DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd, 3rd Floor Parsippany, New Jersey 07054. Ph. 973-331-4900 ORAPharm1_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	09/28/2020-01/29/2021* FEI NUMBER 3013024146

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Sanjay Sydney Samudre, Vice President, Manufacturing and Technical Services

FIRM NAME	STREET ADDRESS
Imprimis NJOF, LLC	1705 Route 46, Ste 6B
CITY, STATE, ZIP CODE, COUNTRY Ledgewood, New Jersey 07852-9720	TYPE ESTABLISHMENT INSPECTED Drug Compounding 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
(REPEAT OBSERVATION)

There is a failure to thoroughly review any unexplained discrepancy, 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,

A) During the review of Adverse Event Investigation ADE2020081 and associated batch record for Dexamethasone/Moxifloxacin, 1/5 mg/ml, PF Injectable solution, lot #(b) (4) it was discovered that the product lot was released for commercial distribution despite multiple failures in routine production in-process and AQL quality checks. Out of (b) (4) boxes (b) (4) vials) manufactured, (b) (4) boxes (b) (4) vials) were released into commercial distribution. The summary of the repeated production in-process and AQL quality checks are as follows:

Batch Record Package Page Numbers	Inspected by Production or Quality	Total Rejects	Defects Found	Inspection Results (Pass/Fail)
71, 72	Production, (b) (4)%	64 Rejects (Theoretical Batch size(b) (4) vials)	-11 fiber particles -46 bad crimps (non-leaking) -5 missing caps -1 empty vial	Pass

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			-1 scratched, marked or scuffed surface	
73	AQL by Quality	8 Rejects (Batch size (b) (4) vials)	-2 bad caps (non-leaking) -6 bad crimps (non-leaking)	**Fail**
74, 75	Production, (b) (4)%	466 Rejects (Batch size (b) (4) vials)	-3 glass particles -10 fiber particles -2 other particles -442 bad caps (non-leaking) -2 embedded particles -7 scratched, marked or scuffed surface	**Fail**
76, 77	Production, (b) (4)%	42 Rejects (Batch size (b) (4) vials)	-32 fiber particles -8 other particles -1 missing cap -1 scratched, marked or scuffed surface	Pass
78	AQL by Quality	10 Rejects (Batch size (b) (4) vials)	-3 other particles -3 bad crimps (non-leaking) [Note: initial AQL failed with 13 bad crimps. Subsequently count corrected to 3 with Passing AQL] -4 dirty vials	Pass

SOP # PDR- GEN-IPG-013, Inspection Technique, in 5.1.21 states that, "(b) (4) ". However, your firm initiated a (b) (4)% inspection after failed AQL for bad crimps, which is not classified as a critical defect. After a (b) (4)% inspection by production, critical defect (3 glass particles) were found, but the firm deviation #

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AUG2020025 was titled for major defect limit 5.41% (exceeding allowed (b) (4) limit). The final AQL by the Quality group was performed and initial AQL failed with 13 bad crimps. Subsequently, the count was corrected to 3 with passing AQL results.

None of the currently applicable SOP indicate that multiple AQL inspections are allowed. The firm continued inspection of the product lot until it passed. The firm had a remaining inventory of (b) (4) boxes (b) (4) vials) at the time of current inspection.

B) Your firm's investigations did not include monitoring of personnel performing critical interventions on sterile products during production including, but not limited to, the following examples where personnel monitoring revealed microbial action limit excursions after performing production operations of products intended to be sterile. These batches have been released after concluding that the product sterility was not affected by the microbial excursions. Review of your investigations since 2019 have uncovered multiple instances where the product sterility may have been compromised. For example:

