DISTRICT ADDRESS AND PHONE NUMBER	D DRUG ADMINISTRATION DATE(S) OF INSPECTION
555 Winderley Place, Suite 200	11/17/2014 - 12/04/2014*
Maitland, FL 32751	FEI NUMBER
(407) 475-4700 Fax: (407) 475-4768	3011158365
Industry Information: www.fda.gov/oc/i	ndustry
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Mr. Marco Loleit, Owner	
	STREET ADDRESS
TO: Mr. Marco Loleit, Owner	STREET ADDRESS 6700 Conroy Road
TO: Mr. Marco Loleit, Owner FIRM NAME OPS International Incorporated dba	
TO: Mr. Marco Loleit, Owner	6700 Conroy Road

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) the base of the one of 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 (0)(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 was not turned on and there was no unidirectional air flow during the sterile processing (filling) of approximately 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,

	vials compounded on 8/26/2014 was not performed to identify and determine conformation	
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TO: Mr. Marco Loleit, Owner	STREET ADORESS	
OPS International Incorporated dba	6700 Conroy	y Road
Olympia Pharmacy	Suite 155	
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835	TYPE ESTABLISHMENT IN Outsourcing	NAS MANAGE
Offando, FL 52655	Toursourcing	J Facility
to cover HbsAg (Hepatitis B virus surface antigen), HAV HIV (Human Immunodeficiency virus) antibodies all liste when the bulk drug substance HCG lot # (b) (4) was rece C. Release testing of finished sterile Human Chorionic Go loss batch size (b) (4) vials compounded on $\frac{8}{6}/2014$ was no specification of (b) (4) of label claim for Human Chori was not performed when the bulk drug substance HCG lot D. Release testing of finished sterile Sermorelin Forte Plu product for injection lot # G9123 batch size (b) (4) vials com determine conformance to the final specification of (b) (4) batch record. API identification and purity testing was not to manufacture this batch to include: Sermorelin Acetate H lot # (b) (4)	at performed to identi- torionic Gonadotropir (Hepatitis A), HCV(ed on the drug substan- eived and used to man conadotropin (HCG) 1 of performed to identi- ionic Gonadotropin (H t # (b) (4) was received as Sermorelin 2.4 mg/ appounded on $7/23/20$) of label claim. t performed when the lot # (b) (4) GHRP-	fy and determine conformance to the final (HCG). API identification and purity testing Hepatitis C), CMV (Cytomegalovirus) and nee certificate of analysis was not performed nufacture this batch. 0,000 IU (b) (4) lot # H9906 for weight fy and determine the conformance to the final HCG). API identification and purity testing wed and used to manufacture this batch. GHRP-2 2.4 mg/GHRP6 1.2 mg (b) (4) 14 was not performed to identify and . These specifications were not listed on the bulk drug substances were received and used 2 Acetate lot # (b) (4) and GHRP-6 Acetate
E. Release testing of finished sterile Sermorelin 3.0 mg G (b) (4) vials compounded on $7/21/2014$ was not performed to (b) (4) of label claim. These specifications were not not performed when the bulk drug substance were received lot # (b) (4) and GHRP-6 Acetate lot # (b) (4)	o identify and determ listed on the batch re	ine conformance to the final specification of cord. API identification and purity testing was
In addition you have not performed preservative effectives that you compound and include in the reconstitution kits for		
OBSERVATION 3		
Aseptic processing areas are deficient regarding the system	m for monitoring env	ironmental conditions.
Specifically, the written procedure Doc. # P-211 Policy of	n the Environmental	
Specifically, the written procedure <i>Doc.</i> # <i>P-211 Policy of</i> 8.1.1.6 requires that during sampling,		(b) (4)
8.1.1.6 requires that during sampling,	. 1	observed that the surface samples are
8.1.1.6 requires that during sampling, collected from the (b) (4)	. 1	(b) (4)
8.1.1.6 requires that during sampling,	. 1	observed that the surface samples are

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Maitland, FL 32751 (407) 475-4700 Fax:(407	32751 00 Fax:(407) 475-4768		FEI NUMBER 3011158365	
	ormation: www.fda.gov/oc/industry			
TO: Mr. Marco Loleit, C				
FIRM NAME		STREET ADDRESS		
OPS International Incorp Olympia Pharmacy CITY STATE ZIP CODE. COUNTRY	orated dba	6700 Conroy Suite 155 TYPE ESTABLISHMENT INS		
Orlando, FL 32835		Outsourcing		
		and the second second		All and a second se
OBSERVATION 4				
The written stability testing program	n is not followed.			
