

FILED	
Department of Business and Professional Regulation	
Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	11/4/2014
File #	2014-08494

**STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION**

**IN RE: PETITION FOR DECLARATORY
STATEMENT,**

DS 2014-141

HETERO USA, INC.

PETITIONER.

DECLARATORY STATEMENT

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "Department"), issues this Declaratory Statement in accordance with Section 120.565, Florida Statutes.

PRELIMINARY STATEMENT

On August 28, 2014, the Department received a document entitled, "Petition for Declaratory Statement before the Department of Business and Professional Regulation." The petition (Exhibit A) was filed on behalf of Hetero USA, Inc. (hereafter, "Hetero" or "Petitioner"). The Petition appeared to be both a Petition for Variance and Waiver and a Petition for Declaratory Statement. However, the Petition failed to meet the requirements for a petition for variance and waiver because it failed to cite a rule from which the Petitioner is seeking a variance or waiver, failed to state the specific facts that would justify a waiver or variance for the Petitioner, and failed to state the

reason why the variance or the waiver requested would serve the purposes of the underlying statute.

However, the Petition did comply with the requirements of Section 120.565, Florida Statutes, in that the Petition stated with particularity the Petitioner's set of circumstances and specified the statutory provision, rule, or order that the Petitioner believes may apply to the set of circumstances. Further, the Petition met the requirements of Rule 28-105.002, Florida Administrative Code, regarding petitions for declaratory statement.

Petitioner is seeking a declaratory statement regarding the applicability of Section 499.01(4)(a), Florida Statutes (2014), to Petitioner's facts.

The Department published notice of the Petition in the September 8, 2014, issue of the Florida Administrative Register.

On or about October 14, 2014, Petitioner supplemented the Petition with additional information relevant to the Petitioner's set of circumstances.

FINDINGS OF FACT

The following findings of fact are based on the information submitted by the Petitioner. The Department takes no position as to the accuracy of the facts, but merely accepts them as submitted for purposes of this Declaratory Statement.

1. Hetero is the U.S. affiliate of Hetero Drugs Limited (hereafter, "HDL") and Hetero Labs Limited (hereafter, "HLL"), manufacturers of prescription drug active pharmaceutical ingredient (hereafter, "API").

2. HDL and HLL manufacture API in Andhra Pradesh, India.

3. Hetero is the U.S.-based affiliate, and performs sales and arranges distributions as the importer of record for API from HDL and HLL to Florida resident prescription drug manufacturers for commercial manufacturing.

4. Hetero is licensed as a wholesale distributor by the New Jersey Department of Health, holding registration number 5004050.

5. HDL and HLL hold FDA establishment registrations.

6. Petitioner seeks a declaratory statement as to the applicability of Section 499.01(4)(a), Florida Statutes, which states:

499.01 Permits--.

* * *

(4)(a) A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1. Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2. Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. [emphasis supplied]

7. Petitioner submitted additional information as follows:

A. Petitioner asserts that the Florida manufacturer recipient of the API will use the API in preparing, processing, producing, or fabricating a prescription drug finished dosage form at the establishment.

B. Petitioner asserts that the API would be received under an approved or otherwise valid abbreviated new drug application.

C. Petitioner asserts that the API has not been withdrawn or removed from the market for public health reasons.

8. Petitioner requests a declaratory statement as to whether the sale and distribution of API by Hetero is exempt from the Florida non-resident manufacturer licensure requirements.

CONCLUSIONS OF LAW

9. The Department is the state agency charged with regulation of drugs, devices, and cosmetics, pursuant to Chapter 499, Florida Statutes.

10. The Department has jurisdiction to enter this order pursuant to Section 120.565, Florida Statutes, and Rule 28-105.003, Florida Administrative Code.

11. Section 120.565, Florida Statutes, provides:

120.565 Declaratory statement by agencies.—

(1) Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.

(2) The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances.

(3) The agency shall give notice of the filing of each petition in the next available issue of the Florida Administrative Weekly and transmit copies of each petition to the committee. The agency shall

issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Weekly. Agency disposition of petitions shall be final agency action.

12. Rule 28-105.003, Florida Administrative Code, provides:

28-105.003 Agency Disposition.

The agency may hold a hearing to consider a petition for declaratory statement. If the agency is headed by a collegial body, it shall take action on a petition for declaratory statement only at a duly noticed public meeting. The agency may rely on the statements of fact set out in the petition without taking any position with regard to the validity of the facts. Within 90 days of the filing of the petition, the agency shall render a final order denying the petition or issuing a declaratory statement.

