DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 ORAPHARM2_RESPONSES@fda.hhs.gov	5/13/2024-5/23/2024* FEI NUMBER 3012384835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Michael R. Morelli, VP, 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

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, your containers do not include the following information:

a) Information to facilitate adverse event reporting: <www.fda.gov/medwatch> and 1-800-FDA-1088

b) Directions for use, including, as appropriate, dosage and administration.

OBSERVATION 2

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Specifically, the following products were compounded and not identified on your report dated December 2023:

a) 031041 FLUOCINOLONE ACETONIDE 0.01% / MINOXIDIL 5% / TRETINOIN 0.025% SOLUTION with NDC # 72934-4348-08

b) 351036 CICLOPIROX 0.77% / SALICYLIC ACID 2% Shampoo with NDC # 72934-7425-06

c) 201070 BENZOCAINE 20% / LIDOCAINE 10% / TETRACAINE 10% Cream with NDC # 72934-2406-04

*DATES OF INSPECTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jared P Stevens, Investigator	Jared P Stevens Investigator	5/23/2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 ORAPHARM2_RESPONSES@fda.hhs.gov	5/13/2024-5/23/2024* FEI NUMBER 3012384835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Michael R. Morelli, VP, 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

5/13/2024(Mon), 5/14/2024(Tue), 5/15/2024(Wed), 5/16/2024(Thu), 5/17/2024(Fri), 5/20/2024(Mon), 5/21/2024(Tue), 5/23/2024(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jared P Stevens, Investigator X Jared P Stevens Investigator Signed By: Jared P. Stevens -S Date Signed: 05-23-2024 14:06:31	5/23/2024

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."