VIA ELECTRONIC MAIL
READ/DELIVERY RECEIPT REQUESTED

February 5, 2026

Millan Bhatt
Managing Director/Owner
Molecular PharmaGroup LLC
755 Central Ave, Unit 2
New Providence, NJ 07974-1116

Dear Mr. Bhatt:

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 May 8, 2018, and most recently on December 30, 2025. From July 28, 2025, to August 11, 2025, FDA investigators inspected your facility, Molecular PharmaGroup LLC, located at 755 Central Ave, Unit 2 New Providence, NJ 07974. 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 August 11, 2025. FDA acknowledges receipt of your facility's response, dated August 29, 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.

For a compounded drug product to qualify for the exemptions under section 503B, it must be compounded in an outsourcing facility that is in compliance with the registration and reporting requirements in section 503B(b), including the requirement to submit adverse event reports to FDA "in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations)" (section 503B(a)(1), (b)(5) of the FDCA [21 U.S.C. § 353b(a)(1), (b)(5)]).

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 your facility did not submit adverse event reports to FDA in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).[3] Specifically, your facility's procedures for reporting adverse events are inadequate. For example, your documented procedures for reporting adverse events do not adequately define what constitutes a serious adverse event (21 CFR 310.305(b)).

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.

[3] For more information, see, FDA's guidance, "Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act," which can be found at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434188.pdf.

Specific violations are described below.

C. Violations of the FDCA

Adulterated Drug Products

FDA investigators noted that drug products 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, the investigators observed that your firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO (b) (4) area. Therefore, your products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination.

FDA investigators also 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 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)).

2. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

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.

Unapproved New Drug Products

You do not have any FDA-approved applications on file for drug products that you compound.[4] Under sections 505(a) and 301(d) of the FDCA [21 U.S.C. §§ 331(d)] 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. 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 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.[5] The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA. Further, it is also 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 response 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. Regarding your smoke studies failing to demonstrate the viable and non-viable air monitoring systems turned on during the visualization of air dynamics of routine aseptic filling process, we acknowledge your firm's new procedure SOP S 700500 Cleanroom Certification and Smoke Study Requirements (effective date: 25AUG2025) which states "smoke studies should be conducted under simulated operational conditions to evaluate airflow patterns because of the risk for contamination of exposed product in the critical area" and "due to the fact that the Aseptic Process Simulation (APS) mimics the production process and represent a worst-case scenario. It is the basis for providing potential interventions to be conducted during the smoke studies." However, information

[4] The specific products made by your firm are drugs within the meaning of section 201(g) of the FDCA [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases and/or because they are intended to affect the structure or any function of the body. 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.

[5] 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).

for which additional APS interventions would be conducted during the smoke study remains unclear. You provided a copy of the associated risk assessment QRM-2025-003, but this document was not fully completed. A detailed and thorough risk assessment is necessary to justify and determine which representative aseptic interventions and manipulations should be included in your future smoke study.

We also acknowledge your firm's impact assessment regarding products already produced and your statement that your firm was in a state of microbial control. However, the referenced reports were not provided to support your conclusion. In addition, two deviations DEV-2025-010 and DEV-2025-02 were referenced for non-viable particle counts exceeding allowable limits. Based on your investigation summary, these events were caused by operators accidentally spraying (b) (4) and had no impact on the ISO (b) (4) environment; however, supporting documents for these deviations were not provided with your response.

2. Regarding the qualification of your (b) (4), your response provided plans to update SOP S 500400 and SOP S 403000, retrain your personnel on the newly updated procedures, and including new biological indicators (BIs) in Performance Qualification (PQ) for the (b) (4). We acknowledge your statements that you have now sourced new BIs and to test each lot of the new BIs against the manufacturer's certificate prior to use. However, you did not include supporting documents, such as a copy of your updated SOP for incoming materials and training records, new BIs purchase records, and the certificate of analysis for our review.

   We also acknowledge your statements that, "The components sterilized in the (b) (4) (b) (4) include a (b) (4), and (b) (4) …All viable air samples taken within the (b) (4)-LAFW since February 2025 to present have resulted in zero microorganisms recovered" and "All batches of Ethanol 70% Injection (v/v) undergo full sterility and endotoxin testing and environmental and personnel monitoring for each lot prior to release, adding an additional point of detection for potential component sterilization failure," but data to support your statements has not been provided.

3. Regarding your response to deficiencies identified in your environmental and personnel monitoring system, we acknowledge your firm's initiation of CAPA-2025-007 to include a risk assessment QRM-2025-002 to be performed "to determine additional environmental and personnel sampling deficiencies." However, we have not received the completed risk assessment for our review. Therefore, we cannot fully evaluate your response to this observation due to the lack of supporting documentation.

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).]

Regarding issues related to the conditions of section 503B of the FDCA, your corrective actions appear adequate. We have reviewed the revised procedures for adverse event reporting you submitted. These revised procedures appear to adequately define what constitutes a serious adverse event.

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 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,

Matthew J. Lash -S

Digitally signed by Matthew J. Lash -S
Date: 2026.02.05 10:54:49 -05'00'

Matthew J. Lash
Acting Director
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research