13. The Petitioner is substantially affected by the statute cited in paragraph six above and has standing to seek a declaratory statement from the Department.

14. The Department is authorized to enforce the provisions of Chapter 499, Florida Statutes.

15. Section 499.01(4)(a), Florida Statutes, provides an exemption from licensure requirements for a wholesale distributor who is permitted as such by the jurisdiction from which prescription drug API is distributed, to allow the distributor to distribute API to a Florida manufacturer so long as the conditions set forth there in are met. According to Petitioner, the API will be distributed by Hetero from its permitted establishment in New Jersey, and sent to manufacturers in this state. The manufacturers will produce finished dosage form prescription drugs under an approved abbreviated new drug application. According to Petitioner, the application, active pharmaceutical ingredient, and finished dosage form have not been withdrawn or removed from the market in this country for public health reasons. Assuming the

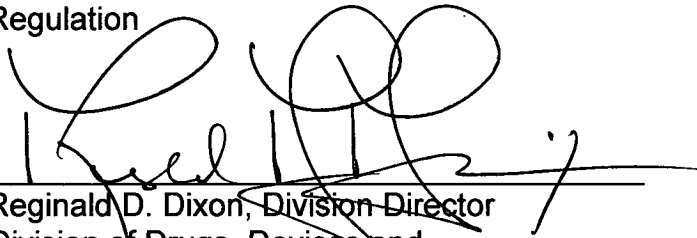
manufacturers and the distributor maintain records in accordance with current law, the Petitioner's facts meet the requirements of the exemption, and no permit under Chapter 499, Florida Statutes, is require for the activities described by Petitioner.

16. Accordingly, the Department declares that the Petitioner is not required to be permitted under Chapter 499, Florida Statutes, to engage in the distribution of API as set forth in the Petition.

Done and ordered this 3rd day of November, 2014, at Tallahassee, Leon County, Florida.

KEN LAWSON, SECRETARY
Department of Business & Professional
Regulation

BY:


Reginald D. Dixon, ~~Division Director~~
Division of Drugs, Devices and
Cosmetics
1940 North Monroe Street, Suite 26A
Tallahassee, FL 32399-1047
Telephone: (850) 717-1800
Facsimile: (850) 414-8240

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. mail to William Chelak, Director, Sales USA, Hetero USA, Inc., 1035 Centennial Avenue, Picataway, New Jersey, 08854, this 4th day of November, 2014.


for: Agency Clerk

NOTICE OF RIGHTS TO APPEAL

THIS FINAL ORDER CONSTITUTES FINAL AGENCY ACTION AND MAY BE APPEALED BY ANY PARTY ADVERSELY AFFECTED PURSUANT TO SECTION 120.68, FLORIDA STATUTES, AND RULE 9.110, FLORIDA RULES OF APPELLATE PROCEDURE, BY FILING A NOTICE OF APPEAL CONFORMING TO THE REQUIREMENT OF RULE 9.110(C), FLORIDA RULES OF APPELLATE PROCEDURE, BOTH WITH THE APPROPRIATE DISTRICT COURT OF APPEAL ACCOMPANIED BY THE APPROPRIATE FILING FEE AND WITH THE AGENCY CLERK, 1940 NORTH MONROE STREET, NORTHWOOD CENTRE, TALLAHASSEE, FLORIDA 32399-2217, WITHIN THIRTY DAYS OF RENDITION OF THIS FINAL ORDER.

Copies furnished to:

Reginald D. Dixon
DDC Division Director

Kathryn E. Price
DDC Chief Attorney





FILED
Department of Business and Professional Regulation
Deputy Agency Clerk
CLERK Brandon Nichols
Date **8/27/2014**
File #

RECEIVED

AUG 27 2014

**Petition for Declaratory Statement before the
Florida Department of Business and Professional Regulations**

Drugs, Devices and Cosmetics

Petitioner: Mr. William Chelak
Hetero USA, Inc.
1035 Centennial Avenue
Piscataway, NJ-00854
Tel: (732)529-0420
Fax: (732)562-8839
wchelak@heterousa.com

VW 2014-315

re: Petition for Waiver and Variance from Chapter 499.01 pursuant to the requirements of 499.01(4)(a) of the Florida Statutes

Hetero USA, Inc. ("Hetero USA") is requesting a waiver from the licensing requirements for a nonresident manufacturer. Hetero is the U.S. affiliate of Hetero Drugs Limited ("HDL") and Hetero Labs Limited ("HLL"), manufacturers of prescription active pharmaceutical ingredients ("API") in Andhra Pradesh, India. Hetero USA, as the U.S. based affiliate, performs sales and arrangements of distribution as the importer of record of API from HDL and HLL to Florida resident prescription drug manufacturers for commercial manufacturing. Hetero USA is properly licensed in its resident state with the New Jersey Department of Health, Registration No. 5004050 with an expiration of January 1, 2015 (see Attachment A).

