STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULAT
DIVISION OF DRUGS, DEVICES, AND COSMETICS

IN RE: PETITION FOR DECLARATORY STATEMENT,

DS 2018-005

SPECTRUM CHEMICAL MANUFACTURING CORP.,

PETITIONER.
_____/

DS 2018-005

DECLARATORY STATEMENT

The Department of Business and Professional Regulation, Division of Drugs, Devices, and Cosmetics ("Department"), issues this Declaratory Statement.

PRELIMINARY STATEMENT

On January 26, 2018, the Department received a petition for declaratory statement (Exhibit A) filed by Ioana Maties, Compliance Manager, Spectrum Chemical Manufacturing Corp., 14422 South San Pedro Street, Gardena, California 90248 (hereafter, "Spectrum" or, "Petitioner"). Spectrum holds two permits with the Department, as further discussed below. Petitioner is seeking a declaratory statement regarding whether one of its Florida customers must possess a prescription drug permit in order to purchase and possess an active pharmaceutical ingredient (hereafter, "API") labeled, "Rx only," (prescription only) distributed by Spectrum, that will be incorporated into the customer's cosmetic and/or over-the-counter (hereafter, "OTC") drug products.

The Department published notice of the petition for declaratory statement in the January 30, 2018, issue of the Florida Administrative Register, volume 44/20.

FINDINGS OF FACT

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

1. Spectrum holds out-of-state prescription drug wholesale distributor permit number 23:2512 at the address of 755-769-777 Jersey Avenue, New Brunswick, New Jersey 08901-3605, and out-of-state prescription drug wholesale distributor permit number 23:2460, at 14422 South San Pedro Street, Gardena, California 90248.

2. Spectrum distributes the bulk API, adenosine. The label on the product states:

> **"CAUTION**: For manufacturing, processing, repacking, or for prescription compounding. Rx Only."

3. Cofran International Corp., 1500 NW 94th Avenue, Miami, Florida 33172 (hereafter, "Cofran"), holds cosmetics manufacturer permit number 06:101. Cofran also holds permit number 21:755, as an OTC drug manufacturer at the same address.

4. Cofran is Spectrum's customer awaiting an order of adenosine.

5. Cofran intends to use the bulk API adenosine that it receives from Spectrum in its cosmetics and/or OTC drug manufacturing process.

6. Spectrum is unsure as to whether it can distribute the adenosine to Cofran since Cofran does not have a permit as a prescription drug wholesale distributor.

7. Spectrum states:

> After reading what a Prescription drug manufacturer is, and more importantly what a prescription drug is, and since my customer in Florida uses Adenosine in a cosmetic product, as wrinkle relaxer (concentration 0.05%) that does not require prescription, it is my conclusion that the OTC and cosmetic permits are adequate and a prescription drug permit is not required on a bulk package of an API labeled RX only because it is not in finished form.

8. In accordance with Sections 499.03, 499.005(15), and 499.01(2)(f), Florida Statutes (2017), an out-of-state prescription drug wholesale distributor such as Spectrum can only distribute prescription drugs into this state to persons holding a valid license or permit or other authorization to receive prescription drugs, including prescription drug API.

9. Spectrum requests a declaratory statement as to whether, pursuant to Section 499.003(40), Florida Statutes (2017):

> A cosmetic company/OTC manufacturer (Cofran International Corp., 1500 N.W. 94th Avenue, Miami, FL 33172) in Florida that possesses an OTC (21755) and Cosmetic permit (06101) would also require a prescription drug permit for an API labeled RX only (Adenosine USP-see label attached) that will be incorporated into a cosmetic product that does not require prescription.

10. Essentially, Spectrum is asking whether, pursuant to Chapter 499, Florida Statutes, it can distribute adensosine API labeled "Rx only" to Cofran, in light of Cofran's current permits, or whether its customer would need the prescription drug wholesale distributor permit in order to receive adenosine API labeled "Rx only" from Spectrum.

CONCLUSIONS OF LAW

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

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

13. Section 120.565, Florida Statutes (2017), 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 Register 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 Register. Agency disposition of petitions shall be final agency action.

14. 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.

15. Declaratory statements are issued based on facts presented by the Petitioning party. In accordance with Rule 28-105.003, Florida Administrative Code, 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.

16. An out-of-state prescription drug wholesale distributor such as Spectrum would be subject to discipline if it distributed a prescription drug to a person in Florida who is not authorized to receive the drug.

17. Spectrum is substantially affected by the Department's statutes, rules, or orders.

18. Adenosine API is a ribonucleoside comprised of adenine bound to ribose, with vasodilatory, antiarrhythmic, and analgesic activities.

19. Spectrum specifically states that the bulk adenosine API that it wishes to distribute to Cofran is labeled, "Rx only."

20. Under Section 499.007(14), Florida Statutes (2017), a drug is misbranded if it is a prescription drug that does not bear one of these statements, (a) "Caution: Federal Law Prohibits Dispensing Without Prescription"; (b) "Rx Only"; (c) The prescription symbol followed by the word, "Only"; or (d) "Caution: State Law Prohibits Dispensing Without Prescription." Likewise, under Section 499.007(15), Florida Statutes (2017), a drug is misbranded if it is not a prescription drug and it bears any of the statements cited above.

21. The Department is not required to determine whether the API adenosine is misbranded, but rather, may rely on the facts stated by Petitioner, that the adenosine is labeled "Rx Only," without taking a position as to the accuracy of the facts.

