U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OPQO DIVISION OF PHARMACEUTICAL QUALITY OPS 3

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations III
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Detroit, MI 48207
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04/09/2024

UPS NEXT DAY
SIGNATURE REQUIRED

Kerry Przybylo, JD, Manager, Boards and Committees Section
Michigan State Board of Pharmacy
Michigan Department of Licensing and Regulatory Affairs (LARA)
Bureau of Professional Licensing/Licensing Division
2407 N. Grand River Avenue
Lansing, MI 48906

Ref: CMS ID: 494233, FEI 3021886842

State Referral Letter
Amended

Dear Ms. Przybylo,

The purpose of this letter is to refer to you, the Michigan State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy you licensed, SNF Holdings, LLC dba Vios Compounding, located at 31035 Schoolcraft Road Livonia, MI 48150 (License #: 5301012340; exp: 04/07/2024).

FDA inspected this firm from February 13, 2023, to March 2, 2023. You were informed of the inspection but did not accompany FDA investigators during the inspection.

A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions with any nonpublic information redacted. In addition, an Untitled Letter was issued by FDA to the firm on September 18, 2023, which can be found at https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions, also with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for drug products compounded by SNF Holdings, LLC dba Vios Compounding, and FDA does not intend to take further actions at this time related to conditions of section 503A of the Federal

Food, Drug, and Cosmetic Act (FD&C Act).

Additionally, the FDA investigators observed deviations from appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. SNF Holdings, LLC dba Vios Compounding, committed to FDA in its response to the Form FDA 483, received March 16, 2023, and in its October 31, 2023, response to the Untitled Letter, to correct the deviations in the Form FDA 483 and Untitled Letter, and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the records, FDA does not intend to take further action at this time with regard to the findings of this inspection. FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to you for follow-up to ensure appropriate corrective action has been taken. We believe you, the State, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce. Please notify us if you become aware of any adverse events or product quality concerns associated with human or animal drug products made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

Additionally, we request that the Michigan State Board of Pharmacy notify FDA when the firm commences compounding of sterile products.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Brian Nicholson, Compliance Officer, at (630) 207-9337 or by email at brian.nicholson@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

Nicholas F. Lyons -S

Digitally signed by Nicholas F. Lyons -S
Date: 2024.04.09 11:07:52 -05'00'

Nicholas F. Lyons
Director, Compliance Branch
Division of Pharmaceutical Quality Operations III

Cc: Fayez Faraj, Owner and Pharmacist-in-Charge
SNF Holdings, LLC dba Vios Compounding
31035 Schoolcraft Road
Livonia, MI 48150