U.S. FOOD & DRUG ADMINISTRATION

VIA ELECTRONIC MAIL
READ/DELIVERY RECEIPT REQUESTED

September 16, 2025

Michael R. Morelli
Vice President for Scientific Affairs
Sincerus Pharmaceuticals, LLC dba SKNV
3265 W. McNab Rd
Pompano Beach, FL 33069-4807

Dear Mr. Morelli:

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 10, 2016, and most recently on November 22, 2024. From February 13, 2025, to March 6, 2025, an FDA investigator inspected your facility, Sincerus Pharmaceuticals, LLC dba SKNV located at 3265 W. McNab Road, Pompano Beach, FL 33069. During the inspection, the investigator noted deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your facility on March 6, 2025. FDA acknowledges receipt of your facility's response, dated March 27, 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]

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

[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.

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.

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 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 have separate or defined areas or such other control systems necessary to prevent contamination or mix-ups (21 CFR 211.42(c)).

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 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:

We acknowledge your corrective actions to ensure adequate documentation of media fill failure investigations, including revising *SOP SC-22 Aseptic Media Fill Verification*. However, this revised SOP was not provided for our review. We also reviewed your *Quality Investigation Q125-07*, but it did not appear to have been reviewed and approved by your Quality team. In addition, we acknowledge receipt of your draft *SOP NC-227 (Rev 01) GMP Cleaning* and your proposed implementation date of April 2025. However, you have not provided the finalized document and staff training records for our review.

Some of your corrective actions appear deficient:

Regarding your firm's failure to conduct a timely investigation into the differential pressure deviations identified before and after production of Magnesium Sulfate for Injection, Lot# 63702, you provided a quality investigation reporting form F-QA-03, quality investigation number: Q125-09, with an initiated date of February 21, 2025. We reviewed your investigation report and acknowledge your assessment that, "there is no expected impact to the finished compounded product." While your firm noted in Logbook 252-2024, "DP alarms triggered during cleanroom restocking and preparatory activities prior to batch compounding on 19SEP24, and after batch compounding was completed, during cleanroom cleaning activities only," this does not explain why an investigation was not performed promptly. When the pressure differential drops below the minimum limit, it is important that the environmental quality of the aseptic processing room be restored and confirmed. All alarms should be documented and deviations from established limits should be investigated in a timely manner. Additionally, you did not provide sufficient supporting documentation for our review, such as evidence of the (b) (4) cleaning, cleanroom recertification, and HEPA filter fan unit replacement.

Furthermore, your *SOP SC-13 Temperature, Relative Humidity, and Pressure Differential Monitoring of the Cleanroom* specifies that "the controlled compounding environment must maintain a minimum differential positive pressure of (b) (4)" water column (WC) between each room." Your scientific justification for this established limit is not clear. FDA has issued a final guidance for industry, *Sterile Drug Products Produced by Aseptic Processing-Current Good Manufacturing Practice*, which recommends a positive pressure differential of at least 0.04-0.06 inches of water gauge be maintained between adjacent rooms of differing classification (with doors closed).

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,

Frances G. Bormel -S

Digitally signed by Frances G. Bormel -S
Date: 2025.09.16 13:05:11 -04'00'

F. Gail Bormel, JD, RPh
Director
Office of Compounding Quality and Compliance
Office of Compliance
Center for Drug Evaluation and Research