

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

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	DATE(S) OF INSPECTION 2/21/2017-3/2/2017*
	FBI NUMBER 3012174424

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jacqueline E. Esqueda , Pharmacist In Charge

FIRM NAME American Specialty Pharmacy	STREET ADDRESS 2414 Babcock Rd Ste 106
CITY, STATE, ZIP CODE, COUNTRY San Antonio, TX 78229-4870	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 I OBSERVED:

OBSERVATION 1

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

On 02/21/2017, I observed the presence of a sink in your firm's Sterile Prep Room # (b)(4) located approximately four feet away from your firm's laminar airflow hood, brand name (b)(4), serial #(b)(4). The firm's laminar airflow hood is utilized to aseptically process sterile drug products.

OBSERVATION 2

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

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

Specifically,

The drug product label for Glycerin 100%, 4 mL, Lot #01262017@1, NDC #00000-0505-4, does not include the statement "Office Use Only".

In addition,

The container label for Glycerin 100%, Sterile, 16 MI, Lot #01262017@1, NDC #00000-0505-4, Distribution date: 02/16/2017, does not include the dosage and route of administration.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jason R Caballero, Investigator	DATE ISSUED 3/2/2017
		X Jason R Caballero Jason R Caballero Investigator Signed by: Jason R. Caballero -S

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2/21/2017(Tue),2/22/2017(Wed),2/23/2017(Thu),2/24/2017(Fri),2/27/2017(Mon),2/28/2017(Tue),3/01/2017(Wed),3/02/2017(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jason R Caballero, Investigator	DATE ISSUED 3/2/2017
		<input checked="" type="checkbox"/> Jason R Caballero Jason R Caballero Investigator Signed by: Jason R. Caballero-S