DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, Nj 07054 Tel: (973) 331- 4900 Fax: (973) 331-4969	04/24/2017 – 07/10/2017* FEI NUMBER 3013024146

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO:
Pramod K. Sharma , Ph.D., Vice President, Quality

FIRM NAME	STREET ADDRESS
Imprimis NJOF, LLC	1705 Route 46 West, suite 6B
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Ledgewood, NJ 07852-9720	Outsourcing Facility

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

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

Specifically,

a. The following batches of ophthalmic sterile drug products that were manufactured, released, and distributed to the market were not environmentally monitored for non-viable and viable airborne particles counts. During these manufacturing operations the (b) (4) and the (b) (4) were not operational. Additionally, the media fills that were produced to support the sterile manufacturing operations of the below lots were also not environmentally monitored for non-viable and viable particle counts.

Product	Lot Number
Prednisolone (1.0%)/Gatifloxacin (0.5%)/Nepafenac (0.1%) (PGN) – Droppers	JAN007 and FEB002
Triamcinolone (15mg/mL)/Moxifloxacin HCl (1 mg/mL) (TM)– vials for injection	JAN008, JAN009, JAN010, JAN017, JAN018, JAN019, and JAN026.
Triamcinolone (15mg/mL)/Moxifloxacin HCl (1 mg/mL)/ Vancomycin (10 mg/mL) (TMV) – vials for injection	JAN021, JAN022, JAN023, FEB006, FEB007, and FEB008
Media Fills	JAN001, JAN002, JAN003, JAN004, JAN005, JAN006, and JAN025

- Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/mL), lots JAN010 and JAN026 received customer complaints in regard to foreign particles.
- Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/mL), lots JAN019 and JAN026 received a customer complaint in regard to a patient who developed endophthalmitis and Staphylococcus epidermidis that was identified by a hospital clinical laboratory.

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b. Personnel monitoring is limited to the employee's (b) (4) taken (b) (4) There is no monitoring of the employee's sleeves, chest, or forehead despite observance that they enter the ISO 5 area during manufacturing.

c. There is no procedure on how to use the information that can be collected during environmental monitoring in order to assess and prevent situations that could impact drug product sterility.

OBSERVATION 2

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

Specifically, the smoke study of the ISO 5 laminar air flow hood was either not provided or lacked critical activities to demonstrate that the HEPA filtered air supply can maintain aseptic conditions. For example:

a. The initial visualization of the unidirectional air flow (smoke study) to support the sterile filling operations in the ISO 5 (b) (4) laminar air flow hood during January and February 2017 was not found or provided during the inspection.

b. The air flow pattern visualization (smoke study) conducted on (b) (4) failed to include critical activities, such as product filling, manipulation and actions when the (b) (4) is present with (b) (4) operators in the laminar air flow hood. The smoke study was conducted with (b) (4) present without the (b) (4) that holds the bulk product while no product filling occurred. This smoke study also failed to demonstrate a continued pattern of unidirectional air flow. The video lasted (b) (4) .

OBSERVATION 3

Written procedures for cleaning and maintenance fail to include description in sufficient detail of methods, equipment and materials used.

Specifically, cleaning procedure EQU-UMR-NJR-007, Cleaning, Disinfection, and Decontamination of Clean Rooms and Equipment, fails to describe in sufficient detail the cleaning techniques and necessary steps to clean and disinfect the laminar air flow hood (ISO 5), used for filling sterile drug products. Additionally, this SOP also fails to describe the method used to clean various fixtures in the ISO 7 filling room such as the plastic curtain, doors, and piping located on the wall.

In addition, the effectiveness of the sanitization procedures have not been demonstrated through surface samples before and after cleaning and disinfection of the ISO 7 and laminar air flow hood (ISO 5) areas.

