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 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 Ml, Lot #01262017@1, NDC #00000-0505-4, Distribution date: 02/16/2017, does not include the dosage and route of administration.

*Dates of Inspection

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Jason R Caballero, Investigator

DATE ISSUED
3/2/2017
**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

**Dates of Inspection**  
2/21/2017-3/2/2017*

**FEIN/FEIN 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

**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)**

**Employee(s) Signature**  
Jason R Caballero, Investigator

**Date Issued**  
3/2/2017

SEE REVERSE OF THIS PAGE