DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Suite 200 Maitland, FL 32751 Ph: (407)475-4700	DATE(S) OF INSPECTION 05/18/2026-05/29/2026* FEI NUMBER 3012384835
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Dr. Spencer J Malkin, Chief Executive Officer	
TO: Sincerus Florida, LLC dba SKNV	STREET ADDRESS 3265 W Mcnab Rd & 2030 W. MCNAB RD
CITY, STATE, ZIP CODE, COUNTRY Pompano Beach, FL 33069	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility CARR 05/29/26

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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process. Specifically,

1) The following deficiencies were identified during the review of the Smoke Visualization studies conducted in October 2025 for the (b) (4) ISO 5 Laminar Air Flow Hood (LAFH) (Equipment ID: 00167) in which sterile 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection is produced:
   a. Processes which occur during routine operations, such as sanitizing the Magnesium Sulfate vial stoppers and drawing 4 mL from the vial using a syringe, sanitizing each 5% Dextrose Bag Injection Port, injecting the contents of the syringe into the Dextrose bag, and placing an IV seal on each IV port injected, were not simulated during the Dynamic Smoke Study.
   b. During the Dynamic Smoke Study, the smoke was positioned away from the technician and the area where the technician was performing operations within the LAFH; as a result, the airflow pattern over the operations could not be visualized.
   c. The set-up of environmental monitoring (EM) plates and units within the LAFH were not simulated during the smoke study and the units were not turned on during the smoke study to demonstrate the air flow pattern.

2) The following deficiencies were identified during the review of the Smoke Visualization studies conducted in May 2025 for the Cleanroom Suite and the (b) (4) ISO 5 Laminar Air Flow Hood (LAFH) (Equipment ID: 00167) in which sterile 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection is produced:
   a. During the Dynamic Smoke Study, no smoke was placed directly over the aseptic processes of injecting the syringe into the Magnesium Sulfate vial and injecting the syringe into the 5% Dextrose 50 mL Bag to visualize the air flow pattern.
   b. Processes which occur during routine operations, such as sanitizing the Magnesium Sulfate vial stoppers, sanitizing each 5% Dextrose Bag Injection Port, and placing an IV seal on each IV port injected were not simulated during the Dynamic Smoke Study.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Annet Rajan -S Digitally signed by Annet Rajan -S Date: 2026.05.29 14:24:28 -04'00'	Annet R. Rajan, Investigator	05/29/2026

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Suite 200 Maitland, FL 32751 Ph: (407)475-4700	05/18/2026-05/29/2026* FEI NUMBER 3012384835
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Dr. Spencer J Malkin, Chief Executive Officer	
TO: Sincerus Florida, LLC dba SKNV	STREET ADDRESS 3265 W Mcnab Rd & 2030 W. MCNAB RD
CITY, STATE, ZIP CODE, COUNTRY Pompano Beach, FL 33069	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility (ARR) 05/29/26

c. The set-up of environmental monitoring (EM) plates and units within the LAFH were not simulated during the smoke study and the units were not turned on during the smoke study to demonstrate the air flow pattern.
d. The smoke generated during the study in the Ante Room (ISO 7) and from the Ante Room (ISO 8) to Ante Room (ISO 7) was insufficient to visualize the airflow pattern at multiple time points.

OBSERVATION 2

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product. Specifically,

The following deficiencies were identified during the facility walkthrough on 05/18/2026 within the (b) (4) ISO 5 Laminar Air Flow Hood (LAFH) (Equipment ID: 00167) which is used for producing sterile drug product 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection:

1) Scratches were observed on the HEPA filter grate, and the grate was observed to be curved inward (indented) on the left side of the ISO 5 LAFH. Additionally, similar inward curve/indentation of the HEPA filter grate was observed in the Dynamic Smoke Study video which was conducted in October 2025; 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection Lots 74946 (BUD: 08JAN26) and 75101 (BUD: 24JAN26) were compounded in the ISO 5 LAFH on (b) (4) and (b) (4), respectively.

2) Cracks were observed on the interior of the plexiglass side panel on the right side of the ISO 5 LAFH. Additionally, similar cracks were observed on the plexiglass in the Static Smoke Study video conducted in October 2025; 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection Lots 74946 and 75101 were compounded in the ISO 5 LAFH on (b) (4) and (b) (4), respectively.

