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 ORAPHARM2_RESPONSES@fda.hhs.gov	2/14/2022-3/2/2022* FEI NUMBER 3009724085

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Marco Loleit, CEO & Owner	
FIRM NAME	STREET ADDRESS
Olympia Compounding Pharmacy dba 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 WE OBSERVED:

OBSERVATION 1

Drug products failing to meet established specifications are not rejected.

Specifically, we identified approximately fifty-nine (59) lots that were out-of-specification (OOS) for potency/reconstitution time and were released by your firm from January 1, 2021 through February 16, 2022. The table below illustrates the eleven (11) lots currently on the market and within expiration date.

Drug Product	Lot #	Result	Specification	BUD	Disposition
BiMix (Papaverine 30mg/Phentolamine 3mg)	(b) (4)	88.8%	(b) (4)	2/22/22	Expired
BiMix (Papaverine 30mg/Phentolamine 3mg)		88.8%		2/22/22	Expired
NAD + (Nicotinamide Adenine Dinucleotide) 500mcg ((b) (4))		Failed Reconstitution Time		3/8/22	Released and on the market
Sincalide 5mcg		110.4%		4/1/22	Released and on the

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Jessica P Mcalister, Investigator
Susan O Oladeji, Investigator
Clinton J Lott, Investigator

X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 03-02-2022 11:18:29

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					market
Sincalide 5mcg	(b) (4)	Failed Reconstitution Time	(b) (4)	4/1/22	Released and on the market
NAD + (Nicotinamide Adenine Dinucleotide) 500mcg ((b) (4))		85.6%		4/5/22	Released and on the market
F9 (Papaverine 0.9mg/1mL, Phentolamine 0.1mg/1mL, Alprostadil 20mcg/1mL, Atropine 0.01mg/1m)		85%		4/19/22	Released and on the market
Sermorelin Acetate 9mg/mL ((b) (4))		79.7%		4/26/22	Released and on the market
T-105 (Papaverine 30mg/Phentolamine 1mg/PGE 10mcg/mL)		115.4%		5/10/22	Released and on the market
T-105 (Papaverine 30mg/Phentolamine 1mg/PGE		115.4%		5/10/22	Released and on the market

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10mcg/mL)					
SB-4	(b) (4)	89.2%	(b) (4)	5/18/22	Released and on the market
SB-4		89.2%		5/18/22	Released and on the market
Hydroxycobalamin 1mg/mL		92.7%		5/21/22	Released and on the market
Sermorelin Acetate 9mg/mL ((b) (4))		79.6%		6/4/22	Released and on the market

OBSERVATION 2

The quality control unit lacks responsibility to reject all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Specifically, we identified approximately one hundred eighty-five (185) microbiological recoveries that were identified for personnel and environmental sampling conducted during production operations within the ISO 5 environment from July 2021 to February 2022. On 9/5/21, your firm-initiated deviation #D-

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2021-022 (closed on 12/15/21) due to post process (b) (4) sampling out-of-specification (OOS) results being found on sticky notes. The investigation stated from September 15, 2020, to September 15, 2021, all environmental monitoring showed no action limits within the critical filling zone, but this is not the case as evidenced by the following examples.

- (b) (4) Settle plate failure (1 cfu on 9/22/21) within Auto filler (b) (4) during production of Zinc Chloride lot # (b) (4). ID: *Staphylococcus warneri.*
- Post processing (b) (4) sampling failure (1cfu on 9/13/21) within Auto filler (b) (4) during production of NAD+ lot # (b) (4). ID: *Paenibacillus agaridevorans*.
- (b) (4) Settle plate failure (8 cfu on 8/4/21) within Auto filler (b) (4) during the production of Testosterone lot # (b) (4). ID: *Staphylococcus capitis capitis.*
- Post processing (b) (4) sampling failure (3cfu on 7/21/21) within Auto filler (b) (4) during production of Lipo Mino Mix lot # (b) (4). ID: *Bacillus azotoformans.*
- (b) (4) Settle plate failure (1 cfu on 7/20/21) within Auto filler (b) (4) during production of SB-6 lot # (b) (4). ID: *Pseudomonas luteola.*

In addition, your Quality Unit (QU) released all potential impacted batches based on passing sterility and endotoxin test results. Your QU failed to evaluate your firm's current cleaning practices to determine if they are effective in inactivation or removal of microorganisms within the ISO 5 environment.

