NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☒ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☒ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Hikma Pharmaceuticals USA Inc.

Physical Address: 2 Esterbrook lane

City: Cherry Hill State: NJ Zip Code: 08003

Telephone: 856-424-3700 Fax: _____

Toll Free Number: 877-845-0689 (Required per NAC 639.708)

E-mail: 503B_CHlicensing@hikma.com Website: Hikma.com

Supervising Pharmacist: Mahmoud El-Rouby ✓ Nevada License #: 23469 ✓

SERVICES PROVIDED

Yes/No

☐ ☒ Parenteral
☒ ☐ Sterile Compounding
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued. ✓

Board Use Only Date Processed: _____ Amount: 500.00 CK - 1484015971

FEI Number (From FDA application): 2220525

Please provide the name of the facility as registered with the FDA and the registration number:
Hikma Pharmaceuticals USA Inc.

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Mahmoud El-Rouby Nevada License Number: 23469

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: _____

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☐

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Original Signature of Person Authorized to Submit Application, no copies or stamps

George J. Muench III

Print Name of Authorized Person

28-Jun-2022

Date

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: Eurohealth (U.S.A.), Inc.

Address: 200 Connell Drive

City: Berkeley Heights State: NJ Zip: 07922

Telephone: (856) 489-2110 Fax: _____

Contact Person: George J. Muench III

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Hikma Pharmaceuticals USA Inc.

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 2 Esterbrook Lane

City: Cherry Hill State: NJ Zip: 08003

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 856-424-3700 Toll Free # (NAC 639.708, NRS 639.23286): 877-845-0689

Fax: _____ Contact Email: 503B_CHLicensing@hikma.com

Website: Hikma503B.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Mahmoud El-Rouby

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23469

Name of Person with direct knowledge of compounding procedures: Mahmoud El-Rouby

Email of Person with direct knowledge of compounding procedures: Melrouby@hikma.com

Telephone of Person with direct knowledge of compounding procedures: 201-912-9479

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Fentanyl Citrate (10 mcg/ml Fentanyl Citrate in 0.9% Sodium Chloride) 100 ml Bags.
Fentanyl Citrate (10 mcg/ml Fentanyl Citrate in 0.9% Sodium Chloride) 250 ml Bags.

4. Will you be utilizing beyond use dates in excess of USP-797? ■ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
All products have completed stability studies supporting their BUD. Hikma's procedure was issued under the scope of Current Good Manufacturing Practice—Guidance
for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act and
ICH Q1A (R2) Stability testing of new drug substances and drug products. The BUDs for compounded sterile products depend on the stability and sterility of the compound. BUDs are assigned based on a full stability program that meets the following requirements:
- The BUD is determined based on bracketing stability studies and the worst case scenario.
- The CSP is tested for sterility and bacterial endotoxins.
- The CSP is submitted to chemical analysis such as Visible Particles, Subvisible Particles, Strength, Color and Clarity, Osmolality, pH, and Enantiomeric purity.

6. What laboratory performs this additional testing?
Name: Hikma Pharmaceuticals USA Inc.
Address: 2 Esterbrook Lane
City: Cherry Hill State: NJ Zip: 08003
Telephone: 856-424-3700

7. What is your procedure for visual inspection of compounded sterile products?
Each final container is visually inspected. 100% Visual inspection is performed on un-labeled products by trained and qualified inspectors. They are trained to identify particles and defects.

8. How often do you perform glove fingertip and medial fill testing?

Not required. The 2 Fentanyl products are compounded from API. Filtration is performed prior to automatic final container filling by the plumat machine (ISO5) in an ISO7 room. The bags are visually inspected then autoclaved.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

N/A

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Personnel who compound are required to complete all SOPs related to gowning and compounding. They learn hands on training with a qualified trainer and are required to perform each process first through observation.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

The production line for the 503B compounding is sanitized with Sporklenz (10 minutes contact/dwell time) followed by IPA (1 minute contact/dwell time) at the start of each batch and Sporklenz after the batch. If interventions are performed, the impacted areas are sanitized with IPA.
The following cleaning is performed to the clean room:
- By end of batch: Cleaning with LpH or vesphene applied with a mop.
- Weekly: Walls /Windows Floor/ Filling Enclosures are cleaned with Spo-Klenz applied with a mop or sprayer.
- Monthly: Walls/ Windows Floor are cleaned with Spor-Klenz applied with a mop or sprayer.

12. Who performs the sterile compounding process at your facility?

Trained and qualified compounders and filling operators perform the compounding.

13. Who is responsible and accountable for the sterile compounding process at your facility?

Operations department. The Pharmacist In Charge provides oversight of the compounding operation.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Hikma Pharmaceuticals USA Inc., ships out 503B controlled substance compounded bags to the Hikma Injectables USA Inc. facility located 45 mins away in Dayton, NJ, for labeling, packing, and distribution. Units are placed in cardboard shipper boxes. Tamper evident tape is used to seal the boxes and loaded onto pallets and shrink wrapped before shipping. A Hikma approved carrier with a dedicated truck picks up from Cherry Hill, NJ for same day delivery to the Dayton, NJ. A cable seal number is provided to the carrier for reference. The driver must provide this number to Hikma personnel prior to loading. Once the product is completely loaded, the truck container doors are secured with a cable seal by a Hikma employee. The seal number is verified upon arrival by a Hikma employee. In the future, Hikma Pharmaceuticals USA Inc. may ship product directly to customers.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

Fentanyl Citrate (10 mcg/ml Fentanyl Citrate in 0.9% Sodium Chloride) 100 ml Bags.
Fentanyl Citrate (10 mcg/ml Fentanyl Citrate in 0.9% Sodium Chloride) 250 ml Bags.

2. What sterilization methods are utilized at your facility?

Filtration prior to final container filling and autoclaving post final container filling for terminal sterilization.

3. Does your facility utilize biological indicators? ■ Yes ☐ No

4. If yes, describe how they are utilized:

Biological indicators are utilized during product sterilization validation, not used routinely in production. Biological indicators are used as part of product sterilization validation to achieve a SAL of 10-6. The biological indicators are placed in the slowest to heat region of the load configuration (determined through PQ studies). The biological indicators in these studies are product containers inoculated with a thermophilic spore suspension (Geobacillus stearothermophilus). Following completion of the sterilization cycle, the biological indicators are transferred to Microbiology for testing (along with positive and negative controls). For a cycle to be successful, the processed biological indicator must be negative for microbial growth, the positive control must be positive, and the negative control must be negative.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mahmoud El-Rouby

Name of Person who Completed the Form

Pharmacist In Charge

Title

Mahmoud El-Rouby

Signature (copies or stamps not accepted)

03/31/2023

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Hikma Pharmaceuticals USA Inc.

Officer/ Director Information

Name	Title	Location
Said Darwazah	Director	Industrial Area, Bayader Wadi El-Seer, P.O. Box 182400, Amman 11118, Jordan
Hussein Arkhagha	Director	Industrial Area, Bayader Wadi El-Seer, P.O. Box 182400, Amman 11118, Jordan
Riad Mechlaoui	Director	Estrada do Rio da Mó, 8, A/B - Fervença 2705-906 Terrugem SNT - Portugal
Brian Hoffmann	President	200 Connell Drive Berkeley Heights, NJ 07922
Yogeshkumar Akhani	Chief Financial Officer	200 Connell Drive Berkeley Heights, NJ 07922
George J. Muench III	Treasurer	2 Esterbrook Lane Cherry Hill, NJ 08003
Turlough Gorman	Secretary	200 Connell Drive Berkeley Heights, NJ 07922

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PUBLIC HEALTH AND FOOD PROTECTION PROGRAM
P.O. BOX 369, TRENTON, NJ 08625-0369
609-826-4935

REPORT OF INSPECTION

Assignment No **13863**
Inspection End Date **02/06/2020**

Registration #	Category	Inspection Type	Evaluation
5002130	**Wholesale Drug/Medical Device**	**Routine**	**Satisfactory**

Name of Owner or Corporation	Trade Name	Activity
HIKMA PHARMACEUTIC		**Manufacturer**

Establishment Street Address	City	ZIP	County
2 ESTERBROOK LN	**Cherry Hill**	**08003**	**Camden**

Establishment Mailing Address (if different)	Phone Number	Fax Number

Name and Title of Inspecting Official	REHS Lic. #	Operational Status	Embargo	Reinspect on or After
Ryan Reighn	**B-2407**	**Operational**	**No**	

Name and Title of Designated Representative	Email
Anibel Carlo - VP	**acarlo@hikma.com**

Products

☒ Prescription Drugs ☐ OTC Drugs ☐ Class I Medical Devices ☐ Class II Medical Devices
☐ Class III Medical Devices ☐ No Products Stored/Handled Onsite

TIME/ACTIVITY REPORT (1-TRAVEL, 2-INSPECTION, 3-ADMINISTRATION, 4-PERSONAL) TOTAL HOURS: 05.00

DATE	CODE	BEGIN	END	CODE	BEGIN	END	CODE	BEGIN	END
01/30/2020	1	09:00	09:30	2	09:30	12:00	1	12:00	12:30
	3	12:30	14:00						

		YES	NO	N/A
	N.J.A.C. 8:21-3A.7 Personnel Requirements			
	Personnel employed by a wholesale distributor have appropriate education and/or experience to assume responsibility for positions related to compliance with State registration requirements	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.8 Facility *Facilities at which drugs are stored, warehoused, handled, held, offered, marketed or displayed:*			
(a) 1	Of suitable size and construction to facilitate cleaning, maintenance, and proper operations	☒	☐	☐
(a) 2	Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions	☒	☐	☐
(a) 3	Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened	☒	☐	☐
(a) 4	Maintained in a clean and orderly condition	☒	☐	☐
(a) 5	Free from infestation by insects, rodents, birds, or vermin of any kind	☒	☐	☐
Note				

		YES	NO	N/A
N.J.A.C. 8:21-3A.9 Security				
(a)	Facility is secured from unauthorized entry	☒	☐	☐
(a) 1	Access from outside premises is kept to a minimum and is well controlled	☒	☐	☐
(a) 2	The outside perimeter of the premises is well-lighted	☒	☐	☐
(a) 3	Entry into areas where drugs are held shall be limited to authorized personnel	☒	☐	☐
(b)	All facilities are equipped with an alarm system to detect entry after hours	☒	☐	☐
(c)	Facilities are equipped with a security system that provides suitable protection against theft and diversion. When applicable, the security system provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records	☒	☐	☐
Note				
N.J.A.C. 8:21-3A.10 Storage				
(a)	All drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, of the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).	☒	☐	☐
(b)	If no storage requirements are established for a drug, the drug is held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected	☒	☐	☐
(c)	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs are utilized to document proper storage of drugs	☒	☐	☐
(d)	For prescription drugs a record is maintained that includes the date, time, thermometer temperature, and the initials of the person recording the data	☒	☐	☐
Note				
N.J.A.C. 8:21-3A.11 Examination of Materials				
(a)	Upon receipt, each outside shipping container is visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination is adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	☒	☐	☐

		YES	NO	N/A
(b)	Each outgoing shipment is carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.12 Returned, Damaged and Outdated Drugs			
(a)	Outdated, damaged, deteriorated, misbranded, or adulterated drugs are quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier	☒	☐	☐
(b)	Drugs whose immediate or sealed outer or sealed secondary containers have been opened or used are identified as such, quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier	☐	☐	☒
(c)	If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.13 Recordkeeping			
(a)	Inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs are maintained	☒	☐	☐
(a) 1	Source of drugs, name and principal address of the seller or transferor, and address from which drugs were shipped are maintained	☒	☐	☐
(a) 2-3	Identity and quantity of drugs received and distributed/disposed, date of receipt and distribution, disposal.	☒	☐	☐
(a) 5	A complete and accurate annual record of all stock of drugs on hand.	☒	☐	☐
(d)	An ongoing listing of all retail and wholesale establishments with whom they do business.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.14 Due Diligence *Firm is performing due diligence of other wholesale establishments with whom they do business, which requires that prior to the initial purchase or acquisition of drugs from another wholesale distributor, a wholesale distributor shall obtain the following information from the selling wholesale distributor.*			
(a) 1	Copies of all state and Federal regulatory licenses and registrations	☒	☐	☐
(a) 2	The wholesale distributor's most recent facility inspection reports	☒	☐	☐
(a) 3	A list of other names under which the wholesale distributor is doing business or by which the wholesale distributor was formerly known	☒	☐	☐