3) Yellow stains that appeared to be sticky and glue like were observed on the interior ceiling of the ISO 5 LAFH and on the bottom of the (b) (4) grate that holds the HEPA filter in place. Additionally, a brown discoloration was observed on the rod within the ISO 5 LAFH which is used to hang the 50 mL Dextrose bags. The firm has not characterized or identified the nature of these residues/potential contaminants. A review of the Compounding Batch Records for 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection Lots 74946 and 75101 revealed that line clearance procedures do not include instructions requiring compounding technicians to perform a visual inspection of the ISO 5 LAFH for assessment of the hood and HEPA filter integrity prior to initiating compounding operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Annet Rajan -S Digitally signed by Annet Rajan -S Date: 2026.05.29 14:24:52 -04'00'	Annet R. Rajan, Investigator	05/29/2026

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Suite 200 Maitland, FL 32751 Ph: (407)475-4700	05/18/2026-05/29/2026* FEI NUMBER 3012384835
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Dr. Spencer J Malkin, Chief Executive Officer	
TO: Sincerus Florida, LLC dba SKNV	STREET ADDRESS 3265 W Mcnab Rd & 2030 W. MCNAB RD
CITY, STATE, ZIP CODE, COUNTRY Pompano Beach, FL 33069	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility CARB 05/29/26

OBSERVATION 3

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet appropriate statistical quality control criteria as a condition for their approval and release. Specifically,

The firm's Quality Unit does not perform independent Acceptable Quality Limit (AQL) sampling and testing of finished sterile drug products following 100% manual visual inspection. The firm's procedure # SC-03 "Final Visual Inspection of Compounded Sterile Preparations (CSPs)" does not include instructions for Quality Unit AQL sampling and testing. Without independent AQL testing by the Quality Unit, there is no objective, statistically sound evaluation of whether released product is essentially free of visible defects.

Specifically, Sterile Drug Product 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection Lot 74946 (Compounding Date: (b) (4) BUD: 08JAN2026; Batch Size: (b)(4) Units) and Lot 75101 (Compounding Date: (b) (4) ; BUD: 24JAN2026; Batch Size: (b)(4) Units) were each released following 100% visual inspection performed solely by the same compounding technician who produced the respective lots, without any independent AQL sampling or testing performed by the Quality Unit prior to release for distribution.

OBSERVATION 4

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess. Specifically,

The firm's procedure# SC-03 "Final Visual Inspection of Compounded Sterile Preparations (CSPs)" does not include instructions for creation and characterization of the defects to be used, including the range of sizes to be used in, and instructions for the qualification of the Visual Inspection Qualification (defect) (b)(4) Specifically, the defect (b)(4) designed on 05NOV2025 and used to qualify manual visual inspectors is inadequate in that the particulates contained in the defect (b)(4) are of unknown size. No threshold studies (e.g., probability of detection studies) have been performed to determine whether the particulates in the (b)(4) represent the range of defect sizes likely to be encountered in the finished sterile drug product, and whether trained personnel can reproducibly detect them. As a result, there is no scientific basis for concluding that the compounding technician, who was qualified on the (b)(4) on 06NOV2025, and who conducted the 100% visual inspection of Sterile Drug Product 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection Lot 74946 (Compounding Date: (b) (4)) and Lot 75101 (Compounding Date: (b) (4) both of which were released for distribution, was adequately qualified to reliably detect visible particulates in the sterile drug product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Annet Rajan -S Digitally signed by Annet Rajan -S Date: 2026.05.29 14:25:16 -04'00'	Annet R. Rajan, Investigator	05/29/2026

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Suite 200 Maitland, FL 32751 Ph: (407)475-4700	05/18/2026-05/29/2026* FEI NUMBER 3012384835
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Dr. Spencer J Malkin, Chief Executive Officer	
TO: Sincerus Florida, LLC dba SKNV	STREET ADDRESS 3265 W Mcnab Rd & 2030 W. MCNAB RD
CITY, STATE, ZIP CODE, COUNTRY Pompano Beach, FL 33069	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility (CARA) (05/29/26)

OBSERVATION 5

Written procedures are not established and followed for the cleaning and maintenance of equipment, including, utensils, used in the manufacture, processing, packing or holding of a drug product. Specifically,

The contact times maintained during the cleaning and disinfecting of the Cleanroom Suite and the ISO 5 LAFH, used for producing sterile drug product 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection Lot 74946 (Compounding Date: (b) (4)) and Lot 75101 (Compounding Date: (b) (4) are not documented. The firm's procedure # SC-17 "Sterile Compounding Area Cleaning and Disinfecting" specifies a required minimum contact time of (b) (4) for (b) (4) and (b) (4) and a minimum of (b) (4) for (b) (4) (b) (4) however, the contact times are not recorded in the compounding batch records or cleaning logs and the firm's procedure SC-17 does not require documentation of the contact time.

OBSERVATION 6

The responsibilities and procedures applicable to the quality control unit are not in writing or fully followed. Specifically,