Specifically, there is no written testi drug products. There is no stability Polidocanol 5% for Injection lot # H mg/ml, Alprostadil 2.9 mcg/ml) for PGE 150 mcg/ml, Atropine 0.2 mg/ for injection lot # H3026 BUD 2/15 Plus (Sermorelin 2.4 mg, GHRP2 2 3mg GHRP-6 3 mg (b) (4) for This deficiency is repeated as item # inspection conducted on 3/4, 5, 20,	data to support expiration 13512 beyond use date (B injection lot # K8018 BU ml) lot # J1029 BUD 10/ ; HCG 10,000 IU (b) (4) .4 mg, GHRP6 1.2 mg) (b injection lot # G84212 BU # 2 from the Warning Lett	dates applied to in UD) 2/15; T-50 (F D 11/15; QM-3 (F 15; Human Chorio for injection I 0 (4) for inject JD 2/15.	njectable drug products to i Papaverine 8 mg/ml, Phenta Papaverine 30 mg/ml, Phen nic Gonadotropin (HCG) 2 ot # H9906 BUD 02/15; Se tion lot # G9123 BUD 01/	nclude: blamine 0.29 tolamine 3 mg/ml, 2,000 IU (b) (4) ermorelin Forte 15 and Sermorelin
OBSERVATION 5			112 III III.	
Separate or defined areas to prevent of drug products.	contamination or mix-up	s are deficient reg	arding operations related to	aseptic processing
Specifically, there was a storage she (b) (4) used to place (b) (4) onto via	elf containing some proce ls in the ISO-5 zone were	ssing materials in stored on a hook i	the ISO 5 processing room in laminar flow hood - ^{(b)(4)}	# ^(b) and (b) (4)
OBSERVATION 6				
Procedures designed to prevent mic adequate validation of the sterilizati		on of drug products	s purporting to be sterile do	not include
Specifically, your media fill validat Papaverine HCl ^{[5](4)} mg/ml lot #(b) as (b) (4)				k drug product such
OBSERVATION 7	in the state of the second sec			
The flow of components, drug prod designed to prevent contamination.	uct containers, closures, i	n-process material	s, and drug products thoug	h the building is not
Specifically, there is a (b) (4)	ISO 5 Room	n # [®] which (b) (4)	. The	ere is also a
EMPLOYEE(3) SIGNATUR			0	DATE ISSUED
SEE REVERSE Joanne E. OF THIS PAGE	King, Investigato	r	All	12/04/2014
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Maitland, FL 32751		FEI NUMBER
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TO: Mr. Marco Loleit, Owner		
FIRM NAME	STREET ADDRESS	
OPS International Incorporated dba	6700 Conroy	Road
Olympia Pharmacy	Suite 155	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSP	ECTED
Orlando, FL 32835	Outsourcing	Facility
refrigerator that opens into this room which could be a so OBSERVATION 8		
The labels of your outsourcing facility's drug pr 503B(a)(10)(A).	oducts do not inclu	de information required by section
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:

CITCOLL.	L FILS SPEED	ne produce mas made.	