HDL and HLL maintain a current and valid FDA Establishment Registration (see Attachments B). Also attached is the most recent FDA Establishment Inspection Report for both facilities (Attachment C and D).

Based on the exemption of API distribution under Chapter 499.01(4)(a), Hetero USA request that the Department of Business and Professional Regulation declare the sale and distribution of API as exempt from the Florida nonresident manufacturer licensing requirements.

Respectfully submitted the 26th day of August, 2014.

William Chelak | Director, Sales US

EXHIBIT A



**NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369
DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION**

0713685

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of \$20.00 shall accompany such notification."

Registered as: manufacturer wholesaler which conducts business at the following locations in this State:

1035 CENTENNIAL AVE PISCATAWAY, NJ 08554-

Reg. No. HETERO USA, INC
5004050 ATTN: SESHU S. AKULA
1035 CENTENNIAL AVE
PISCATAWAY, NJ 08854-

**ISSUED PURSUANT TO
N.J.S.A. 24:6B**

EXPIRES: January 31, 2015

Establishment Copy

FDA Home³ Drug Databases⁴ Drug Establishments Current Registration Site

Drug Establishments Current Registration Site

New Search

Search Results on hetero

Displaying records 1 to 7 of 7

 Download data

Firm Name	Facility Establishment Identifier	Data Universal Numbering System Number	Address	Expiration Date
Hetero Drugs Limited	3003510514	650433076	S. Nos. 213, 214 & 255, Bonthapally Village, Jinnaram Mandal, Medak District, Andhra Pradesh 502313, India (IND)	12/31/2014
Hetero Drugs Limited	3009225386	650531291	Unit IX, Plot No. 1, Hetero Infrastructure Ltd., - SEZ, N. Narasapuram, Nakkapally (Mandal), Visakhapatnam, Andhra Pradesh 531081, India (IND)	12/31/2014
Hetero Labs Limited	3005406526	676162024	Unit III, Plot No. 22-110, Part-II, IDA, Jeedimetta, Hyderabad, Andhra Pradesh 500055, India (IND)	12/31/2014
Hetero Labs Limited	3004378446	650435873	Survey No. 10, I.D.A., Gaddapolharam, Jinnaram Mandal, Medak District, Andhra Pradesh 502110, India (IND)	12/31/2014
Hetero Labs Limited	3008294355	650452548	Unit VI, (SEZ Unit II in APIIC SEZ), Polepally Village, Jadcherla Mandal, Mehboob Nagar, Andhra Pradesh 509301, India (IND)	12/31/2014
Hetero Labs Limited	3008307735	650452530	Unit V, (SEZ Unit I in APIIC SEZ), Polepally Village, Jadcherla Mandal, Mehboob Nagar, Andhra Pradesh 509301, India (IND)	12/31/2014
Hetero Labs Limited	3009093782	650563526	Unit IX, Plot No. 2, Hetero Infrastructure Ltd., - SEZ, N. Narasapuram, Nakkapally Mandal, Visakhapatnam, Andhra Pradesh 531081, India (IND)	12/31/2014

Data Current through: August 08, 2014

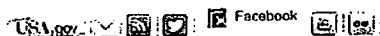
[Return to Drug Firm Annual Registration Status Home Page](#)

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2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/Drugs/InformationOnDrugs/default.htm>

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No Fear Act](#) [Site Map](#) [Transparency](#) [Website Policies](#)

U.S. Food and Drug Administration
 10903 New Hampshire Avenue
 Silver Spring, MD 20993
 Ph. 1-888-INFO-FDA (1-888-463-6332)
 Email FDA



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Division of Manufacturing and Product Quality
International Compliance Team
10903 New Hampshire Avenue
Building #51, Room 4219
Silver Spring, MD 20993