1) No assessment of retain samples, batch records, and laboratory testing data were conducted at the time of receipt of the below listed complaints, as required by the firms procedure# QA-10 "Customer Complaints Management" Steps 7.6.1 and 7.6.3 which states that Quality investigates the complaint to determine if the compounded product may have resulted in a Quality Non-Adverse Event, Adverse Event, or Serious Adverse Event and Quality checks retain samples, batch record, and laboratory testing data for the reported lots, respectively.
   a. Complaint# CR25-540 (SKU: 031098; Product: Holixia Solution (Minoxidil 7%/Progesterone 0.1%; Lot# 71065): Patient Complaint Description: Getting severe migraines and causing scalp to burn/itch.
   b. Complaint# CR25-389 (SKU: 031098, Product: Holixia Solution, Lot# 71065): Patient Complaint Description: Patient experienced itchiness and redness on the skin/itchy scalp.
   c. Complaint# CR25-365 (SKU: 031098; Product: Holixia Solution (Minoxidil 7%/Progesterone 0.1%; Lot# 71065): Patient Complaint Description: Burning scalp and she felt "bumps" on her scalp.
   d. Complaint# CR25-538 (SKU: 141057; Product: Melidu Emulsion; Lot #71466): Patient Complaint Description: Prescription makes her eye swell up.
   e. Complaint# CR25-530 (SKU: 141057; Product: Melidu Emulsion; Lot# 71466): Patient Complaint Description: Prescription made face red and itchy.
   f. Complaint# CR25-708a (SKU: 011554; Product: Diasoxia Cream; Lot #71829): Patient Complaint Description: Patient complaint about it hurting when they rub on their skin due to the texture.
   g. Complaint# CR25-708b (SKU: 011554; Product: Diasoxia Cream; Lot# 73139): Patient Complaint Description: Patient complaint about it hurting when they rub on their skin due to the texture.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Annet Rajan -S Digitally signed by Annet Rajan -S Date: 2026.05.29 14:25:38 -04'00'	Annet R. Rajan, Investigator	05/29/2026

2) No formal risk and product impact assessment for changes implemented under Planned Deviation #25-37: Planned Deviation #25-37 (issued 18JUL2025) was initiated to allow the compounding department to: (i) substitute (b) (4) 5-Fluorouracil API in place of the currently approved and validated (b) (4) 5-Fluorouracil API, and (ii) eliminate the (b) (4) step from the manufacturing process, for Product SKU 021040, Kefunova Cream (Fluorouracil 5% / Calcipotriene 0.005%). These changes represent material alterations to both the drug substance form and the validated manufacturing process. No formal risk assessment or product impact assessment documenting the potential effect of these changes on drug product quality, safety, identity, strength, or purity was performed prior to or in conjunction with the implementation of this deviation. Lots 73314, 73316, and 73325, manufactured under the conditions of this deviation, were released for distribution.

3) Inadequate corrective action for analyst error identified in OOS investigation OOS25-29: OOS25-29 was initiated on 11DEC2025 for an out-of-specification result for Raw Material 5-Fluorouracil USP, Lot FLU2025015M (QC25-5918 1 of (b) (4) failing FTIR testing (Result: 0.89336; Specification: NLT (b) (4) . Reanalysis was performed on 12DEC2025 by the same analyst who conducted the initial failing analysis, yielding a passing result of 0.96227. The initial failing result was attributed to analyst error. Although analyst error was identified as the root cause, no retraining of the analyst in the specific FTIR analytical method was implemented as a corrective and preventive action (CAPA).

4) The Quality Unit has not conducted a documented review of the Smoke Visualization studies conducted by the third-party vendor for either the May 2025 or October 2025 smoke study campaigns. There is no assurance that the Quality Unit evaluated the adequacy of these studies or identified the deficiencies described (above in Observation 1) prior to the manufacture of Sterile Drug Product 2 GM Magnesium Sulfate in 5% Dextrose 50 mL Bag Injection Lots 74946 (Compounding Date: (b) (4)) and 75101 (Compounding Date (b) (4)) in the ISO 5 LAFH. Additionally, the firm does not have an established written procedure governing the review of smoke visualization studies conducted by the third-party vendor.

OBSERVATION 7

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established, written or followed. Specifically,

The firm's non-sterile topical drug products and (b) (4) Water, used in producing the non-sterile drug products, are not routinely tested for objectionable microorganisms such as *Burkholderia cepacia complex (BCC)*. (b) (4) Water is used as an ingredient in the formulation of topical drug products including, but not limited to, Clobetasol Propionate 0.05%/ Niacinamide 4% Solution and Hydrocortisone 0.5%/ Hydroquinone 8% /Tretinoin

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Suite 200 Maitland, FL 32751 Ph: (407) 475-4700	05/18/2026-05/29/2026* FEI NUMBER 3012384835
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Dr. Spencer J Malkin, Chief Executive Officer	
TO: Sincerus Florida, LLC dba SKNV	STREET ADDRESS 3265 W Mcnab Rd & 2030 W. MCNAB RD
CITY, STATE, ZIP CODE, COUNTRY Pompano Beach, FL 33069	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility (CARA) 05/29/26

0.025% Emulsion. Additionally, the firm's procedure# TM-47 "Microbial Analysis of (b) (4) Water at SKNV FL" does not require testing of the (b) (4) Water for *BCC*.

***DATES OF INSPECTION**

05/18/2026 (Mon), 05/19/2026 (Tue), 05/20/2026 (Wed), 05/21/2026 (Thu), 05/22/2026 (Fri), 05/26/2026 (Tue), 05/27/2026 (Wed), 05/28/2026 (Thu), 05/29/2026 (Fri) (9 Days)

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE	Annet Rajan -S Digitally signed by Annet Rajan -S Date: 2026.05.29 14:26:30 -04'00'	Annet R. Rajan, Investigator	05/29/2026

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."