	LTH AND HUMAN SERVICES JG ADMINISTRATION
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor	04/24/2017 - 07/10/2017*
Parsippany, Nj 07054	FEI NUMBER
Tel: (973) 331- 4900 Fax: (973) 331-4969	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 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 SS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION
OBSERVATION 1	
Aseptic processing areas are deficient regarding the sys	tem for monitoring environmental conditions.
Specifically,	*· *
The following batches of anhthalmic sterile drug	products that were manufactured, released, and distributed to the
7	r non-viable and viable airborne particles counts. During these
manufacturing operations the (b) (4)	•
마스 선생님은 사람이 가지를 받는 하 는 사용하다 하는 것이 되었습니다.	fills that were produced to support the sterile manufacturing
and a recognitive account a second for the control of the control	mentally monitored for non-viable and viable particle counts.
operations of the orient total vice also her sitting	monitorio to to the trade data trade particle counts.
Product	Lot Number
,	Dot Painton
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
 regard to foreign particles. Triamcinolone (15 mg/mL)/Moxifloxacin HCl (1 mg/regard to a patient who developed endophthalmitis and clinical laboratory. 	/mL), lots JAN010 and JAN026 received customer complaints in /mL), lots JAN019 and JAN026 received a customer complaint in ind Staphylococcus epidermidis that was identified by a hospital
SEE EMPLOYEE(S) SIGNATURE REVERSE 1.1.0.1.0	EMPLOYEE(S) NAME AND TITLE (Print or Type) Helen Verdel, Consumer Safety Officer
REVERSE OF THIS PAGE Melen Verolil PAGE	Carolyn E. Becker, Director/CDER/OUDLC Louis An, Consumer Safety Officer/CDER/OUDL Jose M. Cayuela, Consumer Safety Officer

	NT OF HEALTH AND HUMAN SERVICES D AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3 rd Floor	DATE(S) OF INSPECTION 04/24/2017 - 07/10/2017*	
Parsippany, Nj 07054 Tel: (973) 331- 4900 Fax: (973) 331-4969	FEI NUMBER 3013024146	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Pramod K. Sharma, Ph.D., Vice President, Q		
FIRM NAME Imprimis NJOF, LLC	STREET ADDRESS 1705 Route 46 West, suite 6B	
CITY, STATE AND ZIP CODE Ledgewood, NJ 07852-9720	TYPE OF ESTABLISHMENT INSPECTED Outsourcing Facility	•

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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 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.

SEE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
REVERSE OF THIS PAGE	Jai M. Coyul	Helen Verdel, Consumer Safety Officer Carolyn E. Becker, Director/CDER/OUDLC Louis An, Consumer Safety Officer/CDER/OUDL Jose M. Cayuela, Consumer Safety Officer	07/10/2017

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

INSPECTIONAL OPSERVATIONS

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	DEPA	FOOD AND DRUG	AND HUMAN SERVICES ADMINISTRATION		
DISTRICT OFFICE A	DDRESS AND PHONE NUMBER			DATE(S) OF INSPE	CTION
	10 Waterview Blvd., 3 rd Floor			04/24/2017 - 07/10	
1605 A) L	00 Fax: (973) 331-4969			FEI NUMBER 3013024146	
NAME AND TITLE O	F INDIVIDUAL TO WHOM REPORT I	IS ISSUED TO:		3013024146	
Pramod I	K. Sharma , Ph.D., Vice President	dent, Quality			
FIRM NAME			STREET ADDRESS		
Imprimis NJOF,	LLC		1705 Route 46 West, suite 6	SB	
CITY, STATE AND Z	ZIP CODE		TYPE OF ESTABLISHMENT INSPE	CTED	
Ledgewood, NJ			Outsourcing Facility		
REPRESENT A FINAL AC IMPLEMENT, CORRECTI OR SUBMIT THIS INFOR	SENCY DETERMINATION REGARDING YOU VE ACTION IN RESPONSE TO AN OBSERV	JR COMPLIANCE. IF YOU HAV /ATION, YOU MAY DISCUSS TO	INSPECTION OF YOUR FACILITY. THEY A YE AN OBJECTION REGARDING AN OBSER HE OBJECTION OR ACTION WITH THE FDA INS, PLEASE CONTACT FDA AT THE PHON	VATION, OR HAVE IMPL REPRESENTATIVE(S) [EMENTED, OR PLAN TO DURING THE INSPECTION
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OBSERVATIO	ON 4		E.		
There is a fail	ure to thoroughly review any	unexplained discrep	pancy whether or not the batc	h has been alrea	dy distributed.
	lly, thorough investigations f implemented or documented		tomer complaints were not co	onducted and cor	rective actions
	mg/mL)/Moxifloxacin HC commercially distributed to viable and viable airborne (b) (4) and the commercially distributed to evaluated to determine if the extended to other batches to The black/grey particles we	o approximately (b) (4) o approximately (b) (4) o approximately (b) hey were contaminately that were also processere not analyzed by	the presence of black/grey probers JAN026 and FEB011. It is a customers without of generation because were not operation (4) customers. The retain seed with particles. The investigated without non-viable and via laboratory to determine their ventive actions were not put it	Lot JAN026 was environmental me the (b) nal. Lot FEB011 samples for both gation into Lot J. iable airborne par identity. Additional control of the control o	released and nonitoring of non- (4) was released and lots were not AN026 was not urticle monitoring.
b.	mg/mL)/Moxifloxacin HCl distributed to approximatel airborne particle counts du (b) (4) it was contaminated with p	I (1 mg/mL), lot num ly (b) (4) customers ring the filling opera were not of particles. The action to	the presence of unknown paraber JAN010. This lot was relawithout environmental monitation because the operational. The retain sample to obtain the vials with particle of 1 month ago. No root cause	leased and commoring of non-via (b) (4) was not evaluates was not comp	nercially ble and viable and the (b) (4) ted to determine if eleted as of
с.	was manufactured and reje process. The visual inspect and no root cause has been MAR035 was manufacture	ected due to unknown tion was stopped, the determined. The sec ed using an identical	Injectable lot MAR034 design crystallization particles observed batch record was not finished cond Moxifloxacin 5 mg/mL (process as MAR034, released inpacted by the same root causting	erved during the d, no investigation (0.5%) Injectable d, and commercia	visual inspection on was initiated, e validation lot
SEE REVERSE	EMPLOYEE(S) SIGNATURE		EMPLOYEE(S) NAME AND TITLE (Helen Verdel, Consumer Safety		DATE ISSUED

PAGE

Helen Verdel, Consumer Safety Officer

Carolyn E. Becker, Director/CDER/OUDLC
Louis An, Consumer Safety Officer

Consumer Safety Officer

O7/10/2017

Jose M. Cayuela, Consumer Safety Officer

Consumer Safety Officer

O7/10/2017

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PREVIOUS EDITION ORSOLETE

DEPARTMENT OF HEALTH FOOD AND DRUG	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3 rd Floor Parsippany, Nj 07054	04/24/2017 - 07/10/2017*
Tel: (973) 331- 4900 Fax: (973) 331-4969	3013024146
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO:	3013024140
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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¥.	
OBSERVATION 5	
There are no written procedures for production and process contr strength, quality, and purity they purport or are represented to po	
	Is how to conduct the (b) (4) test for Moxifloxacin 5 d materials are needed for the test. In addition, the gauge of the brated and there is no established (b) (4) calibration procedure.
	2 0
OBSERVATION 6	ş "
	m 1 122
Production personnel were not practicing good sanitation and he	alth habits.
	of Prednisolone (1.0%)/Gatifloxacin (0.5%)/Nepafenac (0.1%) en the sterile operator's hand passed a bag and a tray from the ands with sterile (b) (4)
OBSERVATION 7	
Examination of a lot of a component, drug product container or deficiently examined against established specifications for such of	5000 (1945-1947); no registration is to the action of the control
Specifically, there is no assurance that the incoming plate following finished drug products are free of (b) (4) testing or have documentation to show that they are free or	residue. Neither Imprimis nor the bottle supplier perform

- 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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OF THIS Helen Verdel PAGE Sin M. Conjucta	Helen Verdel, Consumer Safety Officer Carolyn E. Becker, Director/CDER/OUDLC Louis An, Consumer Safety Officer/CDER/OUDL Jose M. Cayuela, Consumer Safety Officer	07/10/2017

7.3	MENT OF HEALTH AND HUMAN SERVICES OOD AND DRUG ADMINISTRATION
DISTRICT OFFICE ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3 rd Floor	DATE(S) OF INSPECTION 04/24/2017 - 07/10/2017*
Parsippany, Nj 07054 Tel: (973) 331-4900 Fax: (973) 331-4969	FEI NUMBER 3013024146
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISS Pramod K. Sharma, Ph.D., Vice President	
FIRM NAME	STREET ADDRESS
Imprimis NJOF, LLC	1705 Route 46 West, suite 6B
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lodgowood NI 07852-0720	Outsourcing Facility

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

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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EMPLOYEE(S) SIGNATURE
Helen Verdel, Consumer Safety Officer
Carolyn E. Becker, Director/CDER/OUDLC
Louis An, Consumer Safety Officer
O7/10/2017
Jose M. Cayuela, Consumer Safety Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 04/24/2017 - 07/10/2017* 10 Waterview Blvd., 3rd Floor Parsippany, Nj 07054 FEI NUMBER Tel: (973) 331-4900 Fax: (973) 331-4969 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 TYPE OF ESTABLISHMENT INSPECTED CITY, STATE AND ZIP CODE **Outsourcing Facility** Ledgewood, NJ 07852-9720

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

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

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REVERSE OF THIS PAGE	Hiles Verdil	Helen Verdel, Consumer Safety Officer Carolyn E. Becker, Director/CDER/OUDLC	07/10/2017
, , , , ,	fra M. Coyul	Louis An, Consumer Safety Officer/CDER/OUDL Jose M. Cayuela, Consumer Safety Officer	

(b) (4) , lot numbers (b) (4) and (b) (4) used for sterile drug products containing Prednisolone. The label sterilization by (b) (4) ; however, during the inspection, the supplier stated that the sterilization method was active (b) (4) On 05/10/2017, we observed the above deficiency which had not been identified during the incoming inspection and rethis 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), 05/16/2017 (Tue), 05/17/2017 (Wed), 05/18/2017 (Tue), 05/22/2017 (Mon), 05/30/2017 (Tue), and 07/10 /2017 (Mon).			EALTH AND HUMAN SERVICES DRUG ADMINISTRATION	
10 Waterwes Bild., 3° Floor Partspany, N, 07 OPS Tel. (973) 331-4906 Tel. (973) 331-49	DISTRICT OFFICE	ADDRESS AND PHONE NUMBER		
THE (1973) 331-4900 Fax (873) 33				
INDITION OF LICE TYPE OF RETAILUSHMENT INSPECTED Outsourcing Facility TYPE OF RETAILUSHMENT INSPECTED Outsourcing Facility SECONDARY SET ONE ARE INSPECTION OF YOUR PRIME FOLD REPRESENTATIVES OUTSINE HE INSPECTION OF YOUR PRIME FOLD SHAPE AND ADDRESS AROVE. FYOU HAVE ANY GUESTIONS FOR THE FOR REPRESENTATIVES OUTSINE HE INSPECTION OF YOUR PRIME AND ADDRESS AROVE. FYOU HAVE ANY GUESTIONS FOR SHAPE OUTSINE AND ADDRESS AROVE. FYOU HAVE ANY GUESTIONS, PLEASE CONTACT FROM THE PROPE MUMBER AND ADDRESS AROVE. FYOU HAVE ANY GUESTIONS, PLEASE CONTACT FROM THE PROPE MUMBER AND ADDRESS AROVE. FROM AN INSPECTION OF YOUR PRIM WE GOSERAGE. SPECIFICALLY, the suppliers of the following container closure supplier's report of analyses is deficient in that the test results a appropriately validated at appropriate intervals. Specifically, the suppliers of the following container closure systems have not been qualified or audited. In ad there has not been any testing conducted of these containers and closures to demonstrate reliability of the supplication of 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) DESERVATION 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) (b) (4) (c) (4) (d) (5) (4) (d) (5) (4) (e) (4) (d) (e) (4) (d) (e) (1) (e) (1) (e) (1) (f) (f) (f) (g)			■ 0.00 (TEXT) (TEXT)	
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Establishment of the reliability of the container closure supplier's report of analyses is deficient in that the test results a appropriately validated at appropriate intervals. Specifically, the suppliers of the following container closure systems have not been qualified or audited. In at there has not been any testing conducted of these containers and closures to demonstrate reliability of the supplication. 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) DESERVATION 12 The quality control unit lacks the responsibility and authority to approve or reject all packaging material. (c) (a) (b) (4) (c) (b) (4) (d) (d) (d) (e) (e) (f) (f) (g) (g) (g) (h) (h) (h) (h) (h	EPRESENT A FINAL AF IPLEMENT, CORRECT R SUBMIT THIS INFOR	GENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF Y IVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DIS IMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY	YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, SCUSS THE OBJECTION OR ACTION WITH THE FDA REPRE	, OR HAVE IMPLEMENTED, OR PLANT SENTATIVE(S) DURING THE INSPECTI
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