		YES	NO	N/A
(a) 4	A list of corporate officers and managerial employees and designated representatives	☒	☐	☐
(a) 5	A verification of the selling wholesale distributor's status as an authorized distributor of record, if applicable.	☒	☐	☐
(b)	At least annually, a wholesale distributor that purchases prescription drugs from another wholesale distributor updates the information set forth in (a) 1-5 above.	☒	☐	☐
(c)	No purchases were placed from any storage facility, manufacturer or wholesale distributor not having a current license or registration within the jurisdiction of the establishment location from where product is purchased.	☒	☐	☐
(d)	No purchase or acquisition has been made from a firm that has not provided complete information as set forth in (a) 1-5 above.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.15 Availability of Records and Inventories			
(a)	Records and inventories, including those related to salvage and reprocessing, are made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation	☒	☐	☐
(b)	Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means are readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable are made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.16 Policies and Procedures			
(a)	Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of drugs	☒	☐	☐
(a)	Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories	☒	☐	☐
(a) 1	Firm has a procedure where oldest stock is distributed first.	☒	☐	☐
(a) 2	Firm has a procedure for handling recalls/withdrawals of drugs.	☒	☐	☐
(a) 3	Firm has a procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster	☒	☐	☐
(a) 4	Firm has a procedure for handling return of outdated drugs; segregation and written documentation of disposal, by either returning the drug to the manufacturer or destruction of the drug. This documentation shall be maintained for 2 years after disposition of the outdated drugs.	☒	☐	☐

		YES	NO	N/A
Note				
	N.J.A.C. 8:21-3A.17 List of Responsible Persons			
	A current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of prescription drugs is maintained at the firm	☒	☐	☐
	Description of duties and qualifications of personnel is maintained at the firm	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.19 Salvage; Reprocessing			
	Salvaging and reprocessing operation is in compliance with 21 CFR 207, 210, 211	☐	☐	☒
Note				

Inspecting Official

Registered Outsourcing Facilities

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 03/25/2022

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility[1]	Date of Most Recent Registration as an Outsourcing Facility[1]	End Date of Last FDA Inspection Related to Compounding[2]	Was a Form FDA-483 Issued?[2]	Other Action Inspection[2,3]
AnazaoHealth Corporation, Las Vegas, NV	Jaclyn Wong 800-995-4363 Ext=3120	9/23/2014	11/1/2021	9/19/2019	Yes (https://www.fda.gov/media/132898/download)	Warning Lett compliance-i Investigation corporation-i
ANNOVEX PHARMA, LLC, Lorton, VA	Kenneth Erickson 540-907-7436	10/14/2021	10/14/2021	Not yet Inspected	N/A	N/A
Apollo Care, Columbia, MO	Jarred Dudding 573-441-8900	9/14/2017	12/14/2021	9/8/2021	Yes	Open[7]
ASP CARES, San Antonio, TX	Raju Sagi 210-417-4567	2/14/2017	12/16/2021	8/23/2018	Yes (/media/120742/download)	Warning Lett compliance-i Investigation specialty-ph 04052021)
Athenex Pharma Solutions, LLC, Clarence, NY	Lori Giles Aleshin 716-812-9475	4/10/2017	10/18/2021	8/28/2019	Yes (https://www.fda.gov/media/132333/download)	FMD-145 Let
Athenex Pharma Solutions, LLC, Dunkirk, NY	Lori Giles Aleshin 716-812-9475	11/2/2021	11/2/2021	Not yet Inspected	N/A	N/A
Atlas Pharmaceuticals, Phoenix, AZ	Nickolaus Banda 480-208-1855	11/8/2017	1/4/2022	5/21/2021	Yes (/about-fda/fda-commissioner/atlas-pharmaceuticals-llc-phoenix-az-483-issued-05212021)	Open[7]
BayCare Integrated Service Center, LLC dba BayCare Central Pharmacy, Temple Terrace, FL	Kenneth Jozefczyk 813-901-6339	6/4/2019	12/8/2021	12/10/2019	Yes (https://www.fda.gov/media/152762/download)	Untitled Lett
Belcher Pharmaceuticals, LLC, Largo, FL	Shyam Busireddy 727-471-0850	05/18/2021	12/16/2021	Not yet Inspected	N/A	N/A
BPI Labs LLC, Largo, FL	Chandra Kasireddy 727-471-0850	3/4/2019	12/16/2021	4/30/2021	Yes	FMD-145 Iss
Brookfield Medical/Surgical Supply, Inc., Brookfield, CT	James Cangelosi 203-775-0862	1/12/2015	12/30/2021	12/21/2018	Yes (https://www.fda.gov/media/120806/download)	Open

BSO LLC, Lakewood, CO	David W. Hill 877-267-3410	11/24/2015	10/29/2021	3/11/2021	Yes (https://www.fda.gov/media/149780/download)	FMD-145 Issued 9/15/2021
Central Admixture Pharmacy Services, Inc., Allentown, PA	Thomas Kelsey 216-233-0766	2/28/2014	10/22/2021	8/22/2018	Yes (https://www.fda.gov/media/120740/download)	FMD-145 Issued 6/17/2020 (https://www.fda.gov/media/141701/downlo
Central Admixture Pharmacy Services, Phoenix, AZ	Thomas Kelsey 216-233-0766	3/29/2018	10/22/2021	4/26/2019	No	FMD-145 Issued 6/3/2020 (https://www.fda.gov/media/139371/downlo
Central Admixture Pharmacy Services, Inc., San Diego, CA	Thomas Kelsey 216-233-0766	6/4/2014	10/22/2021	9/11/2018	Yes (/about-fda/central-admixture-pharmacy-services-inc-san-diego-ca-483-issued-09112018)	FMD-145 Issued 5/27/2020 (https://www.fda.gov/media/139369/downlo
Complete Pharmacy and Medical Solutions, LLC, Miami Lakes, FL	Charles Richardson 305-397-2035	6/6/2014	12/22/2021	1/23/2019	Yes (https://www.fda.gov/media/128390/download)	Regulatory Meeting Held 11/3/2020
Compound Preferred, LLC, formerly registered as RAM Pharma, Inc., Ammon, ID	Casey Hunter 208-419-0613 Ext=203	7/21/2016	1/12/2022	12/17/2021	Yes	Open[7]
Delta Pharma, Inc., Ripley, MS	Stuart Simpson 662-512-5191	8/6/2014	1/5/2022	2/23/2017	Yes (https://www.fda.gov/media/104654/download)	Consent Decree of Permanent Injunction ente 6/8/2018 (/news-events/press-announcements/federal-judge-enters-consent decree-against-delta-pharma)
Denver Solutions, LLC dba Lehrs Health, Englewood, CO	Ron Stephens 408-292-6772	3/24/2017	11/3/2021	10/7/2021	Yes (https://www.fda.gov/media/156279/download)	FMD-145 Issued 3/29/2022
Eagle Pharmacy, Inc., Hoover, AL	Haleigh Cawood 205-682-7999	6/16/2015	10/21/2021	8/12/2021	Yes (/media/155225/download)	Open[7]
Edge Pharma, Winooski, VT	Tyler Wingood 802-992-1178	1/21/2014	11/3/2021	11/30/2021	Yes (https://www.fda.gov/media/156278/download)	Open[7]
Empower Pharmacy, Houston, TX	Shaun Noorian 877-562-8577	7/16/2016	10/19/2021	3/6/2020	Yes (https://www.fda.gov/media/137544/download)	Warning Letter Issued 10/15/2021 (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/empower-clinic-services-llc-dba-empower-pharmacy-613792-10152021)
Eurofins Advantar Laboratories, Inc., San Diego, CA	Helena Filippone 619-201-5486	1/10/2022	1/10/2022	Not yet Inspected	N/A	N/A
Exela Pharma Sciences, LLC., Lenoir, NC	Arun Koganti 828-758-5474 Ext=181	6/6/2014	12/27/2021	7/18/2019	Yes (https://www.fda.gov/media/131226/download)	WLCO and FMD-145 Issued 4/30/2021
F.H. Investments, Inc., dba Asteria Health, Birmingham, AL	William Fixler 855-771-0505	5/18/2017	12/9/2021	7/10/2018	Yes (/about-fda/fh-investments-inc-dba-asteria-health-birmingham-al-483-issued-07102018)	FMD-145 Issued 9/10/2021
Fagron Compounding Services d/b/a Fagron Sterile Services, Wichita, KS	David Lawn 316-773-0405	10/2/2015	10/21/2021	3/24/2022	Yes (https://www.fda.gov/media/130443/download)	Open[7]
Farmakeio Outsourcing LLC, Southlake, TX	Cody Boatman 817-203-8216	12/12/2018	1/5/2022	10/30/2019	Yes (https://www.fda.gov/media/139181/download)	Warning Letter Issued 7/29/2021 (/inspection compliance-enforcement-and-criminal-investigations/warning-letters/farmakeio-outsourcing-llc-608257-07292021)
Fresenius Kabi Compounding, LLC, Canton, MA	Deborah McHugh 781-298-7577	4/21/2017	11/10/2021	12/4/2018	Yes (/media/123403/download)	FMD-145 Issued 4/22/2020 (https://www.fda.gov/media/139011/downlo

PQ Pharmacy LLC, Brooksville, FL	Angela Kassay 352-477-8977	10/29/2020	11/18/2021	Not yet inspected	N/A	N/A
Primera Compounding, LLC, Rosenberg, TX	Basil Raad 281-202-6136	5/24/2021	10/29/2021	Not yet inspected	N/A	N/A
Prisma Health Outsourcing Facility, Simpsonville, SC	Gary Jones 864-522-3800	12/9/2019	10/23/2021	Not yet inspected	N/A	N/A
Providence Health & Services-Washington, Tukwila, WA	Jacqueline A. Biery 425-687-4460	3/2/2020	11/22/2021	10/5/2020	Yes (https://www.fda.gov/media/154888/download)	FMD-145 Issued 9/10/2021
Qualgen LLC, Edmond, OK	Shaun Riney 405-551-8216	5/23/2014	12/2/2021	6/15/2021	Yes	Open
QuVa Pharma, Inc., Bloomsbury, NJ	Robert Brown 908-388-1719	9/15/2017	12/16/2021	5/31/2019	Yes (https://www.fda.gov/media/128373/download)	Regulatory Meeting Held 11/20/2020
Quva Pharma, Inc., Sugar Land, TX	Robert Nelson 832-495-4216	9/10/2015	12/16/2021	4/23/2019	Yes (https://www.fda.gov/media/124967/download)	Regulatory Meeting Held 11/20/2020
QuVa Pharma, Inc., Temple, TX	Travis Leeah 254-933-4429	12/15/2015	12/16/2021	3/14/2019	Yes (https://www.fda.gov/media/122711/download)	Regulatory Meeting Held 11/20/2020
RC Outsourcing, LLC, Lowellville, OH	Raymond R. Carlson 330-536-8500	10/6/2015	12/8/2021	2/8/2019	Yes (https://www.fda.gov/media/139531/download)	FMD-145 Issued 5/22/2020 (https://www.fda.gov/media/139031/downlo
Right Value Drug Stores, LLC, dba Carle Boyd's Prescription Shop, Irving, TX	Sara Lange 817-282-9376	7/3/2019	11/11/2021	11/12/2019	Yes (https://www.fda.gov/media/134260/download)	Warning Letter Issued 9/20/2021 (/inspection compliance-enforcement-and-criminal-investigations/warning-letters/apothecary-health-solutionsright-value-drug-stores-llc-dba carle-boyds-prescription-shop-610751)
RXQ Compounding LLC, Albany, OH	Tracy Clark 866-280-0031 Ext=8	12/11/2019	1/3/2022	Not yet inspected	N/A	N/A
SCA Pharmaceuticals, Little Rock, AR	Lessley Denton 877-550-5059	12/13/2013	12/9/2021	11/7/2019	Yes (https://www.fda.gov/media/133949/download)	WLCO and FMD-145 Issued 8/19/2021
SCA Pharmaceuticals, Windsor, CT	Lessley Denton 877-550-5059	8/3/2017	12/9/2021	11/19/2019	Yes (https://www.fda.gov/media/134901/download)	FMD-145 Issued 10/22/2021
Sincerus Florida, LLC, Pompano Beach, FL	Michael Morelli 800-604-5032 Ext=313	3/10/2016	11/1/2021	9/17/2018	Yes (https://www.fda.gov/media/120734/download)	FMD-145 Issued 11/16/2020 (https://www.fda.gov/media/144726/downlo
SSM Health Care Corporation, Fenton, MO	Melissa Mays 636-496-2681	2/18/2014	11/29/2021	9/28/2021	Yes (https://www.fda.gov/media/155226/download)	Open[7]
STAQ Pharma, Inc., Denver, CO	Joe Bagan 303-810-6777	2/5/2019	1/4/2022	9/29/2021	Yes	FMD-145 Issued 3/25/2022
STASKA PHARMACEUTICALS, Bennet, NE	Lyndon Leitner 402-782-2207	12/3/2020	12/25/2021	Not yet inspected	N/A	N/A
STERRX, LLC, Plattsburgh, NY	Sue Martin 518-324-7879	5/29/2015	11/29/2021	11/4/2021	Yes (https://www.fda.gov/media/156608/download)	Open[7]
Stokes Healthcare Inc., dba Epicur Pharma, Mt. Laurel, NJ	Michael Tursi 888-508-5032	1/30/2018	1/20/2022	10/9/2020	Yes (https://www.fda.gov/media/144723/download)	Open[7]
Tailstorm Health Inc., Chandler, AZ	Andrew Stasiak 520-465-8496	10/23/2019	1/25/2022	7/21/2021	Yes (https://www.fda.gov/media/155218/download)	Open
The Ritedose Corporation, Columbia, SC	Jody Chastain 803-935-4060	12/20/2019	11/8/2021	3/18/2022	Yes	Open

