DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	4/6/2018-4/13/2018* FEI NUMBER 3009724085

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marco Loleit, CEO & Owner

FIRM NAME	STREET ADDRESS
OPS International Incorporated D/B/A Olympia Pharmacy	6700 Conroy Rd Ste 155
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32835-3515	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

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

A. On 4/9/2018, your technician was observed in Buffer Room (b) (4) (ISO 5 Classified) as having her neck exposed sporadically between the worn sterile hood and gown while aseptic manipulating a (b) (4) transfer of drug product, PGE-2, Lot # D3009.

B. On 4/9/2018, during EM sampling at (b) (4), your pharmacy technician was observed within your Non-Hazardous ISO 7, Prep Room (b) (4) without being adequately gowned while collecting EM samples. Your technician failed to follow your firm's gowning clean room procedure, Hand Hygiene and Garbing, P-404, Version 3, by not wearing a sterile gown.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

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A. Your procedure, Complaint Handling, P-219, Version 2, 28 July 16, fail to provide minimum requirements for an adequate investigation to be conducted in order to determine a root cause, customer complaint assessment requirements to assess for ADR reportability, and the documentation of such actions.

B. Your quality unit failed to have conducted and documented an ADR assessment as part of the following received customer complaints where your firm was made aware of potential side effects for your firm's compounded sterile drug products.

1. CC-2017-005, received 3/31/2017, RX # (b) (6) for compounded sterile drug, 10 Testost CYP 200MG/ML *10 ML* Inj., Lot # A3218.
2. CC-2017-004, received 3/29/2017, RX # (b) (6) for compounded sterile drug, 20 Testost CYP 200MG/ML *10 ML* Inj, Lot # 11725.
3. CC-2017-001, received 2/17/2017, RX # (b) (6) for compounded sterile drug, 600 Polidocanol 0.35% MDV (30 ML).
4. CC-2017-013, received 8/31/2017, RX # (b) (6) for compounded drug, 60 Estriol .1 MG/CLOBET .5% PETROL, Lot # H0016.

C. Your quality unit failed to adequately document and conduct an investigation into the following customer complaints to determine the root cause, and assign appropriate corrective action(s) the customer reported issues:

1. CC-2018-05, received 3/28/2018, documents your firm shipping s Rx # (b) (6) T-50 (PAP 8.8/PHE 0.29/AP 2.9) to the incorrect patient address. Your quality unit failed to adequately investigate to determine the root cause and document corrective actions to

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prevent the recurrence.

2. CC-2018-06, received 3/30/2018, documents your firm's failure to apply an auxiliary label on the finished drug product, RX # (b) (6) TRIMIX (PA 15/PH .5/PG 5) Injection, which documents the sterile finished compounded drug storage conditions.

3. CC-2018-03, received 3/27/2018, documents your firm's shipping the incorrect finished compounded drug to a customer. Your firm incorrectly shipped HCG 10000, Lot # B18A12, BUD 2/19 instead of the correct sterile compounded sterile drug product HCG 5000, Lot # C18005, BUD 3/19.

4. CC-2017-011, received 8/28/17, documents your firm failure to document and have objective evidence in support of such corrective action. Complainant reported receiving Rx # (b) (6) identified on the patient specific label incorrectly as 30 Testost 0.1% (I MG/ML) Cream. The compounded drug should have been labeled as 30 Testosterone 1% (10MG/ML) CRM on the patient specific label.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

D. Your procedure, Cleaning-Sterilizing and Disinfecting of the Compounding Facility, P-304, Version 4 require the use of (b) (4) Ready to Use (Sterliant/Sporicidal) with a contact time of (b) (4), and (b) (4) Ready to Use (Disinfectant) with a contact time of (b) (4) for (b) (4) and (b) (4) clean room cleaning but fail to require the documentation of

contact times as a form of verification for activity. Your documented contact time for (b) (4) Ready to Use (Sterliant/Sporicidal) of (b) (4) failed to meet the manufacturers requirement of (b) (4) .

E. Your firm fails to have scientific data and or performed any studies in support (b) (4) Hand Sanitizer effectiveness as a disinfectant on sterile gloves used within your ISO 8, ISO 7, and ISO 5 classified clean room. The sanitizer is labeled as a hand disinfectant. (b) (4) Hand Sanitizer labeling contains no information reporting it as being sterile and appropriate for use on gloves. (b) (4) Hand Sanitizer has been used as a disinfectant on sterile gloves since 2015.

