

**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	DATE(S) OF INSPECTION 11/18/2019-11/25/2019*
	FEI NUMBER 3011769075

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

FIRM NAME One Way Drug DBA Partell Specialty Pharmacy	STREET ADDRESS 5835 S Eastern Ave, Ste 101
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CITY, STATE, ZIP CODE, COUNTRY Las Vegas, NV 89119-3031	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs
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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

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 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	EMPLOYEE(S) SIGNATURE Zachary L Stamm, Investigator Jolanna A Norton, Generic Drug User Fee Amendments (GDUFA)	Zachary L Stamm Investigator Signed by Zachary L Stamm-S Date Signed 11-25-2019 13:15:50 X	DATE ISSUED 11/25/2019

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

X Jolanna A Norton
Generic Drug User Fee Amendments (GDUFA)
Signed By: Jolanna A. Norton -S
Date Signed 11-25-2019 13:16:39

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Zachary L Stamm, Investigator Jolanna A Norton, Generic Drug User Fee Amendments (GDUFA)	<small>Zachary L Stamm Investigator Signed By: Zachary L. Stamm -S Date Signed 11-25-2019 13:16:50</small> X _____	DATE ISSUED 11/25/2019