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OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, thorough investigations for the following customer complaints were not conducted and corrective actions were not implemented or documented.

a. On 04/04/2017, a consumer complaint reported the presence of black/grey particles in Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/mL), lot numbers JAN026 and FEB011. Lot JAN026 was released and commercially distributed to approximately (b) (4) customers without environmental monitoring of non-viable and viable airborne particle counts during the filling operation because the (b) (4) (b) (4) and the (b) (4) were not operational. Lot FEB011 was released and commercially distributed to approximately (b) (4) customers. The retain samples for both lots were not evaluated to determine if they were contaminated with particles. The investigation into Lot JAN026 was not extended to other batches that were also processed without non-viable and viable airborne particle monitoring. The black/grey particles were not analyzed by a laboratory to determine their identity. Additionally, a root cause was not identified and corrective and preventive actions were not put into place.

b. On 04/28/2017, a consumer complaint reported the presence of unknown particles in Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/mL), lot number JAN010. This lot was released and commercially distributed to approximately (b) (4) customers without environmental monitoring of non-viable and viable airborne particle counts during the filling operation because the (b) (4) and the (b) (4) (b) (4) were not operational. The retain sample was not evaluated to determine if it was contaminated with particles. The action to obtain the vials with particles was not completed as of 05/30/2017 despite receiving the complaint over 1 month ago. No root cause has been identified or corrective and preventive actions put into place.

c. In March 2017, Moxifloxacin 5 mg/mL (0.5%) Injectable lot MAR034 designated as the first validation lot was manufactured and rejected due to unknown crystallization particles observed during the visual inspection process. The visual inspection was stopped, the batch record was not finished, no investigation was initiated, and no root cause has been determined. The second Moxifloxacin 5 mg/mL (0.5%) Injectable validation lot MAR035 was manufactured using an identical process as MAR034, released, and commercially distributed to the market without assurance that it might be impacted by the same root cause.

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OBSERVATION 5

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.

Specifically, there is no established procedure that details how to conduct the (b) (4) test for Moxifloxacin 5 mg/mL (0.5%) Injectable as well as what equipment and materials are needed for the test. In addition, the gauge of the (b) (4) used to perform this (b) (4) test is not calibrated and there is no established (b) (4) calibration procedure.

OBSERVATION 6

Production personnel were not practicing good sanitation and health habits.

Specifically, on 04/26/2017, during the filling operation of Prednisolone (1.0%)/Gatifloxacin (0.5%)/Nepafenac (0.1%) – Droppers lot APR024 we observed two occasions when the sterile operator's hand passed a bag and a tray from the ISO 7 to the ISO 5 area without spraying their gloved hands with sterile (b) (4)

OBSERVATION 7

Examination of a lot of a component, drug product container or closures liable to contamination with extraneous adulterant is deficiently examined against established specifications for such contamination.

Specifically, there is no assurance that the incoming plastic bottles sterilized by (b) (4) and used for filling the following finished drug products are free of (b) (4) residue. Neither Imprimis nor the bottle supplier perform testing or have documentation to show that they are free of residue.

- Prednisolone (1.0%)/Gatifloxacin (0.5%)/Nepafenac (0.1%) - Droppers
- Prednisolone (1.0%)/Gatifloxacin (0.5%) - Droppers
- Prednisolone (1.0%)/Nepafenac (0.1%) - Droppers

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OBSERVATION 8

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically, the following lots of API were used to manufacture sterile drug products without having a certificate of analysis from the supplier and their identification was not verified by conducting at least one test.

a. Vancomycin Hydrochloride, lot number (b) (4) used to manufacture the validation batch Triamcinolone (15 mg/mL)/Moxifloxacin HCL (1 mg/mL)/Vancomycin (10 mg/mL) Injection lot # JAN021. This finished sterile drug product was commercially distributed in 02/2017.

b. Vancomycin Hydrochloride, lot number (b) (4) used for the manufacture of Triamcinolone (15 mg/mL)/Moxifloxacin HCL (1 mg/mL)/Vancomycin (10 mg/mL) lot numbers JAN022, JAN023, FEB006, FEB007, and FEB008. These finished drug products were commercially distributed throughout February and March 2017.

OBSERVATION 9

Adequate lab facilities for testing and approval or rejection of drug products are not available to the quality control unit.