Hikma Injectables USA Inc., Dayton, NJ	J. Barton Kalis 856-489-2247	9/15/2021	1/7/2022	Not yet inspected	N/A	N/A
Hikma Pharmaceuticals USA Inc., Cherry Hill, NJ	J. Barton Kalis 856-489-2247	9/15/2021	1/7/2022	Not yet inspected	N/A	N/A
Hybrid Pharma, LLC, Deerfield Beach, FL	Ponswamy Rajalingam 954-708-2771	1/14/2015	11/24/2021	9/3/2021	Yes	Open[7]
Imprimis NJOF, LLC, Ledgewood, NJ	Heidi Morales 973-804-1623	11/12/2016	12/29/2021	1/29/2021	Yes (https://www.fda.gov/media/151431/download)	Open[7]
IntegraDose Compounding Services, LLC, Minneapolis, MN	Craig Else 612-672-5216	5/8/2018	10/9/2021	8/2/2021	Yes (/about-fda/fda-commissioner/integradose-compounding-services-llc-minneapolis-mn-483-issued-08022021)	Recall Initiated 9/2021 (/safety/recalls-marke withdrawals-safety-alerts/integradose-compounding-services-llc-issues-voluntary-nationwide-recall-cefazolin-injection-products
Kashiv BioSciences, LLC, Chicago, IL	Chandramauli Rawal 732-475-0500 ext=110	5/27/2021	12/2/2021	Not yet inspected	N/A	N/A
KRS Global Biotechnology, Inc., Boca Raton, FL	Charles Richardson 888-502-2050	12/15/2013	12/21/2021	8/14/2019	Yes (https://www.fda.gov/media/134261/download)	Regulatory Meeting Held 7/30/2021
Leesar Inc., Fort Myers, FL	Marla Gautier 239-939-8925	4/30/2014	12/29/2021	10/29/2021	Yes (https://www.fda.gov/media/156685/download)	Open[7]
Medi-Fare Drug, Blacksburg, SC	Anne-Marie Davis 864-839-6500	12/17/2013	12/7/2021	4/6/2017	No	Untitled Letter Issued 3/18/2019 (https://www.fda.gov/media/130385/downlo
MedisourceRx, Los Alamitos, CA	Amy Summers 714-455-1300	2/14/2017	11/2/2021	10/22/2020	Yes (https://www.fda.gov/media/154824/download)	FMD-145 Issued 6/28/2021
Molecular PharmaGroup, New Providence, NJ	Amanda Lanze 908-588-3440	5/8/2018	12/9/2021	Not yet inspected	N/A	N/A
Nephron Sterile Compounding Center, LLC (NSCC), West Columbia, SC	Lou Kennedy 803-569-3110	7/15/2014	1/20/2022	11/15/2019	Yes (https://www.fda.gov/media/137539/download)	Regulatory Meeting Held 11/20/2020
New England Life Care, Inc. dba Advanced Compounding Solutions, Woburn, MA	Roula Samhoun 781-832-5758	3/2/2017	1/4/2022	8/22/2017	Yes (/media/107435/download)	Untitled Letter Issued 8/21/2019 (/media/140560/download)
Nubratorl, Inc., Torrance, CA	Gulshakar Khwaja 310-218-4153	2/24/2017	10/20/2021	12/20/2021	Yes	Open[7]
Olympia Compounding Pharmacy, Orlando, FL	Marco Loleit 407-673-2222	3/10/2014	11/24/2021	3/2/2022	Yes	Open[7]
OurPharma LLC, Fayetteville, AR	Morgan Strickland 479-313-8200	3/15/2019	10/13/2021	9/30/2021	Yes (https://www.fda.gov/media/154264/download)	FMD-145 Issued 3/14/2022
Pharmaceutics International, Inc., Cockeysville, MD	Srilatha Jaini 410-584-0001 ext=1167	4/28/2020	1/7/2022	Not yet inspected	N/A	N/A
Pharmaceutic Labs, LLC, Albany, NY	Ernesto Samuel 518-210-7164	3/10/2014	12/22/2021	9/23/2015	Yes (/about-fda/pharmaceutic-labs-llc-albany-ny-483-issued-09232015)	Warning Letter Issued 5/3/2017 (/inspections compliance-enforcement-and-criminal-investigations/warning-letters/pharmaceutic-labs-llc-492795-05032017)
Pine Pharmaceuticals, LLC, 355 Riverwalk Pkwy, Tonawanda, NY	Alfonse Muto 716-248-1025	3/9/2018	10/21/2021	5/14/2021	Yes (https://www.fda.gov/media/152333/download)	Open[7]

University of Tennessee, Memphis, TN	Harry Kochat 901-448-1440	6/26/2019	12/2/2021	Not yet inspected	N/A	N/A
US Specialty Formulations LLC, Allentown, PA	Kyle Flanigan 610-849-5023	1/31/2014	12/9/2021	7/23/2019	Yes (https://www.fda.gov/media/131067/download)	Regulatory Meeting Held 6/7/2021
Wedgewood Connect, LLC, formerly registered as Leiter's Compounding, San Jose, CA	Paul Yamamoto 408-687-0943	1/31/2014	12/9/2021	12/3/2021	Yes	Open[7]
Wells Pharma of Houston, LLC, Houston, TX	Theaquiata A. Mitchell 346-888-1010 Ext=4811	3/9/2020	12/20/2021	6/17/2021	Yes (https://www.fda.gov/media/155873/download)	FMD-145 Issued 1/10/2022
Wells Pharmacy, Inc., Dyersburg, TN	Melissa Stefko 800-622-4510	6/7/2016	11/10/2021	1/28/2021	Yes (https://www.fda.gov/media/147184/download)	Open[7]

Notes

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and for firms first registering on or after October 1, 2014, the establishment fee was paid in full).

Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. Beginning in fiscal year (FY) 2015 (October 1, 2014 to September 30, 2015), a facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page Compounding: Inspections, Recalls, and Other Actions (/drugs/compounding/compounding-inspections-recalls-and-other-actions) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

Inspections may take place over several days, weeks, or longer. The date of the inspection is the date a Form FDA-483 listing the investigators' observations was issued. If no FDA Form-483 was issued, the date is the last day of the inspection.

3. A Form FDA-483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.

4. This table does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a state enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites.

5. "Closed" means the inspection has been closed without further action. "Open" means that FDA has not made a determination as to whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include: warning letter; seizure; or injunction.

6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A", indicates the registered outsourcing facility has not provided this information. In the future, FDA intends to provide information about whether the outsourcing facility also intends to compound nonsterile drugs from bulk drug substances. That information is not currently available to the Agency.

7. This facility was the subject of at least one previous inspection relating to compounding that resulted in a Form 483, warning letter, or other action. For information about such inspections and resulting actions, see Compounding: Inspections, Recalls, and other Actions (/drugs/compounding/compounding-inspections-recalls-and-other-actions).

Establishment Inspection Report	FEI:	**2220525**
Hikma Pharmaceuticals USA Inc.	EI Start:	9/6/2018
Cherry Hill, NJ 08003-4002	EI End:	9/14/2018

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SUMMARY

The surveillance inspection of this manufacturer of sterile drugs was initiated as per OPQO Division 1 FY'2018 work plan under FACTS Assignment # 11761971, FACTS Operation ID# 9369900, and MACRS Operation ID# 82660. This inspection was also conducted to provide post-approval coverage of NDA 017037 Heparin Sodium Injection, USP, 1,000 units/mL, 5,000 units/mL and 10,000 units/mL. The inspection was conducted in accordance with Compliance Program 7356.002A, Sterile Drug Process Inspections, and Compliance Program 7356.843 Post-Approval Inspections.

The previous surveillance cGMP inspection was conducted from 03/27/2017 – 04/04/2017. The following systems were covered during this inspection: Quality, Production, Laboratory Control and Facilities and Equipment systems. No deficiencies were found during the inspection and no FDA-483 Inspectional Observations was issued.

The current inspection found that the firm continues to operate as a sterile drug manufacturer of both aseptically filled and terminally sterilized small volume parenteral products which are filled in ampuls, single-use vials, multi-dose vials and pre-filled syringes. The current inspection provided coverage of the Quality, Production, Laboratory Control, Packaging and Labeling and Facilities and Equipment systems, with limited coverage of the Materials system. Post-approval coverage was provided for the Prior- Approval Supplements (PAS), Supplement – 173, Supplement – 174, Supplement – 175 and Supplement – 176 for NDA 017037

Heparin Sodium Injection, USP, 1, 000 units/mL, 5,000 units/mL and 10,000 units/mL. During the inspection, we reviewed annual reports, change controls, investigations, product quality complaints, CAPAs, Field Alert Reports, batch records, filling and packaging records, equipment qualifications, validation protocols and reports, environmental monitoring reports and summaries, media fills reports, laboratory out of specification investigations, SOPs, and training documentation. No FDA-483, Inspectional Observations was issued but the inspection concluded with a four (4) point general discussions with management. No samples were collected, and no refusals were encountered.

ADMINISTRATIVE DATA

Inspected firm:	Hikma Pharmaceuticals USA Inc.
Location:	2 Esterbrook Ln Cherry Hill, NJ 08003-4002
Phone:	856-424-3700
FAX:	856-424-8747
Mailing address:	2 Esterbrook Ln Cherry Hill, NJ 08003-4002
Email address:	
Dates of inspection:	9/6/2018-9/7/2018, 9/10/2018-9/14/2018
Days in the facility:	7
Participants:	**Yvesna C Blaise, Investigator** **Nancy M Espinal, Investigator** **Russell J Glapion, Investigator**

(YB)

On 09/06/2018, we, Investigators Yvesna C. Blaise and Nancy M. Espinal, presented our credentials, explained the purpose of our visit and issued a form FDA 482, Notice of Inspection (**Attachment 1**) to Mr. Anibal Carlo, Vice President of Global Injectables Manufacturing who identified himself as the firm's most responsible individual on site. We explained the purpose of the inspection is to conduct a GMP and post-approval coverage for Prior- Approval Supplements (PAS), Supplement – 173, Supplement – 174, Supplement – 175 and Supplement – 176 for NDA 017037 Heparin Sodium Injection, USP, 1000 units/mL, 5000 units/mL and 10,000 units/mL. On 09/10/2018, we issued a second form FDA 482, Notice of Inspection (**Attachment 2**) to Mr. Carlo due to Investigator Russell Glapion joining the ongoing inspection.

On 09/14/2018, a closeout meeting was held with management, during which a general discussion was discussed. A Form FDA 483, Inspectional Observations, was not issued at the conclusion of the current inspection.

The EIR was collectively written by Investigators Yvesna Blaise, Nancy Espinal and Russell Glapion. Our initials indicate the subsequent parts/paragraphs written by either Investigator (YB) for Investigator Yvesna Blaise, (NME) for Nancy M. Espinal, and (RG) for Russell Glapion. Investigators Blaise and Espinal were present on all days of the inspection and Investigator Glapion was present on 09/10 – 14/2018.

