, and resolved at the appropriate location and for the specific product affected.

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).]

In addition, regarding issues related to the conditions of section 503B of the FDCA, your corrective actions appear adequate. Specifically, you state that "STAQ Pharm has added the active ingredients listed on the label to the list of active and inactive ingredients so that they are located in the same location to provide better clarity."

Should you continue to compound and distribute drug products that do not meet the conditions of section 503B, the compounding and distribution of your drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the Drug Supply Chain Security Act requirements.

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 any violations 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 address any violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to

U.S. Food and Drug Administration
Silver Spring, MD 20993
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address them. If you believe your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time within which you will do so.

All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. If you have questions regarding the contents of this letter, please contact compoundinginspections@fda.hhs.gov.

Sincerely,

**Frances G.
Bormel -S**

Digitally signed by Frances G.
Bormel -S
Date: 2025.12.05 09:51:55
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F. Gail Bormel, JD, RPh
Director
Office of Compounding Quality and Compliance
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