Specifically, contract laboratory facilities have not been audited or qualified to determine their adequacy for testing of drug products and media fills:

a. There are no agreements or procedures in place with any of the contract laboratories (chemical and microbiological) to inform Imprimis about issues that occur during laboratory testing such as deviations and out of specification (OOS) results.

b. There is no assurance that the contract laboratory used for the sterility and endotoxin testing for Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/mL)/Vancomycin (10 mg/mL) Injectable lot numbers JAN021 and FEB014, and endotoxin testing for Prednisolone (1.0%)/Gatifloxacin (0.5%)/Nepafenac (0.1%) lot number APR024 has the capability to perform the required testing in an accurate, precise, and reliable way.

c. There is no assurance that the contract laboratory used for the determination and identification of microbiological growth in media fill batches (e.g., JAN001, JAN002, JAN003, JAN004, JAN005, JAN006, JAN025, FEB061, MAR002, and MAR003) has the capability to perform the required testing in an accurate, precise, and reliable way.

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OBSERVATION 10

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 finished product samples taken per batch is dictated by the contract laboratory. There is no Imprimis procedure or sampling plan that is used to determine if a representative quantity of drug product was taken. The following sterile drug products were involved in a customer complaint where a patient developed endophthalmitis and Staphylococcus epidermidis was identified by a hospital clinical laboratory.

a. Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/mL) Injectable lot JAN019, commercially released to the market to approximately (b)(4) customers during 2017 had a batch size of approximately (b)(4) vials. The sample size for chemical analysis (potency) was (b)(4) vials and the sample size for sterility and endotoxin testing was (b)(4) vials. (b) (4) was analyzed for endotoxin testing.

b. Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/mL) Injectable lot JAN026, commercially released to the market to approximately (b)(4) customers during 2017 had a batch size of approximately (b) (4) vials. The sample for chemical analysis (potency) was (b)(4) vials and the sample size for sterility and endotoxin testing was (b)(4) vials. (b) (4) was analyzed for endotoxin testing.

c. Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/mL) Injectable lot FEB036, commercially released to the market to approximately (b)(4) customers during 2017 had a batch size of approximately (b) (4) vials. The sample for chemical analysis (potency) was (b)(4) vials and the sample size for sterility and endotoxin testing was (b)(4) vials. (b) (4) was analyzed for endotoxin testing.

d. Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/mL) Injectable lot FEB037, commercially released to the market to approximately (b)(4) customers during 2017 had a batch size of approximately (b) (4) vials. The sample for chemical analysis (potency) was (b)(4) vials and the sample size for sterility and endotoxin testing was (b)(4) vials. (b) (4) was analyzed for endotoxin testing.

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OBSERVATION 11

Establishment of the reliability of the container closure supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically, the suppliers of the following container closure systems have not been qualified or audited. In addition, there has not been any testing conducted of these containers and closures to demonstrate reliability of the supplier's COA.

a. The supplier that provides the 2 ml amber vials and 13 mm grey stoppers

b. The supplier that provides the plastic bottles and (b) (4)

OBSERVATION 12

The quality control unit lacks the responsibility and authority to approve or reject all packaging material.

Specifically, the quality unit failed to identify discrepancies in the sterilization method of the (b) (4) (the (b) (4) (b) (4), lot numbers (b) (4) and (b) (4) used for sterile drug products containing Prednisolone. The label indicates sterilization by (b) (4); however, during the inspection, the supplier stated that the sterilization method was actually (b) (4)

On 05/10/2017, we observed the above deficiency which had not been identified during the incoming inspection and release of this component. No explanation regarding the discrepancy in sterilization methods was provided.

***DATES OF INSPECTION:**
04/24/2017 (Mon), 04/25/2017 (Tue), 04/26/2017 (Wed), 05/01/2017 (Mon), 05/02/2017 (Tue), 05/03/2017 (Wed), 05/08/2017 (Mon), 05/09/2017 (Tue), 05/10/2017 (Wed), 05/15/2017 (Mon), 05/16/2017 (Tue), 05/17/2017 (Wed), 05/18/2017 (Thu), 05/22/2017 (Mon), 05/30/2017 (Tue), and 07/10 /2017 (Mon).

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