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OBSERVATION 3

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

Specifically,

- Your firm's SOP entitled, "Environmental Monitoring for the Positive and Negative Pressure Cleanrooms at Olympia Pharmacy", is inadequate as it fails to identify the critical sampling locations within your firm's ISO 5 LAFW during filling operations utilizing the (b) (4) and (b) (4). For example, your firm did not provide scientific justification for omitting the product contact surface sample sites such as the filling needle or hopper which houses the stoppers within the (b) (4) filling machine which is in the ISO 5 LAFW.

- Your firm failed to have accountability of the environmental monitoring (EM) samples collected during/after each batch production. On 2/14/22, your firm's QA Specialist was observed unloading the EM plates from the incubator. His process was to discard the sample if no growth was observed. When growth was observed he would set the sample aside to later count the colonies. No documentation occurred during this process. He then printed the EM Forms and recorded the plates that contained growth and for those that he no longer had plates for marked them as having zero counts.

  In addition, on 2/14/22 during our observation of the QA Specialist's plate enumeration, we observed and documented the following discrepancy: Sample site: (b) (4) (ID: (b) (4)) Cleanroom (b) Floor Center he documented 7cfu/plate when we documented and photographed 20+ cfu/plate.

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OBSERVATION 4

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, your July 13, 2021, Deviation #D-2021-007, which covered your April 2021 excursions identified below, was inadequate as it failed to evaluate whether your differential pressure specifications were suitable. In the investigation your firm indicated that your SOP # P-211 entitled, "Policy on Environmental and Personnel Monitoring Program" required a positively pressured specification of (b) (4). Data extracted from your electronic monitoring system reveals a (b) (4) specification from February 2021 to April 2021. In May to September 2021, the specification was changed to (b) (4) and then changed back to (b) (4) towards the end of September 2021 where it has remained. Furthermore, your Quality Director stated that there were no investigations into your June, August and November 2021 pressure excursions as identified within the table below.

Date	Alarm Triggered	Non-HD ISO 5 Cleanroom	Pressure during vial filling operations	Lot(s) affected
8/5/21	n/a	Cleanroom (b) (4)	0.002-0.038	(b) (4)
11/16/21	No	Cleanroom (b) (4)	0.005	(b) (4)

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8/17/21	Yes	Cleanroom (b) (4)	0	(b) (4)
4/5/21	n/a	Cleanroom (b) (4)	0.005-0.032	(b) (4)
4/30/21	n/a	Cleanroom (b) (4)	0-0.032	(b) (4)
6/16/21	yes	Cleanroom (b) (4)	0.001	(b) (4)

In addition to the above, according to SOP # P225.4 entitled, "Continuous Monitoring Systems", effective October 12, 2021, states all differential pressure values (b) (4) are considered action level excursions and should trigger a deviation investigation regardless of the excursion duration. However, a review of electronic data extracted from your differential pressure system reveals that your alarm specification has been set for (b) (4) for (b) (4) since October 12, 2021.

OBSERVATION 5

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

1. Your firm failed to follow your SOP P-224 entitled, "Deviation Management", sections 7.5 Quality Evaluation (determining the impact of the deviation on safety, identity, strength, quality, and purity of the product) and section 7.6 Investigation (the investigation must include or eliminate other batches), etc., as evidenced by the following inadequate deviations conducted.

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a. On 9/1/21 your firm-initiated Deviation #2021-020 due to Complaint #CC 2021-092 for NAD+ Lot # (b) (4). The complainant stated the vials received were evaporated and contained a yellow-like gel substance. Your firm's investigation determined the reason for the incomplete sublimation attributing the root cause as the technician failed to verify the stopper depth and the stopper was inserted too far into the vial. Your investigation stated there is no impact to the product quality and determined this incident to be a cosmetic defect without any evidence that this defect did not impact product quality and safety.

Your firm's CAPA was to retrain the batch department on stopper depth and protocols within the NAD+ batch. However, your Production Manager stated that these set-up instructions listed within the investigation are not documented in any protocols or the batch production record therefore it is uncertain if the machine is being set-up appropriately. The stopper height is a critical parameter during the filling of NAD+ (b) (4) on the (b) (4) machine and your firm failed to evaluate other batches of drug product filled on this machine. In addition, no preventative maintenance is conducted on the filling machine.

b. Biotin 0.05% (0.5mg/mL) Injection 10mL MDV lot # (b) (4), CPD 07 FEB 22, BUD 06 AUG 22 failed batch yield, 106% (spec.: (b) (4)). The target fill volume was (b) (4) and your firm produced (b) (4). The Production Manager stated they may have a potential issue with under-filled vials. During the current FDA Inspection, on 2/18/22, Deviation #2022-004 was opened. At this time the deviation fails to extend to other batches filled on the (b) (4) Filling Machine that have had an OOS for yield. In addition, your firm does not have set-up instructions for the (b) (4) Filling Machine. Your firm also does not have in-process volume checks during filling operations.

