DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	11/17/2014 - 12/04/2014* FEI NUMBER 3011158365

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Marco Loleit, Owner

FIRM NAME	STREET ADDRESS
OPS International Incorporated dba Olympia Pharmacy	6700 Conroy Road Suite 155
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32835	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

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, the laminar flow hoods (b) (4) do not have a flow meter that allows for the sterile technicians to easily determine the status of the unidirectional air flow over the ISO-5 zone used for sterile processing. Laminar flow hood (b) (4) does not have an indicator light that appears to be fully functional so that sterile technicians can easily determine if the flow hood is turned on.

As an example: On 11/18/14 during the processing of T-50 (8 mg Papaverine, 0.29 mg Phentolamine, and 2.9 mcg Alprostadil) for injection lot # K8018 laminar flow hood (b) (4) was not turned on and there was no unidirectional air flow during the sterile processing (filling) of approximately (b) (4) vials. When the status of the hood was acknowledged as not turned on these vials were disposed of and sterile processing was stopped and resumed the following day.

In addition during this processing (b) (4) used to handle sterile and pyrogen free stoppers (some with observable particles) were located inside the laminar flow hood hanging for an unspecified time and were not removed from (b) (4) packaging prior to use, the (b) (4) was used in the ISO 5 zone where filling operations are conducted, and (b) (4) was observed passing over some of the open vials in the ISO 5 zone.

OBSERVATION 2

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. Release testing of finished sterile Human Chorionic Gonadotropin (HCG) 2,000 IU (b) (4) lot # H3026 for weight loss batch size (b) (4) vials compounded on 8/26/2014 was not performed to identify and determine conformance to the final specification (b) (4) of label claim for Human Chorionic Gonadotropin (HCG). API identification and purity testing

to cover HbsAg (Hepatitis B virus surface antigen), HAV (Hepatitis A), HCV(Hepatitis C), CMV (Cytomegalovirus) and HIV (Human Immunodeficiency virus) antibodies all listed on the drug substance certificate of analysis was not performed when the bulk drug substance HCG lot # (b) (4) was received and used to manufacture this batch.

B. Release testing of finished sterile Human Chorionic Gonadotropin (HCG) 2,000 IU (b) (4) lot # G9501 for weight loss batch size (b) (4) vials compounded on 7/1/2014 was not performed to identify and determine conformance to the final specification (b) (4) of label claim for Human Chorionic Gonadotropin (HCG). API identification and purity testing to cover HbsAg (Hepatitis B virus surface antigen), HAV (Hepatitis A), HCV(Hepatitis C), CMV (Cytomegalovirus) and HIV (Human Immunodeficiency virus) antibodies all listed on the drug substance certificate of analysis was not performed when the bulk drug substance HCG lot # (b) (4) was received and used to manufacture this batch.

C. Release testing of finished sterile Human Chorionic Gonadotropin (HCG) 10,000 IU (b) (4) lot # H9906 for weight loss batch size (b) (4) vials compounded on 8/6/2014 was not performed to identify and determine the conformance to the final specification of (b) (4) of label claim for Human Chorionic Gonadotropin (HCG). API identification and purity testing was not performed when the bulk drug substance HCG lot # (b) (4) was received and used to manufacture this batch.

D. Release testing of finished sterile Sermorelin Forte Plus Sermorelin 2.4 mg/GHRP-2 2.4 mg/GHRP6 1.2 mg (b) (4) product for injection lot # G9123 batch size (b) (4) vials compounded on 7/23/2014 was not performed to identify and determine conformance to the final specification of (b) (4) of label claim. These specifications were not listed on the batch record. API identification and purity testing was not performed when the bulk drug substances were received and used to manufacture this batch to include: Sermorelin Acetate lot # (b) (4) GHRP-2 Acetate lot # (b) (4) and GHRP-6 Acetate lot # (b) (4)

E. Release testing of finished sterile Sermorelin 3.0 mg GHRP6 3 mg (b) (4) product for injection lot # G8421 batch size (b) (4) vials compounded on 7/21/2014 was not performed to identify and determine conformance to the final specification of (b) (4) of label claim. These specifications were not listed on the batch record. API identification and purity testing was not performed when the bulk drug substance were received and used to manufacture this batch to include: Sermorelin Acetate lot # (b) (4) and GHRP-6 Acetate lot # (b) (4)

In addition you have not performed preservative effectiveness testing on the Bacteriostatic Water with (b) (4) that you compound and include in the reconstitution kits for these products assembled at your firm.

OBSERVATION 3

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

Specifically, the written procedure *Doc. # P-211 Policy on the Environmental and Personnel Monitoring Program Section 8.1.1.6* requires that during sampling, (b) (4) . I observed that the surface samples are collected from the (b) (4) . I observed that this procedure was not fully implemented in that surfaces sampled were (b) (4)

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OBSERVATION 4

The written stability testing program is not followed.