All post-inspectional correspondence should be addressed to:
Mr. Anibal Carlo, VP of Global Injectable Manufacturing
Hikma Pharmaceuticals USA Inc.
2 Esterbrook Lane
Cherry Hill, NJ 08003
Phone 856-489-2367

HISTORY

(YB)
West-Ward Pharmaceuticals Corp. is a wholly owned, U.S. subsidiary of Hikma Pharmaceuticals PLC (located in Amman, Jordan). Hikma Pharmaceuticals PLC purchased the Cherry Hill, NJ facility in May 2011 from Baxter Healthcare Corporation. One major change noted during the inspection was that on June 26, 2018, as a part of a rebranding incentive, the firm will now operate as Hikma Pharmaceuticals USA Inc. or simply Hikma. According to Mr. Natheer Masarweh, Chief Quality/ Tech Affairs Officer there have not been any changes to the firm's operations since the previous inspection; the firm still manufactures aseptically prepared and terminally sterilized parenteral (injectable) products which are filled into vials (single use and multi-dose), ampuls and pre-filled syringes.

Mr. Masarweh provided us with a PowerPoint presentation of an opening presentation of Hikma (**Exhibit 1**). The former General Manager Mr. James Valenzuela is no longer with the company. Mr. Anibal Carlo, Vice President Global Injectable Manufacturing who is now mainly responsible for the overall operations at the Hikma Cherry Hill site and took over on September 1, 2018.

The Hikma – Cherry Hill facility is approximately 400, 000 square feet composed of two integrated building (10/22 and 9/9A/9B/9C) composed of 178,000 sq. ft. of manufacturing area, 115, 000 sq. ft. of administrative offices, 60, 000 sq. ft. of general warehouse, and 24, 000 sq. ft. of laboratory (QA/QC). The firm's US Headquarters is located at 401 Industrial Way West, Eatontown, NJ 07724. According to Mr. Masarweh this location will be closing in April 2019. A list of all Hikma Pharmaceutical PLC manufacturing locations was provided as **Exhibit 2**.

The facility's manufacturing operational hours are still six days a week and comprise of three (3) shifts. The firm employs approximately 500 employees. Sales revenue for 2017 were approximately over $100 million.

INTERSTATE (I.S.) COMMERCE

(YB)
Hikma Pharmaceuticals USA Inc. continues to manufacture sterile injectable small volume

parenteral drug products under the West-Ward label. Drug products are manufactured and packaged at the Cherry Hill site; 100% of finished drug products are shipped via interstate to the Hikma's Creekside distribution center located in Lockbourne, OH for non-controlled substance or Hikma's Columbus distribution center located in Columbus, OH for controlled substance for further distribution. 90 % of these commercial products are sold to wholesalers.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)
(YB)
Hikma Pharmaceuticals USA Inc. continues to manufacture various finished drug products including, Morphine 10 mg/mL vial, Diltiazem 50 mg/mL vial, Lorazepam 20 mg/10 mL vial, and Fentanyl Citrate Injection, USP 0.05 mg/mL vial. A product list of drug products manufactured at the firm is attached as **Exhibit 3**. The above drug products are subject the FD&C Act. The firm is currently registered as an FDA drug establishment.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
(YB)
Exhibit 4 is the list of all individuals that were present during the opening, provided information on specific topics during the inspection, and closeout meetings. The firm's organizational charts are attached as **Exhibit 5**.

Mr. Anibal Carlo, Vice President Global Injectable Manufacturing is the most responsible person at the Hikma Cherry Hill site. Mr. Carlo manages, directs and oversees all operational activity at this site. He has the power and authority to correct any deficiencies at the site. Mr. Carlo received the form FDA 482, Notice of Inspection issued on 09/06/2018 and 09/10/2018. He was occasionally present during the inspection and was present at the daily closeout meetings. Mr. Carlo reports to Mr. Riad Mechlaoui, CEO Global Injectables, who has an office in the London and Portugal sites.

Mr. Natheer Masarweh, Chief Quality & Technical Affairs Officer is responsible for all quality/ technical operations related to all Hikma injectables sites. He answered inspection related questions, assisted in providing requested information and had employees available when needed. He accompanied us throughout the inspectional walkthroughs. Mr. Masarweh was present throughout the inspection, including the daily wrap-ups and closeout meeting. Mr. Masarweh is stationed in Hikma Portugal site and reports. He reports to Mr. Riad Mechlaoui, CEO Global Injectables, who has an office in the London and Portugal sites.

Mr. Brett Wood, Senior Director, Quality & Technical Operations is responsible for the oversight of all quality assurance and quality control activities at the Hikma Cherry Hill site. Mr. Wood answered inspection related questions, assisted in providing requested information and had employees available when needed. He accompanied us throughout the inspectional walkthroughs. Mr. Wood was present throughout the inspection, including the daily wrap-ups and closeout meeting. He reports to Mr. Natheer Masarweh, Chief Quality & Technical Affairs Officer.

Mr. Harry Lindenmuth, Director, Manufacturing is responsible for the oversight of all finished products at the Hikma Cherry Hill site. Mr. Lindenmuth answered questions, accompanied us during the facility walk-through, made employees available when needed and assisted in providing relevant information. He was also present at the closeout meeting on 09/14/2018. Mr. Lindenmuth reports to Mr. Anibal Carlo, Vice President Global Injectable Manufacturing.

Mr. Asutosh Shah, Associate Director Quality Systems & Compliance is responsible for overseeing, directing, coordinating site audits, APRs and the customer complaints program. Mr. Shah was the primary facilitator for the inspection. Mr. Shah was present on all the inspectional days, assisted in answering inspectional questions, and providing relevant documents. Mr. Shah reports to Mr. Brett Wood, Senior Director, Quality & Technical Operations.

FIRM'S TRAINING PROGRAM

(YB)

The firm has a formal written training program as outlined in the procedure, SOP 6-T-006, Employee Training and Development, Effective Date: 10/27/2017. Mr. Asutosh Shah, Associate Director, Quality Systems & Compliance, provided us with an overview of the firm's training program at the facility. He explained that employee training consists of reading and understanding written procedures applicable to the assigned job function, PowerPoint presentation classroom training, task demonstration, and on-the-job training. Training records are maintained electronically in the firm's ISOtrain System. Curriculums are developed for each position. ISOtrain notifies each supervisor and employee of newly assigned and past due training requirements. In addition, if there is a major or minor change to an SOP, the employee is required to be re-trained on the new SOP changes. All employees are required to complete GMP refresher training annually as outlined in the procedure, SOP 6-T-006. I reviewed the training records for the following personnel: Tammy Campbell, QLAI Analyst; Craig Chammings, Production Operator; Elizabeth Brooks, Filling Operator; and Jamar Gerald, Filling Operator revealed that they were trained in their specific responsibilities and in current good manufacturing practices (cGMPs), no deficiencies were noted with the training program and written procedures.

MANUFACTURING/DESIGN OPERATIONS

(YB, NME, and RG)

The current inspection utilized the six system approach and covered parts of the Quality, Production, Laboratory Control, Packaging and Labeling system, Facilities and Equipment systems with limited coverage of the Materials system. As applicable for the review of the Prior- Approval Supplements (PAS), Supplement – 173, Supplement – 174, Supplement – 175 and Supplement – 176 for NDA 017037 Heparin Sodium Injection, USP, 1,000 units/mL, 5, 000 units/mL and 10,000 units/mL. Coverage of these systems were performed based on the data submitted to the Agency (CDER).

Heparin Sodium Injection, USP 1,000 units/mL, 5,000 units/mL and 10,000 units/mL is a parenteral solution that is compounded, filtered, filled, stopped, sealed, aseptically processed and packaged in 1 mL/2 mL vials. Mr. Autosh Shah (Associate Director, QA and Compliance) provided us with the process flow charts for Heparin Sodium Injection, USP 1,000 units/mL, 5,000 units/mL and 10,000

units/mL **(Exhibit 6)**. On 09/05/2014, the firm submitted a prior approval supplement (S-173) to transfer the manufacturing of Heparin Sodium Injection, USP from aseptic filling room 115 to an alternate aseptic filling room 1117 (Suite C) within the facility. Additional changes included but not limited to the following:

- Changes to Datwyler stopper, 13 mm, siliconized HPP003 FM457/0, Gray, ready to sterilize from 1816 Gray Butyl elastomeric liner
- Change to Dow Corning® Pharma Advanced Pump Tubing from Dow Corning® Silastic® Pump Medical Grade Tubing
- Change to depyrogenation tunnel 1117 (Suite C) from depyrogenation tunnel 115.

The firm received approval the prior approval supplement (S-173) on 12/22/2014. On 06/08/2015, the firm submitted a CBE-30 (S-174) to increase the bulk hold time from 48 hours to 72 hours. The Agency (CDER) issued an approval letter for the change on 12/2/2015. On 06/29/2015 the firm submitted a CBE-0 Supplement (S-175) to revise specifications and analytical procedures based on the revised monographs for Heparin Sodium for Injection, USP and was granted approval on 12/23/2015. Lastly, on 06/30/2015 a prior approval supplement (S-176) to address changes previously submitted for the drug substance and drug product noted in the 2015 Annual Report. The firm received approval for S-176 on 10/30/2015.

The manufacturing processes remain the same for the Heparin Sodium Injection, USP. During the inspection, the firm management a side-by-side comparison of the existing parameter for filling room 115 versus filling room 1117 (Suite C) related to equipment, sterilization, and depyrogenation steps can be found as **Exhibit 7**.

QUALITY SYSTEM

(YB, NME, RG)

The quality management system includes both Quality Control (QC) and Quality Assurance (QA). During the inspection, I (YB) reviewed the Cherry Hill Site Master File, Effective Date: 09/13/2018, which explained the responsibilities of the quality department. Per the Cherry Hill Site Master File, the responsibilities of the quality assurance unit are to review and approve all processes, specifications, procedures, audit and approval of new suppliers. During the inspection, we reviewed the following elements of the Quality System: Deviations, Out-of-Specification investigations, change control, CAPA (corrective and preventative actions), training, batch record reviews, and supplier qualification. I (YB) reviewed Annual Product Quality Report 2014-2017 periods submitted to the Agency since the approval of Heparin Sodium Injection USP, 1,000units/mL, 5,000 units/mL, 10,000 units/mL products. An SOP index was provided to me at the beginning of the inspection.

Deviations

During the inspection, I (YB) reviewed SOP 2-B-038, Manufacturing Investigation Report (MIR) System, Effective Date: 06/29/2018 defines procedures to handle the deviations. The MIR is to be completed and approved within 30 calendar days unless QA approves an extension. A deviation list was provided by the firm. No discrepancies were noted during my review.

I (YB) reviewed the following MIR:

Event Report Form Number	Product	Description	Date Issued	Date Closed
37-2037	Morphine	35 CFU microbial growth were isolated from the left glove sample of the filling operator in Filling Room 1110	04/11/2017	05/03/2017
37-2063	Suite C Filling Room HEPAs	The HEPA filters failed to meet the acceptance criteria for the average filter face velocity of 90-FRM ± 20 %	07/05/2017	08/08/2017
37-2085	Promethazine Ketorolac	A trend investigation was conducted to address the when the overall reject rate exceeded the action limit of 7.8% for stoppered dosettes inspected on Line 418 (filled in 313)	08/23/2017	09/22/2017
38-2043	Hydromorphone Fosphenyloin Morphine	A trend identified for foreign materials found during production	06/18/2018	06/29/2018

Change Control

The facility is currently undergoing renovations and expansion in Area 1 filling lines. Mr. Harry Lindenmuth, Director, Manufacturing, stated the firm (Hikma) is currently installing a new filling

line identified as Suite E with the intention of manufacturing pre-filled syringes at the facility. The firm completed the filling line Suite F, which is undergoing qualification to manufacture single-dose and multi-dose products. The activities for both Suite E and F were not completed by the conclusion of the inspection. No inspectional coverage was provided.

I (YB) reviewed SOP 2-Q-071, Change Control, Effective Date: 04/28/2017. It covers formulations, manufacturing, facilities, equipment, processes, product/material, system or facility changes, and documentation. Quality Assurance is responsible for the pre-approval and post-approval of all changes in the word processing system. The change controls reports include descriptions of the change, justification, impact assessment, evaluation by departments, approval/rejection by QA, implementation, and closure. I did not observe any deficiencies with the procedure.

