

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 7/12-15/16 FEI NUMBER 3012384835
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Alex (NMI) Chervinsky, President and CEO		
FIRM NAME Sincerus Florida, LLC	STREET ADDRESS 3265 W McNab Road	
CITY, STATE, ZIP CODE, COUNTRY Pompano Beach, FL 33069	TYPE ESTABLISHMENT INSPECTED 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.

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically,

• The date the drug was compounded, dosage form, storage and handling conditions, list of inactive ingredients and the statement "Office use only" are not on your drug product labels. For example, labels for the following drug products do not contain the aforementioned:

- Item# (b) (4) - ROSACEA SILICONE GEL (IVERMECTIN 1% / METRONIDAZOLE 1% / NIACINAMIDE 4% / POTASSIUM AZELOYL DIGLYCINATE 5%), lot PC051716IMNP
- Item# (b) (4) - ANTI-FUNGAL NAIL SOLUTION **15ML**(FLUCONAZOLE 4% / IBUPROFEN 2% / ITRACONAZOLE 1% / TERBINAFINE 4%), lot PC061416FIIT
- Item# (b) (4) - ROSACEA SILICONE GEL (NIACINAMIDE 2% / POTASSIUM AZELOYL DIGLYCINATE 15%), lot PC060616NP15
- Item# (b) (4) - MELASMA EMULSION (HYDROCORTISONE 0.5% / HYDROQUINONE 8% / KOJIC ACID 4% / TRETINOIN 0.025%), lot PC0601316HH8K4T
- Item# (b) (4) - MELASMA EMULSION (HYDROCORTISONE 0.5% / HYDROQUINONE 4% / KOJIC ACID 6% / TRETINOIN 0.025% / VITAMIN E 1%), lot PC061516HHKTE

Your firm has produced approximately (b) (4) type of product formulations and shipped approximately (b) (4) units since registering as an outsourcing facility on March 10, 2016.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Latorie S. Jones, Investigator</i>	DATE ISSUED 7/15/16
	<i>Stephanie O. Crockett, INVESTIGATOR</i>	7/15/16