	Polidoca	nol 5% injection	
	Cyanoco	balamin 1mg/mL injection	
	a 1	the second se	
	Human C	Chorionic Gonadotropin 2000 IU injection	
	Bromphe	eniramine 10 mg/mL injection	
		ine 30 mg/mL Phentolamine 3 mg/mL PGE 50 mcg/mL injection	Î
	CONTRACTOR OF A CONTRACTOR A CON	ne 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL Atropir	
		ine 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL injection	
		ne 30 mg/mL Phentolamine 1 mg/mL PGE 10 mcg/mL injection	
	*	ine 4 mg/mL Phentolamine 0.145 mg/mL PGE 1.45 mcg/mL inje	
		ine 30 mg/mL Phentolamine 3 mg/mL PGE 10 mcg/mL Atropine	
	-	ine 8 mg/mL Phentolamine 0.29 mg/mL PGE 2.9 mcg/mL injecti	
		ine 30 mg/mL Phentolamine 1 mg/mL PGE 25 mcg/mL injection	
		ine 30 mg/mL Phentolamine 3 mg/mL PGE 40 mcg/mL injection	
	ruputern		
The fol	lowing di	rug product labels do not contain the statement, "Not for resale":	
1110 101	and the second se	nol 5% injection	13
		lin 3mg injection	
		Chorionic Gonadotropin 2000 IU injection	
		ine 30 mg/mL Phentolamine 3 mg/mL PGE 50 mcg/mL injection	
		ine 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL Atropin	
		ine 30 mg/mL Phentolamine 3 mg/mL PGE 300 mcg/mL injectio	
		ine 30 mg/mL Phentolamine 1 mg/mL PGE 10 mcg/mL injection	
		ine 4 mg/mL Phentolamine 0.145 mg/mL PGE 1.45 mcg/mL inje	
	rapavern	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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	FOOD AND D	CALTH AND HUMAN S DRUG ADMINISTRATION		
Maitland, FL (407) 475-470	one NUMBER ey Place, Suite 200		DATE(S) OF INSPECTION 11/17/2014 - 12/04 FEI NUMBER 3011158365	/2014*
Industry Information: www.fda.gov/oc/industry				
TO: Mr. Marc	co Loleit, Owner	STREET ADDRESS		
and the second s	onal Incorporated dba macy	6700 Conroy Suite 155		*.
Orlando, FL		Outsourcing		
Papaveri Papaveri The following d Polidoca Sermore Human The following d Polidoca Brompho The following d Sermore Human	ine 8 mg/mL Phentolamine 0.29 i ine 30 mg/mL Phentolamine 1 mg ine 30 mg/mL Phentolamine 3 mg rug product labels do not contain unol 5% injection lin 3mg injection Chorionic Gonadotropin 2000 IU rug product labels do not contain eniramine 10 mg/mL injection rug product labels do not specify lin 3mg injection Chorionic Gonadotropin 2000 IU	g/mL PGE 25 mc g/mL PGE 40 mc the statement, "C injection storage and hand the volume of the injection	g/mL injection g/mL injection Office Use Only": Illing instructions: e vial contents:	
Papaveri Papaveri Papaveri Papaveri Papaveri Papaveri Papaveri Papaveri	ine 30 mg/mL Phentolamine 3 mg ine 30 mg/mL Phentolamine 3 mg ine 30 mg/mL Phentolamine 3 mg ine 30 mg/mL Phentolamine 1 mg ine 4 mg/mL Phentolamine 0.145 ine 30 mg/mL Phentolamine 3 mg ine 8 mg/mL Phentolamine 0.29 m ine 30 mg/mL Phentolamine 1 mg ine 30 mg/mL Phentolamine 3 mg	g/mL PGE 50 mc g/mL PGE 300 m g/mL PGE 300 m g/mL PGE 10 mc mg/mL PGE 10 mc mg/mL PGE 10 mc mg/mL PGE 2.9 n g/mL PGE 25 mc g/mL PGE 40 mc	g/mL injection icg/mL Atropine 0.2 mg, icg/mL injection g/mL injection g/mL Atropine 0.2 mg/r mcg/mL injection g/mL injection g/mL injection g/mL injection	
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	DEPARTMENT OF HE	CALTH AND HUMAN		
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Maitland, FL 327	Place, Suite 200 32751		11/17/2014 - 12/04, FEI NUMBER	/2014*
(407) 475-4700 F)7) 475-4700 Fax:(407) 475-4768			
NAME AND TITLE OF INDIVIDUAL TO WHO	ion: www.fda.gov/oc/ind M REPORT ISSUED	dustry		
TO: Mr. Marco Lo	oleit, Owner	STREET ADORESS		
a to the state of the	Incorporated dba	6700 Conros	/ Road	
Olympia Pharmacy		Suite 155		
Orlando, FL 3283	5	Outsourcing		
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