Specifically, there is no written testing program designed to assess the stability characteristics of drug products and low dose drug products. There is no stability data to support expiration dates applied to injectable drug products to include: Polidocanol 5% for Injection lot # H3512 beyond use date (BUD) 2/15; T-50 (Papaverine 8 mg/ml, Phentolamine 0.29 mg/ml, Alprostadil 2.9 mcg/ml) for injection lot # K8018 BUD 11/15; QM-3 (Papaverine 30 mg/ml, Phentolamine 3 mg/ml, PGE 150 mcg/ml, Atropine 0.2 mg/ml) lot # J1029 BUD 10/15; Human Chorionic Gonadotropin (HCG) 2,000 IU (b) (4) for injection lot # H3026 BUD 2/15; HCG 10,000 IU (b) (4) for injection lot # H9906 BUD 02/15; Sermorelin Forte Plus (Sermorelin 2.4 mg, GHRP2 2.4 mg, GHRP6 1.2 mg) (b) (4) for injection lot # G9123 BUD 01/15 and Sermorelin 3mg GHRP-6 3 mg (b) (4) for injection lot # G84212 BUD 2/15.

This deficiency is repeated as item # 2 from the Warning Letter dated 2/18/2014 and Form FDA 483 item # 9 from the inspection conducted on 3/4, 5, 20, and 21/2013.

OBSERVATION 5

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, there was a storage shelf containing some processing materials in the ISO 5 processing room # (b) and (b) (4) (b) (4) used to place (b) (4) onto vials in the ISO-5 zone were stored on a hook in laminar flow hood - (b) (4)

OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, your media fill validation did not include storing non-sterilized intermediate drug products such as the Papaverine HCl (b) (4) mg/ml lot # (b) (4) BUD 11/20/14 for the worst case scenario (b) (4) and sterile bulk drug product such as (b) (4) lot # (b) (4) for up to (b) (4) .

OBSERVATION 7

The flow of components, drug product containers, closures, in-process materials, and drug products though the building is not designed to prevent contamination.

Specifically, there is a (b) (4) ISO 5 Room # (b) which (b) (4) . There is also a

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refrigerator that opens into this room which could be a source of water and potential contamination.

OBSERVATION 8

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

Specifically,

The following drug product labels do not contain the statement "This is a compounded drug" and do not contain the date the product was made:

Polidocanol 5% injection
Cyanocobalamin 1mg/mL injection
Sermorelin 3mg injection
Human Chorionic Gonadotropin 2000 IU injection
Brompheniramine 10 mg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 50 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL Atropine 0.2 mg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 10 mcg/mL injection
Papaverine 4 mg/mL Phentolamine 0.145 mg/mL PGE 1.45 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 10 mcg/mL Atropine 0.2 mg/mL injection
Papaverine 8 mg/mL Phentolamine 0.29 mg/mL PGE 2.9 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 25 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 40 mcg/mL injection

The following drug product labels do not contain the statement, "Not for resale":

Polidocanol 5% injection
Sermorelin 3mg injection
Human Chorionic Gonadotropin 2000 IU injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 50 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL Atropine 0.2 mg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 10 mcg/mL injection
Papaverine 4 mg/mL Phentolamine 0.145 mg/mL PGE 1.45 mcg/mL injection

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Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 10 mcg/mL Atropine 0.2 mg/mL injection
Papaverine 8 mg/mL Phentolamine 0.29 mg/mL PGE 2.9 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 25 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 40 mcg/mL injection

The following drug product labels do not contain the statement, "Office Use Only":
Polidocanol 5% injection
Sermorelin 3mg injection
Human Chorionic Gonadotropin 2000 IU injection

The following drug product labels do not contain storage and handling instructions:
Polidocanol 5% injection
Brompheniramine 10 mg/mL injection

The following drug product labels do not specify the volume of the vial contents:
Sermorelin 3mg injection
Human Chorionic Gonadotropin 2000 IU injection

The following drug product labels do not contain the established name of the drug:
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 50 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL Atropine 0.2 mg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 10 mcg/mL injection
Papaverine 4 mg/mL Phentolamine 0.145 mg/mL PGE 1.45 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 10 mcg/mL Atropine 0.2 mg/mL injection
Papaverine 8 mg/mL Phentolamine 0.29 mg/mL PGE 2.9 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 25 mcg/mL injection
Papaverine 30 mg/mL Phentolamine 3 mg/mL PGE 40 mcg/mL injection

*** DATES OF INSPECTION:**
11/17/2014(Mon), 11/18/2014(Tue), 11/19/2014(Wed), 11/20/2014(Thu), 11/21/2014(Fri), 12/04/2014(Thu)

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