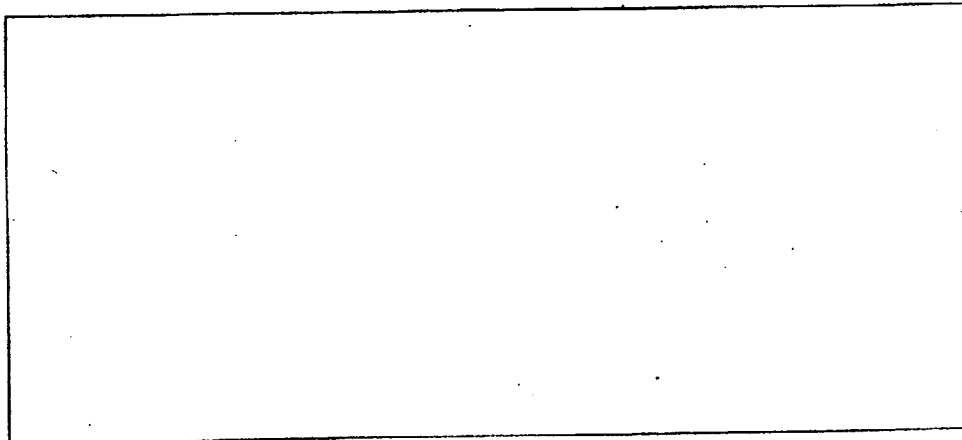
TELEPHONE: (301) 796-3194
FAX: (301) 847-8742

March 8, 2011

Dr. B.P.S. Reddy
Hetero Drugs Limited
Chairman and Managing Director
7-2-A2, Hetero Corporate, Industrial Estates
Sanath Nagar, Hyderabad
Andhra Pradesh, India
500 082

Dear Dr. Reddy:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your facility in Bonthapally Village, Medak District, India by Investigator Farhana Khan on November 8-11, 2010. Based on the profile class covered during the inspection, we are classifying your facility as acceptable.



Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom

of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian L. Belz", with a long horizontal flourish extending to the right.

Brian L. Belz
Compliance Officer
International Compliance Team

Enclosure: BIR



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality
Division International Drug Quality
International Compliance Branch
10903 New Hampshire Avenue
Building #51, Room 4234
Silver Spring, MD 20993

TELEPHONE: (301) 796-3206
FAX: (301) 847-8742

October 19, 2012

Dr. B.P.S. Reddy
Chairman and Managing Director
Hetero Labs Ltd.
No 8-3-166/7/1 Erragadda
Hyderabad 500018
India

Reference: FEI 3004378446

Dear Dr. Reddy:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your API manufacturing facility in Medak District, Andhra Pradesh, India by Investigator Sangeeta M. Khurana during the period of December 5 – 9, 2011.

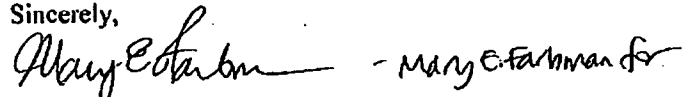
Based on the profile class covered during the inspection, we are classifying your facility as acceptable. This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practice (CGMP).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

 - Mary E. Farman for

Alicia Mozzachio
Branch Chief
Division of International Drug Quality

Enclosure: EIR

2

WILLIAN CHELAK
9174340797
HETERO USA
1035 CENTENNIAL AVE
PISCATAWAY NJ 08854

1.0 LBS LTR

1 OF 1

8/26/2014

SHIP TO:

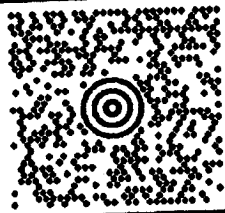
ATTN: CLERK'S OFFICE
DIV OF DRUGS, DEVICES & COSMETICS
1940 N. MONROE STREET SUITE 157A

TALLAHASSEE FL 32399-0500

RECEIVED

AUG 27 2014

Drugs, Devices and Cosmetics



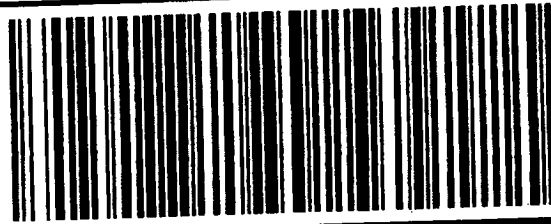
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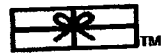
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CS 16.6.05. WNTINV50 54.0A 07/2014



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