

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

DISTRICT ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702	DATE(S) OF INSPECTION 7/17/2017-7/19/2017
	FBI NUMBER 3010839113

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**Stephen V. Hodges , President**

FIRM NAME <b>One Way Drug, LLC dba Partell Specialty Pharmacy</b>	STREET ADDRESS <b>8751 W Charleston Blvd Ste 120</b>
CITY, STATE, ZIP CODE, COUNTRY <b>Las Vegas, NV 89117-5481</b>	TYPE ESTABLISHMENT INSPECTED <b>Producer of Non-Sterile Drugs</b>

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.

*The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.*

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

Your firm has not established written and approved procedures for the cleaning of equipment and utensils used in the preparation of drug products. During the inspection, we observed the cleaning of the following equipment and utensils used in non-sterile production of your drug products: (b) (4) blender for powders, capsule press, glassware, and spatulas. We observed your lab technician using (b) (4) to wash and rinse glassware. We additionally observed your lab technician using the vacuum cleaner to vacuum your (b) (4) brand powder press followed by wiping with (b) (4). Your firm has no evidence to show that your cleaning procedures are adequate in the removal of residual products and the removal of sanitizing agents. Your firm has not established written procedures (SOP's) detailing these cleaning processes for equipment and utensils used in the production of drug products, detailing the cleaning processes required between different batches of the same product, and detailing the processes for cleaning between different product lines.

**OBSERVATION 2**

Drug products failing to meet established specifications are not rejected.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Rumany C Penn, Investigator Eileen A Liu, Microbiologist Kristin M Abaonza, Investigator	Rumany C Penn Investigator Signed By: 2001148009 Date Signed: 7/19/2017 X	DATE ISSUED 7/19/2017

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**Specifically,**

- A. Your firm has not established written procedures to assure that expired finished products stored at your firm have the identity, strength, quality, and purity they purport to possess prior to releasing the product for patient use. The following expired finished products were not rejected and were observed stored in your firm's area for released finished products:

Finished Product	Lot #	Discard Date
B1/B2/B3/B5/B6,	20170407@31	5/7/2017
DMSO in water	20170712@27	7/15/2017
HCG, 200U/0.25 ml SL drops	20170505@58	7/4/2017
Indole-3-carbinol 300 mg capsule	20161220@73	6/18/2017
Betaine HCL/PEPSIN 250 mg/150mg	20170112@71	7/11/2017
Trimix #4	20170531@53	7/15/2017

**OBSERVATION 3**

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

**Specifically,**

- A. Your firm has not established acceptable levels of microorganisms within each drug product. Your firm has also failed to test finished drug products for acceptable levels and the presence of objectionable microorganisms.
- B. Your firm has not established written procedures for assay or potency testing of your finished drug products to assure they conform to appropriate specifications of identity, strength, quality,

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	X <small>Rumany C Penn Investigator Signed By: 2001148009 Date Signed: 7/19/2017</small>	

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or purity. Your lab manager stated that there are no procedures, and that potency testing is conducted on a random schedule with randomly selected drug products.

- a. Specifically, your firm was notified that the potency of Estradiol was out-of-specification (OOS) at 114.1% and 114.9% respectfully (specification requirements (b) (4) for product, "Estra 0.75 Estri 0.75 Prog 100 Capsule" lot # 20151218@18. The potency testing occurred from the receipt of Customer Complaint Number 16007, 02/26/2016, and not due to any routine potency testing.

Eileen A Liu  
Microbiologist  
Signed By: 200047259  
Date Signed: 7/19/2017

Kristin M Abaonza  
Investigator  
Signed By: Kristin M. Abaonza -S  
Date Signed: 7/19/2017

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Rumany C Penn, Investigator Eileen A Liu, Microbiologist Kristin M Abaonza, Investigator	<p align="right">Rumany C Penn Investigator Signed By: 2001145009 Date Signed: 7/19/2017</p> <input checked="" type="checkbox"/>	DATE ISSUED 7/19/2017



Date: September 14, 2017

Stephen V. Hodges  
One Way Drug, LLC dba Partell Specialty Pharmacy  
8751 W Charleston Blvd Ste 120  
Las Vegas, NV 89117-5481

Subject: System Notification

Dear Stephen V. Hodges,

We are notifying you that due to a technical error related to a software update, the FDA Form 483 you received recently inadvertently included a sentence meant only for medical device firms. That statement says, "Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

This statement refers to quality system requirements applicable only to medical device establishments, but was inadvertently included on certain Form 483's issued to non-device establishments for a brief period of time. Please note that the statement has no bearing on the inspection observations themselves, which remain applicable as of the date that you were issued the Form FDA 483.

Should you have any questions, please send to [AskORAIT@fda.hhs.gov](mailto:AskORAIT@fda.hhs.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa Creason".

Lisa Creason  
Director, Office of Information Systems Management  
Office of Regulatory Affairs  
Food and Drug Administration