22. Accordingly, for purposes of this declaratory statement, the bulk adenosine API is prescription only.

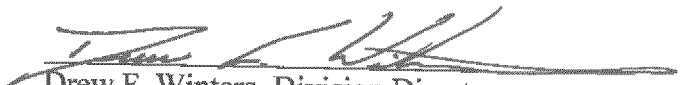
23. Petitioner asks whether the adenosine described in the Petition can be distributed to a person holding a cosmetics manufacturer and an OTC drug manufacturer permit. Section 499.03, Florida Statutes, prohibits the possession of a prescription drug(s) by any person without a prescription or without one of the permits issued under Chapter 499, Florida Statutes, or any other statute that authorizes the possession of prescription drugs. The provision includes certain exceptions, none of which are applicable on these facts. The cosmetics manufacturer licensure provisions, Sections 499.01(1)(p) and (2)(p), Florida Statutes (2017), read together with Section 499.03, Florida Statutes, do not authorize persons holding a cosmetics manufacturer permit to possess or purchase prescription drugs. Likewise, Section 499.01(2)(n)1., Florida Statutes (2017), the OTC manufacturer licensure provision, specifically states that an OTC drug manufacturer may not possess or purchase prescription drugs.

24. Based on the foregoing, the Department answers the Petitioner's question as follows:

> Q: Whether a cosmetic company/OTC manufacturer (Cofran International Corp., 1500 N.W. 94th Avenue, Miami, FL 33172) in Florida that possesses an OTC (21755) and Cosmetic permit (06101) would also require a prescription drug permit for an API labeled RX only (Adenosine USP-see label attached) that will be incorporated into a cosmetic product that does not require prescription.
>
> A: Yes. Based on the facts as presented in the petition, a cosmetic manufacturer and an OTC drug manufacturer (Cofran) would also require a prescription drug wholesale distributor permit in order to receive and possess adenosine API labeled "Rx only" that will be incorporated into an OTC or a cosmetic product that does not require a prescription.

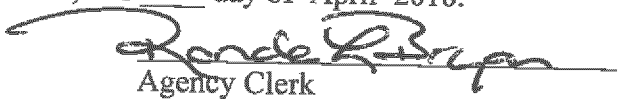
Done and ordered this 25th day of April 2018, at Tallahassee, Leon County, Florida.

JONATHAN ZACHEM, SECRETARY
Department of Business and Professional Regulation

BY: 
Drew F. Winters, Division Director
Division of Drugs, Devices & Cosmetics
2601 Blair Stone Road
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 electronic mail to Ioana Maties, Compliance Manager, Spectrum Chemical Manufacturing. Corp., Imaties@spectrumchemical.com, this 25 day of April 2018.


Agency Clerk

Copies furnished to:
Drew F. Winters
DDC Division Director

Kathryn E. Price
DDC Chief Attorney

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 REQUIREMENTS 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, 2601 BLAIR STONE ROAD, TALLAHASSEE, FLORIDA 32399-2217, WITHIN THIRTY DAYS OF RENDITION OF THIS FINAL ORDER.

spectrum®
CHEMICAL MFG CORP

DS 2018-005

DECLARATORY STATEMENT REQUEST

January 26, 2018

Division of Drugs, Devices and Cosmetics
2601 Blair Stone Road
Tallahassee, FL 32399-1047

Re: Declaratory Statement Request, pursuant to FL Status Chapter 499, in accordance to rules set forth by section 120.565.

Dear Sirs,

I seek clarification on whether a Cosmetic Company/OTC manufacturer (Cofran International Corp., 1500 N.W. 94th Ave., Miami FL 33172) in Florida that possesses an OTC (21755) and Cosmetic permit (06101) would also require a prescription drug permit for an API labeled RX only (Adenosine USP – see label attached), that will be incorporated into a cosmetic product that does not require prescription. Adenosine is a prescription API but it is also a cosmetic ingredient used as wrinkle relaxer. Per FDA it is the responsibility of cosmetic manufacturers to ensure, before marketing their products, that the products are safe when used as directed in their label or under customary conditions of use.

After reading what a Prescription drug manufacturer is, and more importantly what a prescription drug is, and since my customer in Florida uses Adenosine in a cosmetic product, as wrinkle relaxer (concentration 0.05%) that does not require prescription, it is my conclusion that the OTC and Cosmetic permits are adequate and a Prescription drug permit is not required on a bulk package of an API labeled RX only because it is not in finished form.

"499.003 Definitions of terms used in this part.—As used in this part, the term:

(40) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the federal act or s. 465.003(8), s. 499.007(13), subsection (31), or subsection (47), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs."

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843
www.spectrumchemical.com

EXHIBIT A

spectrum®
CHEMICAL MFG CORP

My company has two Out of State Prescription Drug Wholesale Distributor permits for Spectrum Laboratory Products, Inc., New Brunswick NJ (232512) and Gardena CA 90248 (232460).

I ask for an expedited review as I am holding open orders. I would like to thank you in advance for your prompt attention to this matter and I can be reached at tbhagat@spectrumchemical.com, or 310-359-8216.

Regards,

Ioana Maties
Compliance Manager
Spectrum Chemical Mfg. Corp.
14422 S. San Pedro St. Gardena CA 90248
1-310-516-8000 ext 5601
imaties@spectrumchemical.com
www.SpectrumChemical.com

Exp. Date: 00-00-0000

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spectrum®
CHEMICAL MFG CORP

A2183 **1 KG**

Adenosine

(6-Amino-9-β-D-ribofuranosyl-9H-purine)

U.S.P.

CAS 58-61-7

$C_{10}H_{13}N_5O_4$ F.W. 267.25

Assay (Dried Basis)	98.0-102.0%
Specific Rotation	-68.0° to -72.0°
MAXIMUM LIMITS	
Loss on Drying	0.5%
Residue on Ignition	0.1%
Heavy Metals	10 ppm
Organic Impurities	To pass test
Residual Solvents	To pass test

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

KEEP FROM CHILDREN

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers at controlled room temperature.

G 6/D5GHS ? Lot No. XQ####

SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901