My review of the following changes revealed no objectionable observations:

CCR Number	Product	Description
0415102	Heparin Sodium Injection, USP 1,000 units/mL 1mL/2mL vials	Product transfer of the Heparin Sodium Injection, USP from room 115 to Suite C (Room 117)
1216381	N/A	Install Additional Stainless-Steel Sink and Modify Existing WFI Point of Use in Area 1 Equipment Prep, Room 1101
1216393	N/A	Repairs to InTouch PC for EISAI Inspection Machine (G-AIM-7) on Line 418
0417127	Heparin Sodium Injection, USP	Issue Sterility Method BF0006-6 and Bacterial Endotoxin Method PL0253-1
0617176	Hydromorphone Hydrochloride 1mg/mL	Revise Room 1205 (Suite E) Standard Setup Sheet Index
0817266	N/A	Place into Service Nitrogen Tunnel on Room 1117 (Suite C) Filler (G-FIL-38)
1217465	N/A	Installation of wells with new temperature transmitters on the WFI system
0518141	Brevibloc (Esmolol Hydrochloride Injection)	Autoclave 18 Daily Load Sheet and BR/3Z/071 Autoclave 19 Daily Load Sheet to add Load configurations for

		Stoppers/Overseals

In addition, I (YB) reviewed eleven (11) change control reports associated with Heparin from September 2016 to current with no deficiencies noted.

OOS Investigations
(RG)
The firm provided us with a list of Finished Good Rejections from 4/1/2017 to 9/7/2018 (**Exhibit 8**). The list identified 12 lots of drug product that the firm rejected. Seven of the lots were rejected for Out of Specification (OOS) results and five of the lots were rejected for other mechanical or physical errors. Investigator Espinal covered the five OOS investigation associated with Dexamethasone 4 mg/mL.

I (RG) noted no significant deficiencies with:

- The corrective and preventative actions (CAPA) for two OOS investigations on the Finished Good Rejections list (Exhibit 8). One lot of Fentanyl N-Oxide 0.05 mg/mL was rejected when it exceeded a specification for a related compound. Although the written investigation did not identify a root cause or an open CAPA, CDER subsequently approved a request to increase the specification. The other OOS was for a lot of Dipyridamole 5 mg/mL, 10 mL that was rejected when it exceeded specifications for total related compounds. The firm determined that the root cause was a production error. After filling, this light sensitive product was accidentally left exposed to light.

- LIR C-17-07-003 for a lot of Heparin, from the list of confirmed OOS investigations (**Exhibit 10**). The CAPA for this investigation was re-training, as the assay value on the on the C of A was misread and that resulted in a formulation calculation error.

- The four media fill investigations listed in Media Fill Summary Report (**Exhibit 27**) and the three media fill investigations listed in Media Fill Summary Report (**Exhibit 28**).

There were six microbiological deviations associated with Heparin between September 2015 to current. I (NME) reviewed five and noted no deficiencies.

CAPA
There were three corrective actions related to complaints between April 2017 to current. I (NME) noted no deficiencies.

FACILITIES & EQUIPMENT SYSTEM
(YB, NME)
I (YB) received from Mr. Shah Mr. Asutosh Shah, Associate Director of Quality Systems & Compliance a list of all equipment used in the manufacturing of Heparin Sodium for Injection (**Exhibit 9**). The firm also provided us with a PowerPoint Presentation on Heparin Filled in Suite C Validation Summary as **Exhibit 10**.

Hikma Pharmaceuticals USA Inc. is a located on 4.3-acre facility. According to the 'General Firm Information' provided by the firm (**Exhibit 11**), the West-Ward Cherry Hill facility is a parenteral manufacturing facility consisting of two original buildings numbered 10/22 and 9/9A/9B/9C that are connected by means of a covered in-fill known as the Employee Services Building. The manufacturing facility, building 10/22, comprises approximately 200,000 square feet of floor space and is grouped into two areas designated as Area I and Area III (3). Area I include Filling Rooms 1110 (Suite A), vials, Room 1113 (Suite B) ampuls, Room 1117 (Suite C) vials, and Room 1205 (Suite E) pre-filled syringes. Area 3 includes filling rooms 112, 313, and 114 which all filled vials. The manufacturing areas include operations such as Washing and Sterilization, Compounding, Sterile Filling, Inspection, Labeling and Packaging, Maintenance, Quality Assurance, Quality Control (Chemistry, Microbiology and Environmental Monitoring), Raw Material Storage, Batch Record Storage Facilities, WFI Utility and Storage Areas, Terminal Sterilization and Miscellaneous Support and Employee Services.

Building 9/9A/9B/9C covers approximately 214,000 square feet and consists of the following departments: Warehouse, Shipping and Receiving, Physical Testing, Accounting, Audits and Compliance, Engineering, Regulatory Affairs, Technical Services, Training, QA Chemistry, Materials Management and Administration. The facility layout is attached as **Exhibit 12.**

The raw material sampling lab has three classified rooms, 101, 101B and 102. There is also an unclassified room used for sampling acids and another corrosive materials room 110. On 09/06/2018, I (NME) noted that the sampling room 110 in which the sampling hood is located is also used as an office for quality incoming inspections. I reviewed the Raw Material sampling logbook (2P-18-0014) for raw materials sampled in the hood. I noted that for the raw material Acetic Acid Glacial on page 62 of the logbook there is no cleaning verification of the area. The sampling is documented as performed on 07/02/2018 and reviewed approximately a month later, 08/28/2018 (**Exhibit 13**). The 110 room did not have authorized entry (**refer to see General Discussion with Management**).

I (NME) reviewed the "Storage and Sampling of Quarantine Raw Materials" standard operating procedures (2-P-050) (**Exhibit 14**) and noted that the roles and responsibilities section does not include a responsible role for the cleaning or cleaning verification of the sampling rooms prior to a raw material being sampled. However, the procedure section does detail that the analyst is to clean the sampling area prior to sampling. Ms. Karen Deuter stated that the sampling room (areas 101,101B and 102) used for sampling raw materials is cleaned daily by cleaning services. I noted that on 08/06/2018, the full room was not cleaned, there were approximately seven raw materials sampled (Active Pharmaceutical Ingredients and inactive Ingredients). **Exhibit 15** includes the raw material sampling lab cleaning record for 08/03/2018(page 82 of logbook) and 08/07/2018 (page 83 of logbook), and the raw materials sampled on 08/06/2018. The raw material sampling logbook, documents that the sampling area was cleaned prior to each sampling, however the cleaning is not verified on the date performed. I expressed by concern regarding the cleanliness of the room, See General Discussion with Management.

Hikma Pharmaceuticals USA Inc. uses an environmental monitoring and alarm system for the

aseptic areas. A list of unjustified alarms related to Suite A, used for aseptic and terminal product filling, is included as **Exhibit 16**. One of four unjustified alarms were due to an air handling unit shut down causing low differential pressures. The associated event report form (EFR) associated with the event details **(Exhibit 16, page 6)** that at approximately 5:52pm on 08/10/18, during the production of Morphine Sulfate Injection, USP 10mg/mL lot 088318, Air Handler-101 shut off causing a differential pressure of zero between two rooms. The filling room operators reported a strong burning smell. The batch record detailed that actions and that the line was cleared at 5:53pm. I (NME) requested the environmental data leading up to the alarm. Mr. Michael Chropka, Facility Engineering Manager, stated that the data is stored at fifteen-minute intervals, but alarms are stored at the time occurs. Therefore, the immediate data prior to de alert does not contain real-time data. Mr. Chropka provided a summary of the collection and storage of the EMAS data **(Exhibit 17)**. Ms. Judy Bock explained that the loss of differential pressure was between areas of the same classification, and therefore the risk was only to the open units. Mr. Natheer Masarweh, Chief Officer, Quality and Technical affairs stated that the SOP would be reviewed. Ms. Bock provided a statement stating that changes will be made to SOP 3-F-114 "Environmental Monitoring and Alarm System (EMAS) for Aseptic Areas" **(Exhibit 18)**.

Preventative Maintenance

(NME)

The preventative maintenance (PM) system SOP- 4-MA-00, the PM schedule for air handling units and corrective maintenance work orders for the air handling units in the aseptic units were reviewed. A corrective maintenance work order is work done outside the preventative maintenance schedule. I (NME) noted that Suite B had the most corrective orders (10). I reviewed the ten corrective orders and noted that work order 2048110 was created on 03/08/2018 but actions were documented on 05/21/2018. I noted that work order 2052968 was for a change in the differential pressure alarm set point, from 0.05 to 0.03. I reviewed the associated change control and noted no discrepancies. Exhibit NME19 includes the preventative maintenance system SOP, the PM schedule for the air handling units, list of corrective work orders, and the ten work orders for suite B.

I (NME) noted that a door in Area 3, where aseptic filling lines are located, was open. The door had signage that stated that the door must be closed. I saw two employees walkthrough the door and the magnetic function of the door did not function to properly close the door. Mr. Shah provided work order 2065200 to fix the Area 3 exit door **(Exhibit 19)**.

I (NME) noted that a door in Area 3, where aseptic filling lines are located, was open. The door had signage that stated that door must be closed. I saw two employees walkthrough the door and the magnetic function of the door did not function to properly close the door. Mr. Shah provided work order 2065200 to fix the Area 3 exit door **(Exhibit 20)**.

Equipment Cleaning

I (YB) reviewed SOP 3-CS-0233, Guideline for Cleaning Aseptic and Controlled Production Areas, Effective Date: July 28, 2018. The firm has four types of cleaning and disinfecting agents (LpH, Vesphene, Sopor-Klenz and WFI). I also reviewed the Room and Equipment Cleaning, Usage and Maintenance Log, Log Book # 3 CS-18-0039 for multi-dose compounding and Aseptic Area 1

Cleaning Logbook 3 CS-18-0049. I verified that the appropriate cleaning was performed and documented with no deficiencies noted.

Equipment Qualification

I (YB) reviewed the Performance Qualification Protocol and General Technical Report No. 51409 approved on 01/27/14 with Mr. Nicholas Ruggieri, Senior Scientist. No deficiencies were noted.

MATERIALS SYSTEM

(YB, RG)

There have been no changes in the warehouse operations since the last inspection and additional information can be obtained from previous inspection reports. On 09/06/2018, we conducted an inspectional walkthrough of the warehouse with Mr. John Reed (Manager, Warehouse Operations). He provided us with an overview of the warehouse operations. He stated that the materials are received through the loading docks where materials are inspected for damage and acceptable pallet format before being moved. The material is transferred to the receiving area where it is broken down to begin the receiving process. Warehouse personnel checks the packing slip to ensure the proper item was received by the correct vendor. Pertinent information is verified (e.g., supplier name, address, item description, and quantity ordered). The material is placed under quarantine until they are sampled, tested and released by QA for production. The products are sampled in the firm's pharmacy/sampling rooms located in the warehouse. During the walkthrough, we reviewed the sampling rooms logbook (refer to see General Discussion with Management). The contract suppliers that provide the raw ingredients are sourced by the client or the firm depending on the quality agreement. The firm performs full testing on all incoming materials as they are certifying the vendor and material. A receipt is then generated and filed, and labels are created to be placed on the product. The material then can be moved from the receiving location to any available pallet location in the warehouse based on the material's required storage requirements. No deficiencies were noted.

Vendor Management

(YB)

The firm has a procedure in place that describes the vendor management program. I did not observe any deficiencies with the procedure. Testing for materials is conducted as required. Suppliers are required to have a contract and a quality agreement. We reviewed supplier qualification procedures and the list of the firm's current qualified suppliers. No deficiencies were noted.

Water for Injection (WFI) System/Change Controls:

(RG)

Investigators, Blaise, Espinal, and I collectively evaluated the firm's WFI System. One CGMP concern was noted with respect to the procedure for QA sampling and production use. Refer to the section below titled **General Discussion with Management,** item 2.

I (RG) have included with this EIR a schematic of the firm's WFI system **(Exhibit 21).** On 9/10/2018, Investigators, Blaise, Espinal, and I performed an initial inspection of the WFI system.

Investigator Espinal reviewed microbiology test results, and monthly and quarterly trend results for

first and second quarters of 2018 and noted no deficiencies.

