VIA ELECTRONIC MAIL
READ/DELIVERY RECEIPT REQUESTED

June 8, 2026

Stephan Paul Granberry
President and Chief Executive Officer
Denver Solutions, LLC dba Leiters Health
13796 Compark Blvd.
Englewood, CO 80112-7145

Dear Mr. Granberry:

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 March 24, 2017, and most recently on November 28, 2025. From November 13, 2025, to December 11, 2025, an FDA investigator inspected your facility, Denver Solutions, LLC dba Leiters Health, located at 13796 Compark Blvd., Englewood, CO 80112. During the inspection, the investigator 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 December 11, 2025. We reviewed your January 8, 2026, February 13, 2026, and March 13, 2026, responses to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence. 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.

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)

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

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.

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigator 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 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)).

2. Your firm failed to use equipment in the manufacture, processing, packing, or holding of drug products that is of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance (21 CFR 211.63).

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

4. 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)).

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.

C. 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. We acknowledge your firm is in the process of completing disinfectant efficacy studies to support the adequacy of your cleaning and disinfecting processes, with an expected completion date of June 30, 2026. However, it is unclear from the documentation provided thus far whether your firm is currently using an effective sporicidal agent within the ISO 5 syringe filler.

Some of your corrective actions appear deficient:

1. Regarding your firm's repackaging of bevacizumab, we acknowledge your firm is in the process of evaluating the use of a new (b) (4) through extractable and leachable testing and subsequent process validation and has suspended the process of (b) (4) products that fail subvisible particulate testing. However, your firm continues to repackage bevacizumab using a process that has not been adequately validated and equipment that has not been adequately qualified for its intended use and may be leaching (b) (4) particulates into the product, which is not an intended component of bevacizumab.

2. Regarding your firm's use of a (b) (4) non-viable particulate (NVP) monitoring probe in (b) (4) (Automated Syringe Filler (b) (4) we acknowledge your firm completed NVP-ASF-SP-DEN-01, Static and Dynamic Non-Viable Particle (NVP) Placement Study within Automated Syringe Filler (b) (4), and risk assessment NVP-ASF-001-(b) (4)-DEN-01, to evaluate NVP probe placement and quantity. However, you did not provide adequate justification to support your conclusion that, "the current NVP probe location and quantity is appropriate and suitable for the monitoring of nonviable particulate on (b) (4), and as such, revalidation with additional NVP probes is not warranted." For example, this conclusion is based on a single processing run and does not demonstrate consistent performance over time or under varying operational conditions in other "critical operating zones" within (b) (4) (e.g., the area of the filler that contains a syringe bowl, syringe track, and (b) (4) glove sleeves for operator interventions). This data is insufficient to demonstrate that monitoring (b) (4) with a (b) (4) NVP probe located near the filling station will ensure that other critical areas are consistently in a state of environmental control or that events posing a contamination risk during aseptic processing operations will be detected.

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).]

D. 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: 2026.06.08 08:05:22 -04'00'

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