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c. Preserved Ascorbic Acid 500mg/mL lot #(b) (4), (b) (4) and (b) (4), CPD 08 JUN 21, BUD 05 DEC 21 failed batch yield, 106.8% (spec.: (b) (4)). The target fill volume was (b) (4) and your firm produced (b) (4). A note on the batch record states, "some low fills". No deviation was initiated. This batch was released and distributed without Quality review (QC Approved sticker applied to the batch record but not signed) despite the OOS for yield and assay, 89% (spec.: (b) (4)).

d. On 8/18/21, your firm-initiated Deviation #2021-021 for Lipo Mino Mix Lot #(b) (4), due to high assay for (b) (4), 115.2% (spec.: (b) (4)). Your firm attributed the root cause as a technician error during mixing operations. The technician added an unknown amount of (b) (4). The batch required (b) (4) of (b) (4) which according to the technician would take (b) (4) beakers, (b) (4) at a time and due to not adequately recording in the batch record the technician lost track. Your firm's assessment was to reject the batch and instructed both the technician and pharmacist to write down each ingredient within the batch record.

The batch record states to add (b) (4) of the final volume of (b) (4) to the admixture. It also states to add the appropriate amount of (b) (4). Your firm failed to take adequate corrective and preventative actions such as evaluating if the batch record instructions were clear or required revision.

2. Your firm failed to follow SOP P-219 entitled, "Complaint Handling, Drug Safety, and Surveillance", section 7.2 Complaint Review as it states the complaint investigation may include, review of the batch, dispensing and shipping records, examination of the returned complaint

sample and examination or testing of the retained sample. A deviation may be required for the complaint determination as evidenced by the following examples:

a. Your firm received two complaints for low fill volume. Complaint 2021-079 dated 7/21/21 for Methylcobalamin, no lot # provided and Complaint 2021-039 dated 4/27/21 for ST-2, lot #(b) (4). Your firm has failed to implement adequate corrective and preventative actions for low fill volume such as evaluating the set-up of the (b) (4) filling machine and the lack of instructions provided within the batch production record and implementing in-process checks throughout the filling process.

b. Complaint 2021-092 dated 8/31/21 for NAD+ Lot (b) (4). The complainant stated one of the (b) (4) NAD+ vials received was evaporated and contained a yellow-like gel substance. Your firm attributed the root cause of the complaint as an inadequate visual inspection without providing scientific rationale and supporting documentation. Your firm conducted a subsequent manufacturing investigation and determined the root cause to be the stopper depth was too low into the vial causing sublimation during the (b) (4) cycle. However, your firm has failed to implement adequate corrective and preventative actions to prevent this defect from re-occurring.

OBSERVATION 6

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

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Specifically,

1. Your firm's SOP:P-304 entitled, "Cleaning of the Compounding Facility" requires the following cleaning agents and respective contact times: (b) (4) , (b) (4) , (b) (4) (no contact time specified) and (b) (4) used to clean the (b) (4) for (b) (4) , and (b) (4) cleaning but fail to require the documentation of the contact times as a form of verification for the activity conducted. In addition, your firm was unable to provide the manufacturer's specified contact time for the (b) (4) .

   ***This is a repeated observation from the FDA-483 issued on 4/13/18**

2. Your firm has not conducted any challenges for the cleaning validation/sterilization of the (b) (4) Auto filling machine therefore there is no documentation ensuring the residual detergents from your cleaning operations or residue from previous APIs have been adequately removed.

3. On 2/14/22, during the production of Vita Complex MDV, lot # (b) (4) we observed stainless steel carts and chair legs located in the ISO 5 Cleanroom that contained rust-like stains which cannot be adequately cleaned and sanitized.

OBSERVATION 7
Results of stability testing are not used in determining expiration dates.