I (RG) evaluated how the firm managed a change that cut into WFI Loop 2 and added approximately 80 feet of stainless steel piping, removed a valve (YV-862-29), and added a new drop valve (use point) YV-862-30, in Room 1201 (Suite D). This change occurred over the Memorial Day Weekend in 2017. The change was adequately documented and approved, per Change Control 0517155, dated 5/22/2017. The change was in accordance with an approved procedure, Line Entry into WFI System for Maintenance and Calibration, SOP 4-WS-018, Revision 14, Effective date 5/27/2016.
Six 180°C flushes (sanitizations), five minutes each, were documented for Loop 2, on 5/25/2017, in maintenance Log Book 42, WFI Storage and Distribution. Additional microbiology samples were taken before the system was returned to production for use. Those sample results, and subsequent sample results recorded no microbial counts or concerns (Microbiology Testing of Water Notebook #138 and #139, May and June 2017). The current Microbiology Testing of Water Notebook #153, August 2018 indicated no potential problems with the WFI system. The firm's SOP, Microbiological Testing of Water, 2-M-017, Revision 69 incorporated the change control and in sampling points. The current SOP, Revision 71, Effective date 7/27/2018 is included with the EIR **(Exhibit 22)**.

On 9/14/2018 Investigator Blaise and I were able to observe QA sample three sites, Loop 1 AV 850-04, Loop 2 AV 860-04 and Loop 3 AV 870-04.

PRODUCTION SYSTEM
(YB and RG)
The firm continues to manufacture sterile injectable drug products in the form of small volume parenteral. During the inspection, the firm was not manufacturing Heparin Sodium Injection. On 09/06/2018, we conducted a walkthrough of the compounding area in Area #1. Mr. Harry Lindenmuth, Director, Manufacturing provided us with the process flow charts for Heparin Sodium Injection **(Exhibit 6)**. He explained Heparin Sodium Injection is aseptically processed and filled under class 100 conditions. The bulk solution is transferred from the compounding tank into Room 1117 (Suite C). The bulk solution is then drawn from the surge vessel and filled into 2 mL vial. Filled units are physically inspected for articulates and physical defects. The filled units are sealed by the stoppering unit within the sterile filling room. Once the product is removed from the filling areas, it is subjected to the autoclave sterilization process to ensure sterility. After filling and sterilization cycles are complete, products are then inspected, labeled, and packaged During the inspection, we reviewed various on-going production batch records, including but not limited to the following that of:

- Promethazine 50 mg/mL, Lot # 098393 (Equipment set-up in room 313)
- Neostigmine 0.5 mg/mL 10 ml vial, Lot # 098358 (Filling in room 112)
- Morphine 10 mg/mL 1 mL/2mL vial Lot# 0988326 (Filling in Suite A)

No deficiencies with the production system were noted.

I (RG) requested a short brief on the Heparin Sodium Injection manufacturing process. After we received the brief **(Exhibit 6)**, I reviewed the process validation summary; Product Validation

Heparin Sodium Injection, USP 1,000 Units/mL and 10,000 Units/mL 1mL/2ml Vial in Suite C (Room 1117) (Second interim), approved 9/15/2017 (**Exhibit 24**). By agreement of the inspection team, I covered media fills and evaluated the Heparin Sodium Injection stability data.

During the inspection, I (YB) reviewed the Validation Summary in conjunction with process validation protocols and reports for: Heparin Sodium Injection, USP 5,000 units/ml, 1mL/2mL vial in Suite C (Room 1117) Batch Size: 400,000 units (530 L), Report Release Date: 07/20/2015. According to Mr. John Schiller (Sr. Manager, Technical Operations), process validation involves the process design, process qualification and process verification. He further stated that the validation process must include at least three batches manufactured. The firm manufactured three consecutive Validation Batches N045400, N065358, and N065360 of Heparin Sodium Injection, which were manufactured in Suite C as per Process Validation Protocol PVP-5253. I reviewed the following batch records:

- Heparin Sodium Injection, USP 5,000 units/mL, Batch # N065360
- Heparin Sodium Injection, USP 5,000 units/mL, Batch # N065358
- Heparin Sodium Injection, USP 10,000 units/mL, Batch # N107345

Due to the maximum bulk holding duration is being extended from 48 hours to 72 hours within this supplement to the application. I reviewed PV-4776, Product Validation Protocol Heparin Sodium Injection, USP 10,000 unit/mL, 1mL/2mL vial in Room 115 and Technical Report. No deficiencies were noted.

Media Fills

(RG)

The firm was performing media fills on every aseptic line, every six (6) months. I noted no deficiencies or CGMP concerns from my audit of two aseptic drug processing media fills performed in Aseptic Filling Area 1:

- Filling Room 1117 (Suite C), where Heparin for Injection was being manufactured, as identified in the current post-approval assignment request.

- Filling Room 1201 (Suite D) where the firm recently received approval for Propofol For Injection (ANDA 074848, Sup 8) and was preparing to run three process validation lots.

I (RG) reviewed the following documents:

- List of media lots produced from 4/1/2017 to 9/11/2018 (**Exhibit 25**).
- Master Media Fill Schedule Year 2018, Aseptic Filling Areas 1 and 3 (**Exhibit 26**).
- Media Fill Summary Report Filling Room 1117, Suite C Lot # M028375 Executive Summary (**Exhibit 27**).
- Media Fill Summary Report Filling Room 1201, Suite D Lot # M048336 Executive Summary (**Exhibit 28**).
- Executed batch records for media fill lots M028375 and M048336.

- General Procedures for Media Fill Trial, SOP 2-M-253, Revision 17, Effective Date 5/11/2018.

LABORATORY SYSTEM
(YB, NME and RG)

I (NME) noted that glassware used in the chemistry laboratory was heavily etched. Mr. Natheer Masarweh, Chief Officer, quality and technical affairs, provided purchase orders for new glassware **(Exhibit 29)**.

Mr. Michael Jiang, Analyst, demonstrated the assay testing (Method: TM B810 Version 5) for Heparin (18-month stability lot). He used plate reader CHMPLTDR-01, which was in calibration (Due: 09/2018). There is a computer that is used with the plate reader. The observances generated by the plate reader captured by SoftMax Pro-software are used in calculation to determine the results for the test. The Use and Operation of SoftMax Pro Software SOP:2-C-141 **(Exhibit 30, page 4)**, section 5.1.2 states that "user saves data in GXP Softmaxdata folder in format of Product lot number, date(DDMMYY) and initials." The analyst performing the test save each run on the computer. I (NME) noted there were files named similarly **(Exhibit 30, page 8)**. Mr. Michael Parker, Associate Director, Chemistry Operations, provided an evaluation of the files that had similar names. He explained that runs with similar names were usually system suitability failures or associated with investigations. He stated that runs are reconciled with the plate reader logbook and not with the data saved in the SoftMax Pro-Software. He stated that a change will be made so that the data reconciliation occurs from the SoftMax Pro-Software data generated.

As part of Heparin Sodium Injection NDA 017037 Supplement 175 and 176, I reviewed the Nucleotic Impurities method verification, current test method and raw data for two Heparin Sodium USP raw material lots 1710132 and 1807088. The protocol 2014-036 included system suitability, limit of detection, accuracy and precision. I verified that the method used is the USP method. Review included preparations (mobile phase, standards, sample), chromatographic conditions, sample set injection times and random selected chromatograms. No discrepancies were noted with the raw data for the method verification, the comparison of the method verified with the current method used or testing of the two raw materials.

I (NME) reviewed the Benzyl Alcohol method verification, current test method against the USP method. The verification included system suitability, specificity, accuracy, precision, and solution stability studies for standard and sample. I noted that the flow rate was different from the USP method. Also, the verified method has additional rinses to prevent carry over. I noted no discrepancies.

Ms. Karen Deuter, Senior Manager, Chemistry Operations, stated that the firm is changing the software used for chromatographic data analysis. The laboratory is transitioning from Totalchrom to Empower. Mr. Parker stated that a protocol was performed, which evaluated the performance and compared both software. **Exhibit 31** includes the list of instruments and which data system it is currently using, and a data comparison for assay and related compound results for two products that

are on stability.

Stability and Release Finished Product Testing (NDA 017037)
I (RG) reviewed and evaluated:

- Certificates of analysis (C of As) for the four lots (N125348, N125350, N036396, and N077327), included in the room transfer validation study **(Exhibit 32)**.
- The stability summary tables for lots N125348, N125350, N036396, and N077327 **(Exhibit 33)**.
- Analytical method, *Anti-Factor IIA Potency in Heparin Sodium Products*, TM B810-05, Effective Date 4/30/2014 **(Exhibit 34)**.
- *Specifications and Testing Monograph Finished Product and Commercial Stability* for
- *Heparin Sodium Injection, USP 1,000 Units/mL* **(Exhibit 35)** *and 10,000 Units/mL* **(Exhibit 36)** 1mL volume in a 2ml Vial.
- Performed data audit of Heparin Sodium lots N036396, and N077327 (and other data recorded in three notebooks by two different analysts). As reflected in the table below, stability lot N077327, which was commercially distributed, is still within the expiration date of 1/2019.

Lot Numbers	N125348	N125350	N036396	N077327
Strength	10,000 units/ml	1000 units/ml	1000 units/ml	10,000 units/ml
Date of Mfr	12/2015	12/2015	4/2016	8/2017
Date of Exp	12/2017	12/2017	3/2018	1/2019
Initial Assay (C of A)	100.2 **(Exhibit 32, page 1)**	99.1% **(Exhibit 32, page 2)**	98.7% **(Exhibit 32, Page 3)**	98.8 **(Exhibit 32, page 4)**
Stability Summary Tables	**(Exhibit 33, pages 1-5)**	**(Exhibit 33, pages 6-10)**	**(Exhibit 33, pages 11-15)**	**(Exhibit 33, page 16)**
12-month stability data review	----------	----------	----------	98.3% Notebook 2C-18-0266 F.K. Pages 135-139 9/5-10/2018
18-month stability data review	----------	----------	97.4% Notebook 2C-17-0273 H.J. pages 129-133 5/7-8/2018	N/A
24-month stability data review	----------	----------	104.7 Notebook 2C-18-0199 F.K. pages 118-121 5/7-8/2018 **(Exhibit 37)**	N/A

- On 9/12/2018, I was able to coordinate with the firm the opportunity for us to observe the scheduled analytical testing of Heparin Sodium per the analytical method Anti-Factor IIA Potency (Ex I). We observed the analyst pipet a stability sample, dilutions, and blanks into a 96 well microplate. We observed the analysis run on a PerkinElmer Zepher G-3, Automated Workstation (Calibrated 7/24/2018, Due 1/2019). The next day, while I was working on something else, Investigator Espinal had the opportunity to review the integrated results and informed me that there were no concerns.

The firm has a procedure in place that addresses stability testing, SOP 2-QSC-001, Commercial Stability Sampling, Storage, scheduling and Inspection, Effective Date: 08/24/2018. During the inspection, I (YB) reviewed laboratory notebooks and analytical methods for finished product release and stability testing pertaining to NDA 017037 Heparin Sodium Injection, USP, 5000 units/mL, Lot # N045400, Room Temperature Condition: 25°C, stability time points: 0, 6, 12, 18 and 36 months. I also reviewed the chromatographic raw data and test results for assay and found no discrepancies.

Microbiology Laboratory
(RG)
Investigator Blaise and I inspected the Microbiology Laboratory and we noted no significant deficiencies.

The microbiology laboratory appeared adequately staffed **(Exhibit 38)** and managed. Ms. Judy Bock was the Senior Manager of Sterility Assurance and Environmental Monitoring with approximately 14 department employees. Ms. Sonal Patel was the Microbiology Laboratory Supervisor with approximately 15 department employees.

The microbiology laboratory appeared adequately equipped. As reflected in the floor plan of the microbiology department **(Exhibit 39)**, and the Microbiology Lab Function Overview **(Exhibit 40)**, the microbiology laboratory was sub-divided into five main laboratories plus support areas. There was a Sterility Laboratory with two isolator chambers and three isolator preparatory chambers; an Environmental Monitoring Laboratory; an Analytical Laboratory; an Identification Laboratory with a Vitek II and a Dupont RIBO Printer G-RIBO Qualicom; and a Support Laboratory with media preparation batch tanks, a bottle capper and other equipment.