(1) Deviation MAY2020012 was opened on May 14, 2020 because operator (b) (6) had a microbial action limit excursion of 1 cfu on her left hand during the sterile filling of Prednisolone Acetate (1%) / Moxifloxacin (0.5%) sterile ophthalmic suspension, lot:(b) (4) . The action limit for gloved fingertips inside the ISO 5 area is (b) (4) (b) (4) This product was filled on the firm's (b) (4) filling machine (b) (4)), where operators must (b) (4) place the empty bottles in the turntable and (b) (4) cap the bottles using (b) (4) . As part of the investigation you verified cleaning records for the filling line, differential pressure of the room throughout the run, environmental monitoring results (air monitoring, personnel monitoring, and surface sampling), and finish product sterility testing. Since the test results reviewed in your investigation were within specification the batch was released on July 07, 2020 with a BUD of April 30, 2021. However, the investigation did not take into consideration if operator (b) (6)) was involved in interventions throughout the run where the operator could have come in to close contact with open product on the line and the firm could not explain how the sample size of (b) (4) bottles is representative of the entire product lot that is potentially contaminated.

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No stratified sampling of bottles was considered during the firm's investigation. In addition, your firm does not reject bottles after interventions.

(2) Deviation JUN2020007 was opened on June 04, 2020 because operator ((b) (6)) had a microbial action limit excursion of 2 cfu on his right hand during the sterile filling of Klarity PF® sterile ophthalmic solution, lot: (b) (4). The action limit for gloved fingertips inside the ISO 5 area is (b) (4) This product was filled on the firm's (b) (4) filling machine (b) (4) where operators must (b) (4) place the empty bottles in the turntable and (b) (4) cap the bottles using (b) (4). As part of the investigation, you verified cleaning records for the filling line, differential pressure of the room throughout the run, environmental monitoring results (air monitoring, personnel monitoring, and surface sampling), and finish product sterility testing. Since the test results reviewed in your investigation were within specification the batch was released on June 18, 2020 with a BUD of May 22, 2021. However, the investigation did not take into consideration if operator (b) (6) was involved in interventions throughout the run where the operator could have come in to close contact with open product on the line and the firm could not explain how the sample size of (b) (4) bottles is representative of the entire product lot that is potentially contaminated. No stratified sampling of bottles was considered during the firm's investigation. In addition, your firm does not reject bottles after interventions.

(3) Deviation JUL2020010 was opened on July 15, 2020 because operator (b) (6)) had a microbial action limit excursion of 1 cfu on their right hand during the fill of Prednisolone Acetate (1%) / Bromfenac (0.75%) sterile ophthalmic suspension, lot: (b) (4). The action limit for gloved fingertips inside the ISO 5 area is (b) (4) (b) (4) This product was filled on the firm's (b) (4) filling machine (b) (4), where operators must (b) (4) place the empty bottles in the turntable and (b) (4) cap the bottles using (b) (4) As part of the investigation you verified cleaning records for the filling line, differential pressure of the room throughout the run, environmental monitoring results (air monitoring, personnel monitoring, and surface sampling), and finish product sterility testing. Since the test results reviewed in your investigation were within specification the batch was released on August 10, 2020 with a BUD of January 01, 2021 However, the investigation did not take into consideration if operator (b) (6)) was involved in interventions throughout the run where the operator could have come in to close contact with open product on the line and the firm could not explain how

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the sample size of (b)(4) bottles is representative of the entire product lot that is potentially contaminated. No stratified sampling of bottles was considered during the firm's investigation. In addition, your firm does not reject bottles after interventions.

(4) Deviation SEP2020020 was opened on September 23, 2020 because operator (b)(6)) had a microbial action limit excursion of 1 cfu on their right hand and mechanics (b)(6) had an action limit excursion of 1 cfu on their left hand, 1 cfu on their right hand and 2 cfu on their right forearm and (b)(6)) had action limit excursions of 1 cfu on their left hand and 2 cfu on their right hand during the sterile filling of Prednisolone Acetate (1%) / Moxifloxacin (0.5%) / Bromfenac (0.075%) sterile ophthalmic suspension, lot:(b)(4) . This product was filled on your (b)(4) filling machine (b)(4)). As part of the investigation, you verified cleaning records for the filling line, differential pressure of the room throughout the run, environmental monitoring results (air monitoring, personnel monitoring, and surface sampling), and finish product sterility testing. In addition, mechanic ((b)(6) stated that the mechanics were working on a part of the equipment that is normally sealed off and filling operation was paused at the time. However, the investigation did not take into consideration if the operators or mechanics were involved in interventions in the ISO 5 area system throughout the run where they could have come in to close contact with open product on the line, the batch record does not state how many bottles were rejected after the stoppage due to mechanical failures, and the firm could not explain how the sample size of (b)(4) bottles is representative of the entire product lot that is potentially contaminated. No stratified sampling of bottles was considered during the firm's investigation. In addition, your firm does not reject bottles after interventions and when bottles are rejected the reason for rejection is not documented.

OBSERVATION 2
(REPEAT OBSERVATION)

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

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Specifically,

The process validation for Prednisolone Acetate/Bromfenac (1/0.075) % Sterile Ophthalmic Suspension, product code (b) (4), is deficient. Process Validation lots (b) (4) (b) (4) were manufactured in 2020 according to process validation protocol PPC-VAL-NJR-047. The (b) (4) PV lot (b) (4) failed specification limits according to the COA provided by the external testing lab when results for sample representing (b) (4) the batch for Bromfenac potency failed the test with a value of 110.4% against a specification limit of (b) (4) %. The firm accepted the failing results and counted the batch as an acceptable PV lot.

In addition, the firm rejected the (b) (4) PV batch (b) (4) when potency values (for Prednisolone Acetate) were found OOS for samples representing (b) (4) the batch. The resulting OOS investigation concluded that the lower amount of bulk suspension left over for this batch (i.e. (b) (4) ml) contributed to the lower potency results. However, the firm failed to scientifically explain how the (b) (4) PV lot (b) (4) that has a comparatively similar bulk leftover of (b) (4) ml had passing results. The summary of bulk left over in (b) (4) batches are presented below:

Lot Number	Bulk Left Over	Total Number of Units Filled	Average Fill weight	Comments
(b) (4)			(b) (4)	Counted towards PV
				Lot rejected. Not counted towards PV.
				Counted towards PV
				Counted towards PV. Failed potency on COA from external lab.

Furthermore, additional deficiencies were found during review of PV documents include, but are not limited to:

- Firm failed to initiate a deviation or investigate when the operators allegedly did not stop the filling process during the (b) (4) PV batch after filling (b) (4) units.
- Batch records used to document bulk hold time (using the same PV protocol) incorrectly referenced Moxifloxacin and Bromfenac Phase and wrong lot number (b) (4) throughout

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the batch records for Phase A (Bromfenac). This was neither caught nor corrected during quality review of the batch records.

PV batches (b) (4) were released for commercial distribution. In addition, approximately more commercial batches were released for commercial distribution after the process validation batches.

OBSERVATION 3
(REPEAT OBSERVATION)

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established:
Specifically,

A) The media fill performed does not represent the number and complexity of routine and nonroutine interventions that occur during production of commercial sterile injectable products.

B) A procedure is not established to determine the number of open vials inside the (b) (4) system to be rejected after a filling equipment downtime or nonroutine intervention.

For example:

During the production of Prednisolone Acetate (1%)/Bromfenac (0.075%) Sterile Ophthalmic Suspension, Lot: (b) (4), on (b) (4), the filling line was stopped due to mechanical challenges for a total downtime of 57 minutes. Throughout the 57 minute downtime there were various interventions performed by the mechanic and operator inside the ISO 5 (b) (4) system. The firm's procedure does not require the operators to account or document the type and complexity of interventions performed during a filling run.

The media fill performed by the firm only includes routine interventions (b) (4) per media fill run. Since the number and types of interventions are not documented during production, there is no assurance that the media fill studies performed accurately represent production conditions. In addition, the firm does not

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reject open units inside the filling line that could be potentially exposed to microbial contamination during routine interventions, non-routine interventions, or equipment stoppage.

OBSERVATION 4

Your outsourcing facility has not submitted an adverse event report to FDA in accordance with the content and format requirements established through guidance or regulation under 21 CFR 310.305 as required by section 503B(b)(5).

Specifically,

The following Adverse Event Reports were not reported to FDA in 15 calendar days after first receiving information about the adverse event.

ADE Number	Product	Lot Number	ADE Received	ADE Reported to FDA
2017012	Triamcinolone (15mg/mL)-Moxifloxacin (1mg/mL) Suspension Injection	(b) (4)	8/1/2017	8/18/2017 (17 days)
2017014	Triamcinolone (15mg/mL)-Moxifloxacin (1mg/mL) Suspension Injection		8/10/2017	9/20/2017 (40 days)
2017015	Triamcinolone (15mg/mL)-Moxifloxacin (1mg/mL)-Vancomycin (10mg/mL) Suspension Injection		8/11/2017	9/18/2017 (37 days)
2017016	Triamcinolone (15mg/mL)-Moxifloxacin (1mg/mL) Suspension Injection		9/4/2017	10/2/2017 (28 days)
2017017	Prednisolone (1%)-Gatifloxacin (0.5%)-Nepafenac (0.1%) Suspension		9/20/2017	10/31/2017 (41 days)

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2019003	Moxifloxacin 1mg/mL Solution Injection	(b) (4)	8/28/2019	9/24/2019 (26 days)
2019015	Triamcinolone (15mg/mL)-Moxifloxacin (1mg/mL) Suspension Injection		11/8/2019	11/27/2019 (19 days)
2019027	Triamcinolone (15mg/mL)-Moxifloxacin (1mg/mL) Suspension Injection		12/4/2019	12/20/2019 (16 days)
2020005	Moxifloxacin 5mg/mL Solution Injection		10/9/2019	3/30/2020 (170 days)
2020081	Dexamethasone (1mg/mL)-Moxifloxacin (5mg/mL) Solution Injection		10/4/2020	11/12/2020 (38 days)

In addition, the following Adverse Event Reports received in 2018-2019 were not reported to FDA in 15 calendar days after first receiving information about the adverse event. The following Adverse Events were retrospectively investigated in response to the Warning Letter the firm received in 2019. Each retrospective complaint investigation which was determined to be an adverse drug event was reported to the FDA in 2020 upon completion of the firm's investigation.

ADE Number	Product	Lot Number	ADE Received	ADE Reported to FDA**
2020020	Triamcinolone (15mg/mL)/Moxifloxacin (1mg/mL) Suspension Injection and Prednisolone/Gatifloxacin-Bromfenac Suspension	(b) (4)	5/16/2019	7/9/2020
2020021	Moxifloxacin 5mg/mL Solution Injection		3/26/2019	7/9/2020
2020022	Dexamethasone (1mg/mL)/Moxifloxacin (5mg/mL) Solution Injection		2/18/2019	7/9/2020
2020023	Prednisolone (1%)/Bromfenac (0.075%) Suspension		5/2/2019	7/9/2020

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2020024	Triamcinolone (15mg/mL)/Moxifloxacin (1mg/mL) Suspension Injection	(b) (4)	5/20/2019	7/9/2020
2020025	Dexamethasone (1mg/mL)/Moxifloxacin (5mg/mL) Solution Injection		6/24/2019	7/9/2020
2020027	Midazolam/Ketamine/Ondansetron (3/25/2) mg Troche		5/29/2019	7/9/2020
2020028	Triamcinolone (15mg/mL)/Moxifloxacin (1mg/mL) Suspension Injection		11/6/2018	7/9/2020
2020029	Prednisolone (1%)/Moxifloxacin (0.5%)/Nepafenac (0.075%) Suspension		7/15/2019	7/9/2020

****reported after retrospective investigation following the last FDA inspection.**

OBSERVATION 5
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The quality control unit lacks the responsibility and authority to reject all in process materials and drug products.

Specifically,

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During inspectional walkthrough on 09/29/2020, 11 lots of expired compounded sterile drug products were found on "HOLD" status in the Distribution Room # (b) (4) for released product.

Part Number	Part Description	Lot Number	Quantity in Quarantine	Expiry Date	Days Expiration Overdue
(b) (4)	Triamcinolone Acetonide (15 MG)/ Moxifloxacin Hydrochloride (1mg/mL)	(b) (4)	3 vials	07/02/2020	88
(b) (4)	Prednisolone Sodium Phosphate (1%)/Bromfenac (0.075%) - 20 5mL Bottles/Box		105 boxes	12/06/2019	297
(b) (4)	Prednisolone Acetate/Moxifloxacin/Nepafenac (1/0.5/0.1)% 5 mL Bottles 20 per box		96 boxes	04/27/2020	154
(b) (4)	Prednisolone Acetate/Moxifloxacin/Nepafenac (1/0.5/0.1)% 5 mL Bottles 20 per box		98 boxes	08/22/2020	37
(b) (4)	Prednisolone Acetate/Moxifloxacin/Nepafenac (1/0.5/0.1)% 5 mL Bottles 20 per box		87 boxes	08/22/2020	37
(b) (4)	Prednisolone Acetate/Moxifloxacin/Nepafenac (1/0.5/0.1)% 5 mL Bottles 20 per box		99 boxes	08/23/2020	36
(b) (4)	Prednisolone Acetate/Moxifloxacin/Nepafenac (1/0.5/0.1)% 5 mL Bottles 20 per box		100 boxes	07/27/2020	63

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(b) (4)	Prednisolone - Nepafenac Ophthalmic Drops (1/0.1)% (5 mL) Box of 20 Bottles	(b) (4)	52 boxes	06/08/2020	112
(b) (4)	Prednisolone - Nepafenac Ophthalmic Drops (1/0.1)% (5 mL) Box of 20 Bottles		63 boxes	06/22/2020	98
(b) (4)	Prednisolone - Nepafenac Ophthalmic Drops (1/0.1)% (5 mL) Box of 20 Bottles		63 boxes	07/08/2020	82
(b) (4)	Prednisolone - Nepafenac Ophthalmic Drops (1/0.1)% (5 mL) Box of 20 Bottles		96 boxes	07/10/2020	80

The expired lots are required to be rejected and documented according to SOP #PRD-GEN-NJR-009, Compounded Drug Product Release and Reporting to FDA, Section 6.12. (b) (4) " Once rejected, it will be prepared for destruction according to SOP #SCM-GEN-NJR-007, Material Destruction Procedure. However, SOP SCM-GEN-NJR-007 does not provide a timeline for disposition or instructions on how the expired material should be removed from Released Product Distribution Room # (b) (4) and prepared for destruction. The firm does not have clear procedures in place to monitor the product in the distribution center for expiry or have specific instructions for Quality to update a disposition to Rejected. In addition, the firm's current material management procedures do not have any provision for tracking inventory of expired materials.

Furthermore, 5 unlabeled totes with sterile drug products were found in the same room on 9/29/2020 as summarized below:

Totes 1 – 3 UNLABELED	Klarity-C® (Cyclosporine) Emulsion Eye Drops, (b) (4), (b) (4) units	(b) (4) bags with (b) (4) units per bag finished product to be distributed to (b) (4)

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Sanjay Sydney Samudre, Vice President, Manufacturing and Technical Services	
FIRM NAME Imprimis NJOF, LLC	STREET ADDRESS 1705 Route 46, Ste 6B
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Totes 4-5 UNLABELED	Multiple single unit finished product, left over, not packaged in (b)(4) [redacted] boxes	Miscellaneous products and lot numbers, including: Prednisolone /Moxifloxacin/Nepafenac; Prednisolone /Moxifloxacin/Bromfenac; Triamcinolone /Moxifloxacin; Moxifloxacin; Tropicamide/Phenylephrine; Klarity-C®; Tropicamide/Proparacaine/Phenylephrine/Ketorolac; and other products.

The firm has no specific procedures to dictate how individual totes with multiple left over finished compounded products are handled. In addition, the firm has no written procedures to dictate the final disposition of unreleased left-over compounded drug products.

OBSERVATION 6

There is a lack of written procedures assigning responsibility, providing cleaning schedules describing in sufficient detail the methods, equipment and materials to be used for sanitation.

Specifically,

The current facility certification is provided by an external contractor. The firm's quality unit is not involved in the review, and approval of the firm's facility certification. No written procedures are established to cover this task. For example, Return Air ducts in all production rooms including ISO 5, ISO 7, and ISO 8 are not covered during the facility certification process. During inspectional walkthrough on 10/06/2020, return air duct in Room # (b)(4) (ISO 7) was found visibly dirty with unknown residue. The firm was on active shut down from (b) (4) [redacted], where facility cleaning and certification took place.

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In addition, there is no established frequency for preventative maintenance and no records are available for cleaning of air ducts on periodic basis. The firm's Preventative Maintenance Program for facilities and manufacturing is incorporated in (b) (4) Management Software. It was noted that (b) (4) (b) (4) Management Software Installation Qualification (IQ) was completed in (b) (4), however, post implementation of Software, a PQ was not performed.

The firm's SOP #EQU-UMR-NJR-007, Cleaning, Disinfection, and Sterilization of Classified Areas and Equipment, in 6.4 provides Cleaning Frequency Table for (b) (4) cleaning equipment and areas in ISO5, ISO7 and ISO 8, which includes floors, wall, ceiling, and other surfaces and equipment. However, neither Preventative Maintenance Program SOP # FAC-GEN-NJR-012 nor SOP #EQU-UMR-NJR-007, Cleaning, Disinfection, and Sterilization of Classified Areas and Equipment include air duct cleaning.

OBSERVATION 7
(REPEAT OBSERVATION)

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, the number of units analyzed for endotoxin testing is not representative of the entire commercial batch size. Four examples of compounded sterile drug products are listed below:

a) Moxifloxacin intraocular injection (0.5%) (5mg/mL), lot #(b) (4) had a batch size of (b) (4) units released for commercial distribution. The sample size for sterility was (b) (4) vials and (b) (4) vial was analyzed for endotoxin testing.
b) Prednisolone Acetate/Bromfenac ophthalmic drops (1/0.075) %, lot # (b) (4) had a batch size of (b) (4) units released for commercial distribution. The sample size for sterility was (b) (4) bottles and (b) (4) bottle was analyzed for endotoxin testing.

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c) Dexamethasone/Moxifloxacin intraocular injection (1/5 mg/ml), lot #(b) (4) had a batch size of (b) (4) units released for commercial distribution. The sample size for sterility was (b) (4) vials and only (b) (4) vials were analyzed for endotoxin testing.

d) Prednisolone Acetate/Moxifloxacin/Bromfenac ophthalmic drops (1/0.5/0.075) %, lot # (b) (4), had a batch size of (b) (4) units released for commercial distribution. The sample size for sterility testing was (b) (4) bottles and only (b) (4) bottles was analyzed for endotoxin testing.

OBSERVATION 8

Your outsourcing facility compounds drug products that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

Specifically,

Your firm compounded the following drug products as topical ophthalmic suspension drugs with Bromfenac Sodium as an active ingredient. Approximately (b) (4) lots were manufactured since October 2017. Approximately (b) (4) lots were released to commercial distribution.

Product (Suspension Eye Drops)	Strength	Product Code	No. of Lots Compounded	No. Lots Released	Fill Volume
Prednisolone Acetate/Bromfenac	(1/0.075) %	(b) (4) (discontinued)	(b)	(b)	3.5 mL
Prednisolone Acetate/Bromfenac	(1/0.075) %	(b) (4) (discontinued)	(b) (4)	(b) (4)	3.5 mL
Prednisolone Acetate/Bromfenac	(1/0.075) %	(b) (4)	(b) (4)	(b)	5 mL

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Prednisolone Acetate/Moxifloxacin/Bromfenac	(1/0.5/0.075) %	(b) (4)	(b) (4	(b) (4	5 mL
Prednisolone Acetate/Moxifloxacin/Bromfenac	(1/0.5/0.075)%	(b) (4)	(b) (4)	(b)	8 mL

OBSERVATION 9

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically,

You compound drug products that:

(a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or
(b) are not identical or nearly identical to an approved drug but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Examples of compounded drug products that are essentially a copy of one or more approved drugs include:

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Ledgewood, New Jersey 07852-9720

TYPE ESTABLISHMENT INSPECTED
Drug Compounding Outsourcing Facility

Drug Name (Product Code)	Product Strength	Dosage Form	Route of Administration
Moxifloxacin (b) (4)) Moxifloxacin (b) (4))	1 mg/mL 5 mg/mL	Solution/Injections Solution/Injections	Intraocular
Epinephrine/Lidocaine (b) (4))	0.25/7.5 mg/ml	Solution/Injections	Intraocular
Prednisolone Acetate (b) (4))	1 %	Suspension/Drops	Ophthalmic
Cyclosporine (b) (4))	0.10%	Emulsion/Drops	Ophthalmic
Phenylephrine/Lidocaine (b) (4))	15/10 mg/ml	Solution/Injections	Intraocular
Prednisolone Acetate/Bromfenac (b) (4))	1/0.075%	Suspension /Drops	Ophthalmic
Tropicamide/Proparacaine/Phenylephrine Ketorolac (b) (4))	1/0.5/2.5/0.5 %	Solution/ Drops	Ophthalmic
Tropicamide/Phenylephrine (b) (4))	1/2.5 %	Solution/Drops	Ophthalmic
Prednisolone Acetate/Moxifloxacin/Nepafenac (b) (4))	1/0.5/0.1 %	Suspension/Drops	Ophthalmic
Dexamethasone/Moxifloxacin (b) (4))	1/5 mg/ml	Solution/Injections	Intraocular
Triamcinolone/Moxifloxacin (b) (4))	15/1 mg/ml	Suspension /Injections	Intraocular
Dexamethasone/Moxifloxacin/Ketorolac (b) (4))	1/0.5/0.4 mg/ml	Solution Injections	Intraocular

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Emmanuel J. Ramos, CSO

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OBSERVATION 10

Records are not maintained so that data therein can be reviewed (b) (4) to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically,

The firm has not generated (b) (4) product reviews for 17 out of (b) (4) current compounded active drug products released in commercial distribution. The firm has failed to follow the applicable procedures for (b) (4) product review delineated in SOP # AUD-POL-NJR-001, (b) (4) Product Quality Review. The following are the only (b) (4) Product Reviews completed since 2017:

Product Code	Product Name	(b) (4) Time Frame	Product Status
(b) (4)	Dexamethasone (1mg/ml)-Moxifloxacin (5mg/mL) Solution Injection	(b) (4)	Active
(b) (4)	Prednisolone(1%)-Gatifloxacin(0.5%) Suspension Drops		Discontinued (August 2019)
(b) (4)	Triamcinolone Acetonide (15mg/ml)- Moxifloxacin HCl (1mg/ml) Suspension Injection		Active
(b) (4)	Moxifloxacin (5mg/ml) Injection		Active
(b) (4)	Dexamethasone (1mg/ml)-Moxifloxacin (0.5mg/ml)-Ketorolac (0.4mg/ml) Solution Injection		Active
(b) (4)	Hyaluronidase (175units/ml) PF, Solution Injection		Discontinued

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		(b) (4)	(March 2020)
(b) (4)	Phenylephrine (15mg/ml)-Lidocaine (10mg/ml) Solution Injection		Active
(b) (4)	Epinephrine (0.25mg/ml)-Lidocaine (7.5mg/ml) Solution Injection		Active

OBSERVATION 11

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

Specifically, the following product, Klarity PF®, Product Code (b) (4) , Solution, Ophthalmic Eye Drops, was compounded and not identified on your report dated June 2020, or December 2020 report.

OBSERVATION 12

Your outsourcing facility compounds drug products using bulk drug substances that cannot be used in compounding under section 503B because they (a) are not used to compound drug products that appear on the drug shortage list in effect under section 506E of the Act and (b) do not appear on a list developed by FDA of bulk drug substances for which there is a clinical need.

Specifically, Chondroitin Sodium is listed as an ingredient in Klarity PF®, Product Code(b) (4) , Solution, Ophthalmic Eyedrops.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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09/28/2020, 09/29/2020, 09/30/2020, 10/01/2020, 10/02/2020, 10/05/2020, 10/06/2020, 10/07/2020, 10/08/2020, 10/09/2020, 10/13/2020, 10/15/2020, 10/16/2020, 10/21/2020, 01/25/2021, 01/29/2021

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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."