

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

DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax: (404)253-1202	DATE(S) OF INSPECTION 6/19/2017-6/26/2017*
	FEI NUMBER 3012384835

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Dr. Spencer J Malkin , Chief Executive Officer

FIRM NAME Sincerus Florida, LLC	STREET ADDRESS 3265 W McNab Rd
CITY, STATE, ZIP CODE, COUNTRY Pompano Beach, FL 33069-4807	TYPE ESTABLISHMENT INSPECTED 503B 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**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, your monitoring program for classified areas within the (b) (4), including the ISO 5 laminar air flow hood and ISO 7 (b) (4) room used to produce sterile drug products is deficient in that:

- (a). Viable and non-viable air and surface monitoring is only conducted on a (b) (4) basis as part of room qualification activities.
- (b). Personnel monitoring is not conducted during routine production and such monitoring only includes (b) (4) as part of a sterile operator's aseptic processing assessment.
- (c). The effectiveness of your cleaning and sanitization procedures within the cleanroom have not been demonstrated through routine (b) (4) the cleaning process.

**OBSERVATION 2**

Procedures designed to assure that correct labeling and packaging materials are used for drug products are not written and followed.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Bonita S Chester, Investigator	DATE ISSUED 6/26/2017
		<input checked="" type="checkbox"/> Bonita S Chester Bonita S Chester Investigator Signed by: Bonita S. Chester -S

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Specifically, packaging and labeling procedures that describe the receipt, examination, issuance, and storage of labeling; that describe the operations involved in the packaging and labeling of drug products produced and distributed by your firm have not been established.

**OBSERVATION 3**

The labels of your outsourcing facility's drug products are deficient.

Specifically,

The correct dosage form is not stated on your product label for Magnesium Sulfate Solution/50ml, as required by section 503B(a)(10)(A).

**\*DATES OF INSPECTION**

6/19/2017(Mon),6/20/2017(Tue),6/21/2017(Wed),6/22/2017(Thu),6/23/2017(Fri),6/26/2017(Mon)

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