Specifically,

3. According to your Quality Manager, your firm lacks stability studies for your erectile dysfunction, vitamin, vein care, iv therapy and anti-aging sterile injectable drug products. Your firm did not conduct studies to demonstrate specifications including but not limited to potency,

endotoxin, sterility, and container closure integrity remain suitable throughout each product's shelf life. Examples are identified in the table below:

Product	BUD	Product Distributed from 7-1-21 to 2-14-22 in vials
MICC 10 ml and 30 ml	6 months	(b) (4)
Lipostat Plus	6 months	
Lipo-Mino-Mix 10 ml and 30 ml	6 months	
Semorelin 3mg and 9 mg	6 months	
Ascorbic Acid 30ml	6 months	
Biotin	6 months	
Methylcobalamin 10ml and 30ml	6 months	
Erectile Dysfunction Single mix drugs	12 months	
Erectile Dysfunction Double Mix drugs	12 months	
Erectile Dysfunction Tri-Mix drugs	12 months	
Erectile Dysfunction Quad-Mix drugs	12 months	
NAD	12 months	
Myers Cocktail	6 months	
Olympia Vita Complex	6 months	
Vit D 3	6 months	
Tri Immune Boost	6 months	

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Glycerin	6 months	(b) (4)	
Sodium Bicarbonate	6 months		
Alpha Lipoic	6 months		
Folic Acid	6 months		
L Proline	6 months		
Odanestron	6 months		
Sodium Tetradecyl (STS)	6 months		
L Carnitine	6 months		
Ultratest	12 months		
Olympia Mineral Blend	6 months		
Amino Blend	6 months		
Pyridoxine	6 months		
Calcium Chloride	6 months		
L-Taurine	6 months		
L-Glutamine	6 months		
L-Arginine	6 months		
Dexpanthenol	6 months		
Zinc chloride	6 months		
Magnesium Chloride	6 months		
Acetyl Cysteine	6 months		
Sod Selenite	6 months		
L-Lysine	6 months		
B12 Hydroxo	12 months		
B12 Cyano	6 months		

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Sincalide	12 months	(b) (4)	
Lidocaine 1%	6 months		
Lidocaine 2%	6 months		
Lido 1% and Epi	6 months		
Glyc/Lido/Epi	6 months		
Sodium Bicarbonate	6 months		

4. Your Glutathione 5ml stability study failed potency at its 3-month timepoint in December 2021. You paused this stability study but continue to manufacture and distribute this product with a 3-4-month BUD. Examples of lots released with a 4-month BUD are: (b) (4), (b) (4), (b) (4), (b) (4). From 7/1/21 to 2/14/22, your firm manufactured and distributed (b) (4) vials of this drug.

5. Your January 2021 Mitomycin 30ml stability study failed container-closure testing at its time 0 and 3-month timepoints. In your July 2021 OOS investigation, a commitment was made to discontinue distribution and discard any in-stock product. However, according to your dispensing report and Quality Manager, your firm continued to distribute this product with a 2-month BUD until November 2021. From July 2021 to November 2021 your firm dispensed (b) (4) vials of this drug.

6. The following products have not undergone antimicrobial effectiveness studies to verify that the preservative system is effective and protects the product over its shelf life: F2, Erectile Dysfunction drugs, Semorelin, Vit D 3, Sincalide and Mitomycin.

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OBSERVATION 8

Approved components, drug product containers and closures are not retested or reexamined as appropriate for identity, strength, quality and purity after exposure to conditions that might have an adverse effect with subsequent approval or rejection by the quality control unit.

Specifically, finished drug product, Sincalide 5mcg/Vial lot #(b) (4), CPD 01 April 21, BUD 01 April 22 utilized expired (2/13/21) (b) (4), lot (b) (4) to manufacture the batch. Your firm also failed to locate the complete batch production record (only the formulation sheet which identifies the Sincalide bulk lot #(b) (4) with no expiry date recorded for which your firm cannot locate the corresponding COA, labeling sheet and testing records were provided).

OBSERVATION 9

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, your firm lacks scientific data to support a hold time of approximately (b) (4) for Preserved Ascorbic Acid 500mg/mL, lot #(b) (4) prior to (b) (4) to determine its bioburden.

OBSERVATION 10

The labels of your outsourcing facility's drug products are deficient.

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Marco Loleit, CEO & Owner	
FIRM NAME	STREET ADDRESS
Olympia Compounding Pharmacy dba Olympia Pharmacy	6700 Conroy Rd Ste 155
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Orlando, FL 32835-3515	Outsourcing Facility

7. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

    4. The address and phone number of the outsourcing facility. Examples of product labels that do not contain this information:
    Chloramphenicol 50 mg/Sulfamethoxazole 50 mg/Amphotericin B 5mg Capsules

    5. The storage and handling instructions. Examples of product labels that do not contain this information:
    Chloramphenicol 50 mg/Sulfamethoxazole 50 mg/Amphotericin B 5mg Capsules

    6. A list of inactive ingredients, specifically the quantity or proportion of each ingredient. Examples of product labels that do not contain this information:
        a. Lipoderm (Benzocaine 20%, Lidocaine 10%, Tetracaine 10%) Topical Cream
        b. Lipoderm (Benzocaine 20%, Lidocaine 8%, Tetracaine 6%) Topical Cream
        c. Lipoderm (Benzocaine 20%, Lidocaine 6%, Tetracaine 4%) Topical Cream
        d. Lipoderm (Benzocaine 23%, Tetracaine 7%) Topical Cream
        e. Lidocaine 23%/Prilocaine 10%/Phenylephrine 0.5% Topical Ointment

***This is a repeated observation from the FDA-483 issued on 4/13/18**

OBSERVATION 11

The container labels of your outsourcing facility's drug products are deficient.

