DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1
You produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

Your firm has not demonstrated that (b) (4) and disposable germicidal wipes used by your employees to wipe down your (b) (4) hoods, equipment, and utensils between uses is capable of deactivating hazardous drug substances. The (b) (4) hoods, equipment, and utensils are non-dedicated and are used for producing hazardous and non-hazardous drug substances.

For example, on 11/18/2019 we observed dispensing/production of the following hazardous drug; (b) (4) g of Progesterone (b) (4) (b) (4), Lot# (b) (4), Exp. 3/30/22 used to compound (b) (4) Progesterone 130 mg Capsules, Lot# 20191118@54, followed by dispensing of the following non-hazardous drug in the same (b) (4) hood, (b) (4) g of Naltrexone Hydrochloride, USP (b) (4), Lot# (b) (4), Exp 1/31/22, used to compound (b) (4) Naltrexone IR (Ascorbic Acid) 4.5 mg Capsules.

*DATES OF INSPECTION

SEE REVERSE OF THIS PAGE

Zachary L Stamm, Investigator
Jolanna A Norton, Generic Drug User Fee Amendments (GDUFA)
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**FOOD AND DRUG ADMINISTRATION**

**DISTRICT ADDRESS AND PHONE NUMBER**
1201 Harbor Bay Parkway  
Alameda, CA 94502-7070  
(510) 337-6700 Fax: (510) 337-6702

**FIRM NAME**
One Way Drug DBA Partell Specialty Pharmacy

**STREET ADDRESS**
5835 S Eastern Ave, Ste 101

**CITY, STATE, ZIP CODE, COUNTRY**
Las Vegas, NV 89119-3031

**TYPE ESTABLISHMENT INSPECTED**
Producer of Non-Sterile Drugs

**DATES OF INSPECTION**
11/18/2019 (Mon), 11/19/2019 (Tue), 11/20/2019 (Wed), 11/21/2019 (Thu), 11/22/2019 (Fri), 11/25/2019 (Mon)

**NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED**
Jeffrey S. Lang, Pharmacist-In-Charge

**EMPLOYEE(S) SIGNATURE**
Zachary L Stamm, Investigator  
Jolanna A Norton, Generic Drug User Fee Amendments (GDUFA)

**DATE ISSUED**
11/25/2019