DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	8/30/2018-9/17/2018*
	FEI NUMBER 3012384835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Spencer J. Malkin, Owner and CEO

FIRM NAME	STREET ADDRESS
Sincerus Florida, LLC	3265 W McNab Rd
CITY, STATE, ZIP CODE, COUNTRY Pompano Beach, FL 33069-4807	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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Each lot of components is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically, non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Your firm uses (b) (4) or (b) (4) Solution in the formulation of your non-sterile drug products. However, your firm did not provide any documentation supporting this component, which is not USP grade. Your firm does not conduct any microbial testing on any drug products that use (b) (4) or (b) (4)

OBSERVATION 2

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm has failed to perform release testing for potency on each batch of drug product produced at your facility. Examples include, but are not limited to the following:

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jennifer L Huntington, Investigator
June P Page, Investigator

X Jennifer L Huntington
Investigator
Signed By: Jennifer L. Huntington
Date Signed: 09-17-2018 11:20:06

DATE ISSUED
9/17/2018

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- Product 031041- Fluocinolone Acetonide 0.01%/Minoxidil 5%/Tretinoin 0.025%, Lot 031041AIBFCABI@14, BUD 09/14/18
- Product 031089- Fluocinolone acetonide 0.01%/ Minoxidil 7%/ Progesterone 0.1%/ Tretinoin 0.025%, Lot 031089AFDBCABI@5, BUD 06/30/18
- Product 031070- Tacrolimus 0.1%, Lot 031070AIDACABI@14, BUD 09/29/18
- Product 031101- Ketoconazole 2% / Minoxidil 7% / Tretinoin 0.05%, Lot 031101AHBGCABI@14, BUD 08/15/18
- Product 041013- Betamethasone Dipropionate 0.05% / Menthol 2% / Pramoxine HCL 1% / Tranilast 0.5%, Lot 041013AICICABI@14, BUD 09/27/18
- Product 141030- Hydroquinone 8%, Lot 141030AJAFCABI@14, BUD 10/05/18
- Product 201017- Lidocaine 23%/ Prilocaine 5% (Oleabase), Lot 201017AIBGCABI@1, BUD 02/12/19

OBSERVATION 3

The in process control procedures were deficient in that they did not include an examination of the adequacy of mixing to assure uniformity and homogeneity.

Specifically, your firm failed to validate your current formulary procedures are in accordance with your reference procedures to ensure homogeneity and blend uniformity are obtained.

OBSERVATION 4

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm has not performed stability testing on any drug product to ensure the shelf-life of the drug products. Examples include, but are not limited to:

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SEE REVERSE OF THIS PAGE	Jennifer L Huntington, Investigator June P Page, Investigator	X Jennifer L Huntington Investigator Signed By: Jennifer L. Huntington -S Date Signed: 09-17-2018 11:20:06	9/17/2018

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- Product 501010- Magnesium sulfate in 5% Dextrose, Lot 501010SAGBDCABI@1, BUD 06/22/18
- Product 141030- Hydroquinone 8%, Lot 141030AJAFCABI@14, BUD 10/05/18

OBSERVATION 5

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

Specifically, multiple complaint investigations into adverse events lacked a thorough investigation into the root cause for the complaint. Examples include, but are not limited to:

- Complaint 18-52- Five patients experienced redness during use of Product 201019-Lidocaine 23%/Tetracaine 7%, Lot 201019ABAECABI@6, BUD 05/09/18. There was no root cause or potential root cause identified.
- Complaint 18-84- Four patients experienced a rash after use of Product 011009- Niacinamide 4%/Trentinoin 0.05%, Lot 011009BBCBCABH@8, BUD 12/21/17. There was no root cause or potential root cause identified.
- Complaint 18-138- Multiple patients experienced redness, hives, itching, or swelling within five (5) minutes of applying Product 201016- Lidocaine 7%/Tetracaine 7%, Lot 201016ADCJCABI@2, BUD 09/25/18. There was no root cause or potential root cause identified.

OBSERVATION 6

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

Specifically, hazardous drugs, hormones, and antibiotics were produced in your firm's non-sterile suite area without providing adequate cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination. However, your firm does not have a cleaning procedure for these drug products to ensure cross-contamination does not occur. In addition, your firm places dedicated utensils in the dishwasher with non-dedicated utensils

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used in production. On 08/30/2018, we observed hazardous/antibiotics being produced under the same hood as non-hazardous drugs.

We also observed powdered residue on your firm's (b) (4) used in the production of cream and emollient drug products. According to your firm's Pharmacist-In-Charge, this equipment's status was clean.

***DATES OF INSPECTION**
8/30/2018(Thu), 8/31/2018(Fri), 9/17/2018(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jennifer L Huntington, Investigator June P Page, Investigator	X Jennifer L Huntington Investigator Signed By: Jennifer L. Huntington Date Signed: 09-17-2018 11:20:06	DATE ISSUED 9/17/2018