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CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

8. The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B). Specifically, your containers for Chloramphenicol 50 mg/Sulfamethoxazole 50 mg/Amphotericin B 5mg Capsules do not include the following information:

    7. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088; and

    8. Route of administration

***This is a repeated observation from the FDA-483 issued on 4/13/18**

OBSERVATION 12

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Specifically, the following products were compounded and not identified on your report dated December 2021.

9. Hydroquin 8%/Tretin 0.05%/Hydrocort 2.5% Cream
10. Azithromycin (ABX) 250mg
11. B12 Cyanocobalamin 2mg/ml
12. CantharadinPlus 10ml
13. Dexamethasone 0.33%
14. Glycolic Acid 50%

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica P Mcalister, Investigator Susan O Oladeji, Investigator Clinton J Lott, Investigator	X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 03-02-2022 11:18:29	3/2/2022

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15. Hair Growth Formulation: Minoxidil 5%/Fluocinolone 0.01%/Tretinoin 0.01%
16. Hydroquin 4%/Tretin 0.05%/Hydrocort 2% Derm Cream
17. Hydroquin 6%/Tretin 0.25%/ Kojic Ac 4%/ Hydrocort 0.05% Cream
18. Hydroquinone 6% Cream
19. Keto Topical: Keto 10%/Cyclobenz 2%/Baclof 2%/Lido 2/5%/Prilo 2.5% Topical Cream
20. Loomicaine (Prilocaine 14% /Lidocaine 14%)
21. Lido 10%/Prilo 10%/Tetra 4% Flavored (b) (4)
22. Lido 23%/Tetra 7%/Prilo 2% (b) (4)
23. MONTH 1 NON INJ Weight Management Days 1-30, Naltrexone 1.5 mg, Sermorelin 500 mcg RDT, Lipo Trim Spray
24. MONTH 2 Weight Management Days 31-60, Naltrexone 3 mg, Sermorelin 9 mg, Lipo Trim Spray
25. MONTH 3+ Weight Management Days 61+, Naltrexone 4.5 mg, Sermorelin 9 mg, Lipo Trim Spray
26. Naltrexone 3 mg tablets
27. Naltrexone 4.5mg tablets
28. NeuroTopical – Gabapentin 6%, Lidocaine 2.5%, Prilocaine 2.5%
29. Phenol 89% Topical Solution
30. Polidocanol 2%
31. Progesterone 25mg E4M capsules
32. Progesterone 50 SR capsules
33. SB6
34. Scream Cream (Aminophylline 3%/Arginine 6%)
35. Sincalide 5mcg ((b) (4))
36. Terbutaline 3mg
37. Tretinoin 0.1% /Clindamycin 2% Cream
38. Tretinoin 0.1%/Hyaluronic Ac 0.5% Cream

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This is not an all-inclusive list.

***This is a repeated observation from the FDA-483 issued on 4/13/18**

OBSERVATION 13

Your outsourcing facility compounds drug products using bulk drug substances that cannot be used in compounding under section 503B because they (a) have been identified in a federal register notice as not being placed on the 503B Bulk List and do not appear on the drug shortage list in effect under section 506E of the Act or (b) appear on the 503B Category 2 (bulk drug substances identified by FDA as presenting significant safety risk).

Specifically, your firm compounds drug products using bulk drug substances that are prohibited under section 503B, including, but not limited to folic acid.

*DATES OF INSPECTION

2/14/2022(Mon), 2/15/2022(Tue), 2/16/2022(Wed), 2/17/2022(Thu), 2/18/2022(Fri), 2/21/2022(Mon), 2/22/2022(Tue), 2/23/2022(Wed), 3/02/2022(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jessica P Mcalister, Investigator Susan O Oladeji, Investigator Clinton J Lott, Investigator	X Jessica P Mcalister Investigator Signed By: Jessica L. Mcalister -S Date Signed: 03-02-2022 11:18:29	3/2/2022

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."