We observed/inspected/evaluated:

- Sample accountability within the laboratory.
- Sterility sample testing in the isolator.
- Environmental monitoring plate reading.
- Purchased environmental monitoring media growth promotion release testing.
- Equipment calibration and maintenance including: the isolators; the two automated instruments used for organism identification (the Vitek II and the Dupont RIBO Printer G-RIBO Qualicom); incubators; refrigerators, and laboratory autoclave.
- Media Fills and WFI testing and procedures, as discussed under separate headings.

PACKAGING AND LABELING SYSTEM

(NME)

There are 12 lines at Hikma. These lines are used for either inspection/labeling/packaging or a combination of operations. A list of the firms filling, and packaging lines is included as **Exhibit 23.** Out of 12 lines 6 lines perform automatic visual inspection. Line 417 is used to inspect, label and package Dossett (single dose) vials. Sodium Chloride Injection Lot 088391, EXP 08/2021 was running on line 417 on 09/10/2018. The line has a vial washer. The washer uses DI water. The vials then go through an automatic visual inspection equipment. The Eisai AIM, Model 2022 is designed to inspect 2-mL Dosette vials for both particulate and gross cosmetic defects in the main vial body, upper body, and crimp. I reviewed the installation and operational qualification. I noted that the product selected for the cosmetic defect operational qualification was not the most viscous product. Mr. Nicholas D. Ruggieri, explained that the system is only looking for visual defect on the vial using a CCD camera and not particulates for that portion of the qualification. The most viscous product was used for particulate testing which is inspected by the SD Photodiode array sensor stations. **Exhibit 41** includes the installation qualification, Operational Qualification, most recent equipment re-qualification and the validation plan used to determine re-qualification of products on the automatic inspection machines.

Lines 418 and 417 are separated by a wall.

Labeling materials such as labels, inserts and patient information are inspected prior to being released. A computer system is used for proofing incoming labels. Samples of labeling are received from the supplier. Labels were stored in the labeling area, which has authorized personnel entry controls. Storage areas are labeled with a bar code. Once labeling materials are released the materials can be issued to the line. Only full rolls are issued to packaging lines. Only full rolls are returned to the labeling room. The packaging line destroys any partially used rolls. Reconciliation of labels is performed per lot. I noted no discrepancy with the expiration dates on labels.

Mr. Wood provided a status report (**Exhibit 42**) for serialization requirements under the Drug Supply Chain Security Act. I had no comments regarding the status of the process.

MANUFACTURING CODES

(YB)

The firm's batch numbering system did not change since the previous inspection. The firm primarily uses the batch number for commercial products manufactured at the Hikma Cherry Hill site. The batch number contains six (6) numerical code. The first two digits represents the month in which the batch is issued, the next digit represents the represent the year (e.g. "8" represents 2018), and the last three digits indicates the sequential batch assignment within the month (e.g. 001). A letter following this six-digit code indicates a sub-lot. Codes are prefixed by letters for Pilot/Submission ("P") and Clinical ("C") lots as well as for media fills ("M").

For example:
Lot # 058024 would be coded as the 24th lot manufactured in May 2018.

COMPLAINTS
(NME)
Three field alert reports were reviewed.

Product Name	NDA	Problem
Nicardine Hydrochloride Injection	022276	Stability failure at 18 months
Dexamethasone Sodium Phosphate Injection, USP	084282	Stability failure at 9 months
Lorazepam Injection USP	018140	API manufacturing change

A field alert report for Nicardine Hydrochloride Injection was submitted to the agency. The 2015 annual stability lot failed to meet related substances stability specification (Result: 2.1% Spec: NMT 2.0%). The failure was for a known impurity Nitrophenylpyridine derivate (NPP). Mr. Natheer Masarweh, Chief Officer, stated the product remained on the market as the product was on the drug shortage list. A prior approval supplement (PAS) was submitted to the agency to increase the specification from 2.0% to 3.0%. **Exhibit NME2** includes the final report and information regarding drug shortage and the PAS approval.

A field alert report for Dexamethasone Sodium Phosphate 4mg/mL Injection, USP for an OOS observed during the 9-month test station stability analysis failure of a known impurity Dexamethasone Adduct (related compound), (Result: 2.39%, Limit NMT 2.3%) was reviewed. All manufactured lots were removed from the market. The root cause identified was that the Dexamethasone Adduct formation is affected by pH, and that stricter the in-process pH controls were required. Mr. Michael Parker, Associate Director Chemistry Director, stated that the pH data for submission batches, impurity profile and formulation were evaluated and a change to the in-process controls for pH was submitted as a Change Being Effected (CB-30). The change was to increase the pH parameter from 7.7-7.9 to 8.0-8.1. The stability protocol was continued to obtain critical product history information regarding when the Dexamethasone Adduct formation reaches the peak of growth. **Exhibit NME3** includes the final field alert report, the current stability summary data, and the historical information for the in-process parameters.

A field alert report for Lorazepam Injection USP for a problem discovered by an FDA investigator at the API manufacture concerning the validity of a process step addition. There was only one raw material lot received that was affected by the manufacturing change. There were 3 finished products lots manufactured with the raw material. I reviewed the complaints received for lorazepam since the last inspection and noted no discrepancies. **Exhibit NME4** contains the final field alert report and the list of complaints reviewed.

I reviewed the Processing Customer Complaints/Inquiries SOP: 2-QCS-014 **(Exhibit NME5 page**

1-16) and noted that the complaints are assigned classifications such as "Critical, High, and Normal." The description of a critical complaint is "may include vents related to death, micro contamination (Unused units), Chemistry OOS (unused units) and confirmed incorrect labeling". Mr. Shah reported that there are no critical or high complaints for the timeframe of April 2017 through the current inspection **(Exhibit NME5 pages 17-41)**. I stated to Mr. Natheer Masarweh, Ms. Suzan Juraydini and Mr. Shah that the definition was not clear as there was a complaint regarding the death of two dogs **(Exhibit NME5 page 34, WWCH-Comp-1727)**. Ms. Suzan stated that the complaints are related to "off label" usage of the drug and therefore those complaints may not need to be investigated as per the note in the SOP **(Exhibit NME5, page 8)**. The complaint trend report included 14 adverse events complaints **(Exhibit NME5, page 44)**. Mr. Natheer Masarweh stated that the Processing Customer Complaints/Inquiries SOP: 2-QCS-014 would be reviewed to clarify the vagueness in the classification process.

Complaints WWCH-Comp-1550 and 1727 are for animal related adverse events. Hikma Pharmaceutical USA Inc. does not have any animal new or abbreviated drug applications. However, human drug products are distributed to veterinary drug suppliers. Complaint WWCH-Comp-1550 is for Hydromorphone 2 mg/mL 20mL vial lot 037406. The complaint details that after being "injected with the product, two dogs yelped like it stings and tried to bite the people restraining them" **(Exhibit 43, page 1)**. Complaint WWCH-Comp-1727 is for Hydromorphone 2 mg/mL 20mL vial lot 037406. The complaint details that "the product was administrated for a sedation protocol and 2 of the patients (dogs) passed away during the procedure" **(Exhibit 43, page 25)**. There was no field alert report or adverse event submitted for either complaint **(Exhibit 43, page 53-54)**. Refer to General Discussion with Management.

There were 16 complaints with the failure mode "vial label". Complaint WWCH-Comp-1710 was regarding a vial received at a pharmacy without a label and with a black X on the top of the cap. Corrective action (commitment) WWCH-CMP-1161 was issued to evaluate an alternative method to identify the missing label challenge vial used on the packaging line. Another vial label failure mode was that the barcode was not reading on the first try (WWCH-Comp-1526), there was no report of product and barcode scanned information mix-up.

There were 28 complaints with the category of missing. This category includes missing units, empty units, package shortage, lack of safety seal/tamper seal and labels. Hikma Pharmaceutical USA Inc. manufactures controlled substances such as Fentanyl, Hydromorphone, Testosterone, Morphine and Midazolam. Out of 28 complaints 18 are related to controlled substances products.

The firm does not salvage products as listed on their registration.

The firm does accept returns, but returns are not restocked or shipped to other customers.

I (YB) reviewed six (6) complaint reports associated with Heparin Sodium Injection from September 2016 to current with no deficiencies noted.

RECALL PROCEDURES

(NME)

Dexamethanodone Sodium Phosphate Injection, USP 4mg/mL. 1mL vials and 5mL were recalled due to the failure of a known impurity to meet stability specification (Result: ~2.39% Spec: Not More Than 2.3%). Refer to Complaint section for the related Field Alert Report review. The update for recall numbers D-0093-2018 and D-0094-2018 was provided by Mr. Shah.

The recall procedure was reviewed, and no discrepancies were noted.

Exhibit NME1 includes the recall SOP and the recall status report.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

(YB, NME, and RG)

On 09/14/2018, we, Investigators Blaise, Espinal, Glapion held a close-out meeting with the following individuals: Mr. Anibal Carlo, Vice President Global Injectable Manufacturing; Mr. Natheer Masarweh, Chief Quality & Technical Affairs Officer; Mr. Brett Wood, Senior Director, Quality & Technical Operations; Mr. Harry Lindenmuth, Director, Manufacturing; Mr. Asutosh Shah, Associate Director Quality Systems & Compliance; Mr. John Barton Kalis, Senior Director Global Regulatory Affairs Injectable; Mr. George Allen, Director of Engineering; Ms. Joanna Siers, Quality Associate- QA compliance; and Ms. Alice Reese, Executive Assistant. No FDA-483, Inspectional Observations, was issued but we verbally discussed the following deficiencies at the closeout meeting and throughout the inspection.

1. Report of Adverse Events associated with Human drugs used for animals

(NE): There were two complaints (**Exhibit 43**) associated with adverse events for "off-label" use of human drugs on animals. I discussed the importance of animal adverse event reporting of human drugs used for animals. Mr. Natheer Marsarweh and Mr. John Barton Kalis provided a commitment letter (**Exhibit 44**) stating to evaluate a process for submission of adverse events related to animal deaths. I clarified that these adverse events would be submitted to the Center for Veterinary Medicine.

2. Raw Material Sampling area cleaning, cleaning verification and controlled access

The classified sampling area (102, 101B and 101) room cleaning was not performed on 08/06/2018 **(Exhibit 15)**. The room was used to sample approximate 7 raw materials, which include active pharmaceutical ingredients. I expressed my concern regarding the sanitation of the room, and

cleaning processes in between sampling of active pharmaceutical ingredients. Mr. Wood provided a summary of cleaning for the time frame of 08/03/2018-08/07/2018, cleaning procedures (which includes sanitizing cleaning area prior to sampling), frequency of cleaning, and the calculation of air changes in room 102 for the assurance of contamination prevention **(Exhibit 45).**

The fume hood cleaning is not verified prior to sampling **(Exhibit 13).** Sampling for raw material Acetic Acid performed on 07/02/2018 was reviewed on 08/28/2018. Mr. Shah provided two change controls forms; (1) the Sampling and Storage SOP and (2) Raw Material Sampling log to add the requirement of cleaning verification prior to sampling **(Exhibit 46).**

The fume hood sampling area where acid and corrosive materials are sampled is not in a controlled access area. Mr. Shah emailed the corrective actions performed to control access to the raw material sampling office in which the fume hood used to sample acids and corrosive materials are located **(Exhibit 47).**

3. WFI QA Sampling and Production Use Inconsistency

(RG): According to the Water Sampling Procedure (**Exhibit 48**), QA personnel are required to open the sample point valves and allow the WFI system to drain (flush) for a minimum of one minute before taking a sample. As observed, the QA personnel have a stop watch with them when taking water samples.