OBSERVATION 4

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

Specifically, no lyophilized sterile drug product reconstitution specification has been established to be used as part of the released criteria prior finished sterile drug product distribution. For example, your firm failed to establish a reconstitution specification for the release of the following drug products:

- HCG
- Sermorelin
- Sermorelin GHRP

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OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, on 4/9/2018, your pharmacy technician was observed touching door between Ante Room (b) (4) (ISO 8 Classified) and Prep Room (b) (4) ISO 7 Classified) during the entry and exiting of the two rooms at the time of batch compounding mixing the drug product, PGE-2, Lot # D3009 without re-sanitizing sterile gloved hands with (b) (4) while transferring components in preparation for compound batch mixing.

OBSERVATION 6

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your procedure, Policy on the Environmental and Personnel Monitoring Program, P-211, Version 7 reports the (b) (4) recording of differential pressure shall be performed for all room. Your differential pressures are recorded (b) (4) and visually observe throughout the course of the day. On 4/9/2018, your firm was observed compounding the sterile drug product, PGE-2, Lot # D3009 which you began compounding at 2:20 pm and finished undergoing your (b) (4) process at 5:13 pm. Your recorded differential pressure for the non-hazardous clean room occurred at 7:00 am. No recorded differential pressure readings are available for the time in which the sterile drug PGE-2 was mixed, compounded, and filled to show no excursions in differential pressure occurred.

OBSERVATION 7

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Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, during a review of your 2017 smoke study for your (b) (4) located in your non-hazardous sterile clean room, Buffer Room (b) (4) failed to adequately assess the most complicate filling configuration to ensure equipment appropriately designed and unidirectional air flow in the prevention of contamination that would alter the safety, identify, strength, quality, or purity of the sterile finished drug product. The firm's smoke study only assessed the filling for (b) (4) 10 mL clear vials in a tray.

OBSERVATION 8

Product Reporting:

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A). The following are examples of products that were compounded and not identified on your December 2017 product report:

F. alprostadil (PGE) 250 mcg/mL
G. 300 mcg/mL and 350 mcg/mL injection
H. anastrozole 0.5 mg and 0.75 mg capsule
I. ascorbic acid 250 mg/mL and 500 mg/mL MDV
J. avanafil 200 mg and 300 mg troche
K. bacteriostatic water
L. estradiol cypionate/testosterone cypionate 2 mg/50 mg/mL
M. estradiol cypionate 2 mg/mL and 5 mg/mL injection

N. L-carnitine 500 mg/mL MDV
O. lysine 62.5 mg/arginine 50 mg cream
P. papaverine 30 mg/mL injection MDV
Q. phenylephrine 1 mg/mL injection
R. sildenafil citrate 110 mg and 150 mg troch
S. tadalafil 20 mg, 25 mg, 40 mg, and 75 mg troche
T. terbutaline 3 mg capsule
U. vardenafil 40 mg and 75 mg troche
V. vitocin (oxytocin) spray 40IU/spray
W. zinc chloride 10 mg/mL MDV.

This is not an all-inclusive list.

OBSERVATION 9

Product Labeling:

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

X. The exact date the drug was compounded. Examples of product labels that do not contain this information include:
   - NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; alprostadil 30 mcg/ml)

Y. The expiration date. Examples of product labels that do not contain this information include:
   - NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; alprostadil 30 mcg/ml)

Z. Lot or batch number. Examples of product labels that do not contain this information include:

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- NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; alprostadil 30 mcg/ml)

AA. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Examples of product labels that do not contain this information include:

- NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; alprostadil 30 mcg/ml)
- QM4 (papaverine 30 mg/ml; phentolamine 3 mg/ml; alprostadil 300 mcg/ml; atropine 0.2 mg/ml)

OBSERVATION 10

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

Specifically,

BB. The phone number, 1-800-FDA-1088, to facilitate adverse event reporting. Examples of product labels that do not contain this information include:

- NB-343 (papaverine 30 mg/ml; phentolamine 3 mg/ml; alprostadil 30 mcg/ml)
- Polidocanol 2% injection
- Sodium bicarbonate 8.4% injection
- Testosterone cypionate 200 mg/mL injection
- HCG 10,000IU (lyophilized powder)

***DATES OF INSPECTION**

4/06/2018(Fri), 4/09/2018(Mon), 4/10/2018(Tue), 4/11/2018(Wed), 4/12/2018(Thu), 4/13/2018(Fri)

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