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(973) 331-4900 Fax: (973) 331-4969 JU2289/129 ORAPHIARMRESPONSESSIGAhbs.gov JU2289/129 Michael J. Moore, Senior Director Compounding Operations JU2289/129 Michael J. Moore, Senior Director Compounding Operations JU2289/129 Michael J. Moore, Senior Director Compounding Operations JU2289/129 Michael J. Moore, Senior Director Compounding Coperations JU2289/129 Michael J. Moore, Senior Director Compounding Coperations JU2289/129 Michael J. Moore, Senior Director Compounding Operations JU2289/129 Michael J. Moore, Jule J. Moore, Jule J. Moore, Jule J. Moore, Jule J. J						
ORAPRARMI_RESPONSES® fda.hhs.gov Wate AN WIGH RECOVER VERSEE Michael J. M. Moore, Senior Director Compounding Operations Tenume Set Status Rd Tenume Set Status Rd Tenume Set Status Rd Dayton, NJ 08810-1540 Outsourcing Facility This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observation, or have implemented, or plants to implement, corrective action in response to an observation, you may discuss the objection or action with the PDA representative(s) during the inspection or status. If you have any question, or have implemented, or plants to implement, corrective action in response to an observation, you may discuss the objection or action, please contact PDA at the phone number and address above. DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 Asseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically: 1.Your airborne particulate monitoring program for aseptic operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be strile. You do not monitor airborne particulates to ISO 5 air classifications throughout aseptic operations and the orientation of the particle counter (b) (4) in cleanroom 142-6 within ISO 5 (b) (4) Luminar Flow Hood No: (b) (4) in cleanroom 142-6 within ISO 5 (b) (4) Luminar Flow Hood No: (b) (4) in cleanroom 142-6 within ISO 5 (b) (4) Luminar Flow Hood No: (b) (4) in cleanroom 142-6 within I				3022897129		
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Parsippany, N	NJ 07054		FEI NUMBER 3022897129	
	Fax: (973) 331-4969		3022897129	
ORAPHARM1_RES	SPONSES@fda.hhs.gov			
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED			
Michael J. Mo	oore, Senior Director Comp	ounding Oper	ations	
FIRM NAME		STREET ADDRESS	- H:	
Hikma Injecta		36 Stults Rd		
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
Parsippany, No (973)331-4900 ORAPHARM1_RESI	one number 7 Blvd., 3rd Floor		DATE(S) OF INSPECTION 5/23/2022-6/8/2022* FEI NUMBER 3022897129			
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Michael J. Moore, Senior Director Compounding Operations					
Contract and the second second second	a Injectables USA Inc 36 Stults Rd					
CITY, STATE, ZIP CODE, COUNTR Dayton, NJ 088	Second start Management of the Second Second	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility				
compounding and aseptic filling of your drug products intended to be sterile. Inspectional evaluation of your ISO 5 area airflow pattern studies; Document No.: (b) (4) Risk Assessment Regarding the Equivalency of the LFH through the process of (b) (4) smoke studies, Approved Date: $05/26/2022$; and List of Commercial Batches Compounded related with hood smoke studies in (b) (4) , revealed that (b) (4) products/lots were produced during the period $02/22/2022$ to the present through aseptic operations performed in ISO 5 (b) (4) Laminar Flow Hoods for which there was no direct (b) (4) airflow pattern evaluation. For example: Fentanyl Citrate 50 mcg/ml (100 mcg per 2 ml) in 0.9% Sodium Chloride Injection, NDC (b) (4) , Lot No.: (b) (4) , Expiry: 07/15/2022, was produced in cleanroom suite 142-7 and filled in ISO 5 (b) (4) Laminar Flow Hood No.: (b) (4) which was not directly assessed in an airflow pattern study for the aseptic syringe filling operation. Furthermore, your (b) (4) airflow pattern studies performed in ISO 5 (b) (4) Laminar Flow Hoods did not consider the condition when the cleanroom suite (housing the ISO 5 Hoods) (b) (4) (b) (4) during aseptic operations.						
OBSERVATION 3 An adequate number of batches of each drug product are not tested to determine an appropriate expiration date. Specifically: 1. Your drug product stability program for commercial drug products labeled with a (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) (c) (4) (c) (4) (c) (4) (c) (4) (c) (b) (4) (c) (4)						
SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Edmund F Mrak, Investigator Samir C Gala, Investigator Jay B Shah, Investigator			Edmand F Mink Investigator Bigned OF:58mmd F. Mink Jr-8 Date Symmet 0F-08-2022 X	date issued 6/8/2022	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL C	BSERVATI	ONS	PAGE 3 of 4 PAGES	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
Parsippany, NJ (973)331-4900 E	ND PHONE NUMBER iew Blvd., 3rd Floor		TION DATE(S) OF INSPECTION 5/23/2022-6/8/2022* FEI NUMBER 3022897129		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Michael J. Moore, Senior Director Compounding Operations					
FIRM NAME Hikma Injectab	les USA Inc	STREET ADDRESS 36 Stult	s Rd		
CITY, STATE, ZIP CODE, COUNTRY Dayton, NJ 08810-1540		TYPE ESTABLISHMENT INSPECTED Outsourcing Facility			
 2. Your drug product stability program for commercial drug products labeled with a ^{(b) (4)} (b) (4) does not include testing of container closure integrity at or beyond the labeled ^{(b) (4)} For example: your Report# ^{(b) (4)}, Compounding Development and Stability Report for 50µg/mL Fentanyl Citrate Injection (PF) for the Dayton Outsourcing Facility does not include container closure integrity testing results for a timepoint at or beyond the labeled ^{(b) (4)}. 					
*DATES OF INS 5/23/2022(Mon),	SPECTION 5/24/2022(Tue), 5/25/2022(Wed),	5/26/2022	(Thu), 5/27/2022(Fri), 6/08	8/2022(Wed)	
Samir C Gala Investigator Signed By: 2002953776 Date Signed: 08-08-2022 11:	39:15 Jay B Shah Investigator Signed 30:00-08-2022 11:59:53				
SEE REVERSE E	MPLOYEE(S)SIGNATURE Edmund F Mrak, Investigator Samir C Gala, Investigator Jay B Shah, Investigator		Edmund F Mink Institution Date Signet: 0F-08-2022 11:5828	date issued 6/8/2022	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL C	DBSERVATIONS	PAGE 4 of 4 PAGES	

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."