Since the procedure requirement is open ended, a minimum of one minute, and since there is a catch drain below almost all of the sample valves, the QA personnel are not constrained by the volume limitations of a catch bucket. As a matter of practicality and observation, the QA personnel can flush the valves for several minutes before taking the sample, while they update sample collection paperwork. I pointed out that subsequent microbial sample data from an extended flush (approximately three to five minutes as observed) may resulted in lower microbial counts then those actually being obtained by production, if production is using that one minute flush as the maximum amount of time that they have to wait before they can start using the water to manufacture a batch of drug product. The firm acknowledged the concern and agreed to correct the potential inconsistency in their procedure

4. Discrepancies in the gowning of packaging employees

(YB): During the walkthrough of Building 10/22 on 09/06/2018, we observed several employees engaged in the secondary packaging area that did not have their hairnet properly positioned to cover all their hair. The concern for the lack of proper gowning during the packaging of the drug products was reiterated during the inspectional daily closeout meeting. On September 07, 2018 due to observation the Inspection and Packaging personnel were provided with an awareness training **(Exhibit 49).**

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

1(YCB) Hikma Site Presentation, 12 pages
2(YCB) A list of all Hikma Pharmaceutical PLC manufacturing locations, 3 pages
3(YCB) Hikma Product List, 5 pages
4(YCB) 2018 Hikma Atendees list FDA, 4 pages
5(YCB) Orangizatonal Chart
6(YCB) Process flow charts for Heparin Sodium Injection, USP 1,000 units/mL, 5,000 units/mL and 10,000 units/mL , 3 pages
7(YCB) Heparin Sodium Injection Side by side comparsion room 115 to room 1117 (Suite C), 3 pages
8(YCB) A list of Finished Good Rejections from 4/1/2017 to 9/7/2018 , 1 page
9(YCB) List of all equipment used in the manufacturing of Heparin Sodium for Injection, 2 pages
10(YCB) PowerPoint Presentation on Heparin Filled in Suite C Validation Summary, 5 pages
11(YCB) General Firm Information, 5 pages
12(YCB) Facility Layout, 4 pages
13(YCB) Raw Material Sampling Logbook # 2P-18-0014, 2 pages
14(YCB) SOP 2-P-05, Storage and Sampling of Quarantine Raw Materials, Effective Date: 03/31/2017, 20 pages
15(YCB) Raw material sampling lab cleaning record, 9 pages
16(YCB) EMAS Alarms related to Suite A (April - Present), 10 pages
17(YCB) Summary of the collection and storage of the EMAS data/SOP 3-F-114, Environmental Monitoring and Alarm System (EMAS) for Aseptic Areas, Effective Date: 11/03/2017, 19 pages
18(YCB) Memo dated 09/13/2018 for SOP Revision , 1 page
19(YCB) SOP 4-MA-009, Preventive Maintenance System, Effective Date: 12/09/16, 23 pages
20(YCB) Work Order #: 2065200, Area 3/ Exit door not working, 3 pages
21(YCB) A schematic of the firm's WFI system, 1 page
22(YCB) SOP 2-M-017, Microbioloical Testing of Water, Effective Date: 07/27/18, 28 pages
23(YCB) List of the firms filling, and packaging lines, 1 page
24(YCB) Product Validation Heparin Sodium Injection, USP 1,000 Units/mL and 10,000 Units/mL 1mL/2ml Vial in Suite C (Room 1117) (Second interim), approved 9/15/2017, 19 pages
25(YCB) Media Lot from 04/01/2017 - 09/11/2018, 1 page
26(YCB) Master Media Fill Schedule for Year 2018, 2 pages
27(YCB) Media Fill Summary Report, Filling Room 1117, Suite C (Lot# M028375), 11 pages
28(YCB) Media Fill Summary Report, Filling Room 1201, Lot # M04836, 10 pages
29(YCB) Purchase Order Requistion Pr. No. 3000172412 dated 09/11/2018, 13 pages
30(YCB) SOP 2-C-141, Use and Operation of Softmax Pro Software, Effective Date: 01/19/18, 22 pages
31(YCB) List of Chromatography Systems, 3 pages
32(YCB) Certificates of analysis for the four lots (N125348, N125350, N036396, and N077327), 4 pages

33(YCB) Stability summary tables for lots N125348, N125350, N036396, and N077327 , 16 pages
34(YCB) Analytical method, Anti-Factor IIA Potency in Heparin Sodium Products, TM B810-05, Effective Date 4/30/2014, 12 pages
35(YCB) Specifications and Testing Monograph Finished Product and Commercial Stability forHeparin Sodium Injection, USP 1,000 Units/mL Effective Date: 05/18/2018, 7 pages
36(YCB) Specifications and Testing Monograph Finished Product and Commercial Stability for Heparin Sodium Injection, USP 10,000 Units/mL, 7 pages
37(YCB) Laboratory Notebook 2C-18-0199, 5 pages
38(YCB) Microbiology Organizational Chart, 4 pages
39(YCB) Facility Layout of Microbiology Department, 1 page
40(YCB) Microbiology Lab Function Overview, 2 pages
41(YCB) Report #49247 Installation Qualification, Operational Qualification, most recent equipment re-qualification and the validation plan, 82 pages
42(YCB) Cherry Hill Serialization Status Report - September 2018, 1 page
43(YCB) WWCH Complaint Report # 1550 and 1727, 55 pages
44(YCB) Commitment Memo - submission of Animal Adverse, dated 09/14/2018, 1 page
45(YCB) Raw Material Sampling Lab Cleaning Usage Log, 12 pages
46(YCB) SOP 2-P-050, Storage and Sampling of Quarantine Raw Materials, Effective Date: 03/31/2017, 28 pages
47(YCB) Corrective Action for New Card Reader Installation Project, 3 pages
48(YCB) 2-M-017, Microbiological Testing of Water, Effective Date: 07/27/2018, 28 pages
49(YCB) Memo provided on 09/07./2018, 1 page
50(YCB) Recall documents, 16 pages
51(YCB) Nicardipine HCl FAR Documents , 16 pages
52(YCB) Dexamethasone Sodium Phosphate Injection FAR Documents , 9 pages
53(YCB) Lorazepam Injection FAR Documents , 7 pages
54(YCB) Complaint SOP and April 2017 to current complaint list, 44 pages

ATTACHMENTS
1(YCB) Form FDA 482, Notice of Inspection, issued 09/06/2018, 3 pages
2(YCB) Form FDA 482, Notice of Inspection, issued 09/10/2018, 3 pages

X Yvesna C Blaise
Investigator
Signed By: 2001786948
Date Signed: 10-03-2018 12:38:13

X

X

State	Business Name on License	License Number	License Type	License Original Issue Date	License ExpirationDate	License Status
Federal	Hikma Pharmaceuticals USA Inc	946499745	Human Drug Compounding Outsourcing Facility	9/15/2021		
Federal	Hikma Pharmaceuticals USA Inc	RW0415643	DEA Certificate- Manufacturing	9/22/2021	10/31/2022	Active
Federal	Hikma Pharmaceuticals USA Inc	RW0415667	DEA Certificate- Importer		10/31/2022	Active
Federal	Hikma Pharmaceuticals USA Inc	RW0415655	DEA Certificate- Analytical Lab		10/31/2022	Active
New Jersey	Hikma Pharmaceuticals USA Inc	5002130	Dept. of Health Consumers and Environmental Health Service (NJDOH)		1/31/2023	Active
New Jersey	Hikma Pharmaceuticals USA Inc	CM00026400	Controlled Dangerous Substance- Manufacturer		3/31/2023	Active
New Jersey	Hikma Pharmaceuticals USA Inc	CA00025400	Controlled Dangerous Substance- Analytical Lab	2/5/2021	3/31/2023	Active
Montana	Hikma Pharmaceuticals USA Inc	PHA-WDD-LIC-83504	Wholesale Drug Distributor		11/30/2022	Active
Hawaii	Hikma Pharmaceuticals USA Inc	E15822	Registration for Controlled Substances		10/31/2022	Active
Pennsylvania	Hikma Pharmaceuticals USA Inc	1000004240	Manufacturer- Controlled Substance	11/19/2021	12/31/2022	Active
Wisconsin	Hikma Pharmaceuticals USA Inc		Exemption			
Louisiana	Hikma Pharmaceuticals USA Inc	10528	Distributor of Legend Drugs Or Legend Devices	2/15/2022	12/31/2022	Active
Louisiana	Hikma Pharmaceuticals USA Inc	CDS.061905-MFR	CDS License- Manufacturer	1/27/2022	1/27/2023	Active
Rhode Island	Hikma Pharmaceuticals USA Inc	CDIS03737	CSR-Drug Manufacturer-Out of State	2/21/2022	9/30/2022	Active
Rhode Island	Hikma Pharmaceuticals USA Inc	BIS03737	Drug Manufacturer-Out of State	2/21/2022	9/30/2022	Active
Indiana	Hikma Pharmaceuticals USA Inc		Exemption			
Georgia	Hikma Pharmaceuticals USA Inc	PHMA000616	Manufacturing Pharmacy	2/17/2022	6/30/2023	Active
Oregon	Hikma Pharmaceuticals USA Inc	M-0003680	Manufacturer	2/11/2022	9/30/2022	Active
Oregon	Hikma Pharmaceuticals USA Inc	M-0003680-CS	Controlled Substance	2/11/2022	9/30/2022	Active
Colorado	Hikma Pharmaceuticals USA Inc	NOF.0000011	Non-Resident 503B Outsourcing Facility	4/7/2022	10/31/2022	Active
Connecticut	Hikma Pharmaceuticals USA Inc	CSM.0002110-OOS	Out of State Manufacturer of Drugs, Cosmetics and Medical Devices	11/23/2021		Active
Wyoming	Hikma Pharmaceuticals USA Inc	CSB01132	Controlled Substance Registration	2/16/2022	6/30/2023	Active
Wyoming	Hikma Pharmaceuticals USA Inc	WD2266	Wholesale Distributor License	2/16/2022	6/30/2023	Active
Washington	Hikma Pharmaceuticals USA Inc	PHWH.FX.61263993	Pharmaceutical Wholesaler License	4/20/2022	9/30/2022	Active
Texas	Hikma Pharmaceuticals USA Inc	1003375	Food & Drug License - Cosntrolled Substance, Prescription	4/7/2022	11/3/2023	Active
South Dakota	Hikma Pharmaceuticals USA Inc	600-3421	Wholesale	4/20/2022	12/30/2022	Active
Mississppi	Hikma Pharmaceuticals USA Inc	18250 / 13.5	Sterile Product Outsourcer	4/27/2022	12/31/2023	Active
Mississppi	Hikma Pharmaceuticals USA Inc	CS-19330	Controlled Substance Registration	4/27/2022	12/31/2022	Active
Alaska	Hikma Pharmaceuticals USA Inc	194581	Outsourcing Facility	5/3/2022	5/3/2024	Active
Maine	Hikma Pharmaceuticals USA Inc	MF 30002024	Manufacturer	5/4/2022	12/31/2022	Active
Idaho	Hikma Pharmaceuticals USA Inc	OSF66405	Outsourcing Drug Outlet (Non-Resident)	5/9/2022	12/31/2022	Active
West Virginia	Hikma Pharmaceuticals USA Inc	MR0552340	Manufacturer	5/9/2022	6/30/2024	Active
Arizona	Hikma Pharmaceuticals USA Inc	M001941	Manufacturer	4/13/2022	10/31/2023	Active
Washington DC	Hikma Pharmaceuticals USA Inc	CF2200020	Non-Resident Manufacturer Controlled Susbstance Registration	5/16/2022	5/16/2024	Active
Washington DC	Hikma Pharmaceuticals USA Inc	DM2200077	Non-Resident Manufacturer	5/16/2022	5/31/2023	Active

Details for Hikma Pharmaceuticals USA Inc

License Information

Name:	Hikma Pharmaceuticals USA Inc
City, State, Zip, Country:	Cherry Hill NJ 08003 United States
Profession:	Pharmacy
License Type:	Pharmacy - Class C
License Number:	12907187-1710
Obtained By:	Application
License Status:	Active
Original Issue Date:	07/15/2022
Expiration Date:	09/30/2023
Agency and Disciplinary Action*:	NO DISCIPLINARY ACTIONS OR NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107
Docket and Citation Number(s):	N/A
E-Prescriber:	
Specialty(s):	
Manufacturer, Distributor	
Controlled Substance License(s) 12907187-8913	View Controlled Substance License

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*NOTE: The disciplinary documents linked to this website include final orders issued by DOPL, with the exception of citations. Click here for citations.

Details for Hikma Pharmaceuticals USA Inc

License Information

Name:	Hikma Pharmaceuticals USA Inc
City, State, Zip, Country:	Cherry Hill NJ 08003 United States
Profession:	Pharmacy
License Type:	Dispensing Controlled Substance License
License Number:	12907187-8913
Obtained By:	Application
License Status:	Active
Original Issue Date:	07/15/2022
Expiration Date:	09/30/2023
Agency and Disciplinary Action*:	NO DISCIPLINARY ACTIONS OR NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107
Docket and Citation Number(s):	N/A
E-Prescriber:	

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STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

HIKMA PHARMACEUTICALS USA INC.
0100487525

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign For-Profit Corporation was registered by this office on June 20, 1991.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and registered office are:

C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 5th day of April, 2023

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6141926523

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp