**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768 | 2/13/2025-3/6/2025* |
| | FEI NUMBER<br>3012384835 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael R. Morelli, VP of Scientific Affairs

| FIRM NAME | STREET ADDRESS |
|---|---|
| SKNV | 3265 W Mcnab Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Pompano Beach, FL 33069-4807 | Outsourcing Facility |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

A. On 09/18/24 in anticipation of your production batch of Magnesium Sulfate for Injection, Lot (b) (4), BUD 11/03/24, your quality unit reviewed and identified atypical behavior in the differential pressure readings in the ISO 7 ante-room. Specifically, your quality unit identified 19 occurrences where differential pressure values were as out of specification on 09/18/24 from around 10:18am - 10:43am and 3:45pm - 5:24pm; the readings were below and above the specification of (b) (4)" water, ranging from -0.04 - 0.25. Your quality unit attributed the aberrant findings to pre-operation activities and later determined the HEPA motor as a contributor to the failures. Your firm was unable to provide an investigation, or equivalent documentation, which would include product impact assessment, to capture information on the events with supporting scientific justification. This lot was ultimately released for distribution.

B. On 06/13/24, your team conducted a media fill where a microbiologic personnel sample (garb) yielded the presence of *Priestia* flexa. You were unable to provide a written investigation, or equivalent, to explain the scientific justification on topics such as origin of introduction, appropriate cleaning actions, and suitable preventive actions.

C. On 11/18/24, your chemist generated results that lead to an out of specification investigation (89.2%) of Tretinoin Assay (specification: (b) (4)) for product 011009, Lot (b) (4). During the Phase I investigation, you found that method (b) (4) was used in the analysis;

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Jennifer Lalama, Investigator<br>X Jennifer Lalama Investigator Signed By: JENNIFER LALAMA - S Date Signed: 03-06-2025 15:30:43 | 3/6/2025 |

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however, your quality unit released (b) (4) on the same day that the OOS results were generated (11/18/24). Your quality unit authorized the investigation to continue to Phase II, which included replicate preparations by multiple analysts, and failed to assign laboratory error for use of an incorrect method, which would have resulted in a repeat test (one preparation).

**OBSERVATION 2**

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, Document Number N-227, GMP Cleaning, Revision 00, fails to provide directions for deactivating, decontaminating, and cleaning of production and processing areas and equipment used to produce hazardous drugs.

**OBSERVATION 3**

The container of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

A. Your firm's magnesium sulfate injection product container does not include:
   1. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088;
   2. Directions for use, including, as appropriate, dosage and administration.

B. The containers for your firm's non-sterile compounded products, including Harviva HP Solution, Holixia Solution, Melondis Emulsion, Medorfa HP Emulsion, Nobela Cream, Aluris Cream, Nolira Ointment, Aluris Plus Cream, and Rositara Gel, do not include:
   1. Directions for use, including, as appropriate, dosage and administration. More

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specifically, the route of administration is not included.

***DATES OF INSPECTION**

2/13/2025(Thu), 2/14/2025(Fri), 2/18/2025(Tue), 2/19/2025(Wed), 2/20/2025(Thu), 2/21/2025(Fri), 3/06/2025(Thu)

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| | Jennifer Lalama, Investigator<br>X Jennifer Lalama Investigator Signed By: JENNIFER LALAMA - S Date Signed: 03-06-2025 15:30:43 | 3/6/2025 |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."