

## INTERNATIONAL TRADE COMMISSION

[Docket No. 2912]

### Certain Reduced Folate; Nutraceutical Products and L-Methylfolate Raw Ingredients Used Therein; Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled Certain Reduced Folate Nutraceutical Products and L-methylfolate Raw Ingredients Used Therein, DN 2912; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

**FOR FURTHER INFORMATION CONTACT:** Lisa R. Barton, Acting Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>, and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000.

General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <http://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of South Alabama Medical Science Foundation; Merck & Cie, and PamLab LLC on September 10, 2012. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after

importation of certain reduced folate nutraceutical products and L-methylfolate raw ingredients used therein. The complaint names as respondents Gnosis SpA of Italy; Gnosis Bioresearch SA of Switzerland; Gnosis USA Inc. of PA; and Macoven Pharmaceuticals LLC of TX.

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR

210.4(f)). Submissions should refer to the docket number ("Docket No. 2912") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf)). Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: September 11, 2012.

**Lisa R. Barton,**

*Acting Secretary to the Commission.*

[FR Doc. 2012-22758 Filed 9-14-12; 8:45 am]

**BILLING CODE 7020-02-P**

## INTERNATIONAL TRADE COMMISSION

[USITC SE-12-026]

### Government in the Sunshine Act Meeting Notice

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** September 19, 2012 at 1 p.m.

**PLACE:** Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205-2000.

**STATUS:** Open to the public.

### MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes
3. Ratification List
4. Vote in Inv. No. 731-TA-1104 (Review) (Polyester Staple Fiber from China). The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before September 28, 2012.

5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.  
Issued: September 12, 2012.

**William R. Bishop,**

*Hearings and Meetings Coordinator.*

[FR Doc. 2012-22958 Filed 9-13-12; 4:15 pm]

**BILLING CODE 7020-02-P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 12-31]

#### Cleveland J. Enmon, Jr., M.D.; Decision and Order

On April 26, 2012, Administrative Law Judge Gail A. Randall (ALJ) issued the attached recommended decision. Neither party filed exceptions to the decision.

Having reviewed the entire record in this matter, I have decided to adopt the ALJ's recommended rulings, findings of fact,<sup>1</sup> conclusions of law, and recommended order. Accordingly, I will order that Respondent's registration be revoked and that his pending application to renew and modify his registration be denied.

<sup>1</sup> The ALJ made several factual findings based on the statements made to a Special Agent by two employees of the Brunswick Wellness Center (BWC) during the execution of a search warrant, as well as statements made during interviews the Special Agent conducted of several patients of Respondent's subsequent clinic. See ALJ Slip Op. at 7 (statements of BWC employees that clinic lacked basic medical equipment and attracted patients from out-of state who did not appear to be in pain), *id.* at 9-10 (statement of Ocean Care patient that he obtained controlled substances from Respondent in order to sell them on the street and that Respondent did not perform a physical examination and increased prescription upon request). While the ALJ found the Special Agent's testimony credible, as do I, the ALJ did not apply the factors for assessing the reliability of the underlying hearsay statements as set forth in the case law of either the Eleventh or DC Circuits. See *Basco v. Machin*, 514 F.3d 1177, 1182 (11th Cir. 2008); *J.A.M. Builders v. Herman*, 233 F.3d 1350, 1354 (11th Cir. 2000); *Hoska v. United States Dep't of the Army*, 677 F.2d 131, 138 (DC Cir. 1982). However, I conclude that this does not constitute prejudicial error because the ALJ's legal conclusions are amply supported by substantial evidence, including the uncontroverted testimony of the Government's Expert, and the ALJ did not cite these statements as support for her conclusion that Respondent repeatedly prescribed controlled substances without a legitimate medical purpose and outside the course of professional practice in violation of both federal and state law. See ALJ Slip Op. at 38-44 (citing 21 CFR 1306.04(a) and Ga. Code Ann. 16-13-41(f)).

### Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. BE9655284, issued to Cleveland J. Enmon, Jr., M.D., be, and it hereby is, revoked. I further order that the pending application of Cleveland J. Enmon, Jr., M.D., to renew and modify his registration, be, and it hereby is, denied. This Order is effective immediately.<sup>2</sup>

Dated: August 31, 2012.

**Michele M. Leonhart,**

*Administrator.*

*Brian Bayly, Esq.,* for the Government

*Cleveland J. Enmon, Jr., M.D.,* for the Respondent

### RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Gail A. Randall, Administrative Law Judge.

#### I. PROCEDURAL BACKGROUND

The Administrator of the Drug Enforcement Administration ("DEA" or "Government"), issued an Order to Show Cause and Immediate Suspension of Registration ("Order") dated January 10, 2012, immediately suspending the DEA Certificate of Registration, No. BE9655284, of Cleveland J. Enmon, Jr., M.D. ("Respondent"), pursuant to 21 U.S.C. 824(d), and proposing to revoke his DEA Certificate of Registration as a practitioner, pursuant to 21 U.S.C. 824(a)(4), and to deny any pending applications for renewal of such registration, pursuant to 21 U.S.C. 823(f), because the continued registration of the Respondent would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f). [Administrative Law Judge Exhibit ("ALJ Exh.") 1 at 1].

The Order stated that Respondent is registered with the DEA as a practitioner with authority to handle controlled substances in Schedules II-V, and that his registration expired by its terms on August 31, 2011. [*Id.*]. The Order further stated that although Respondent submitted a timely renewal application, which would have allowed him to lawfully handle controlled substances under 5 U.S.C. 558(c) (2006), his current practice location is not at his DEA registered address because he abandoned that location. Therefore, he is not permitted to issue controlled substances from his current practice location. [*Id.*].

The Order alleged that Respondent issued controlled substances prescriptions from locations in Brunswick, Georgia and Jesup, Georgia, without obtaining permission from the Government to change his DEA registered address to either of these locations. [*Id.* at 2].

<sup>2</sup> For the same reasons that I concluded that Respondent's conduct posed an imminent danger to public health and safety and warranted the Immediate Suspension of his registration, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

Next, the Order alleged that Respondent had prescribed oxycodone and hydrocodone to at least nineteen patients with no or insufficient medical history, with no relevant physical examinations, without diagnosing any medical conditions warranting such medications and without monitoring the patients to determine if the patients were diverting the controlled substances. [*Id.*]. The Order also asserted that Respondent had prescribed alprazolam to eighteen of these patients with no diagnosis or other justification except for checking a boilerplate form marked "anxiety" in the patient file. [*Id.*].

Lastly, the Order alleged that Respondent prescribed two hundred and thirty dosage units of oxycodone to patient, M.B.S. based on a diagnosis with no documentation. [*Id.*]. The Order alleged that this patient was admitted to a local hospital emergency room and that the hospital subsequently determined that the patient was opiate dependent and needed detoxification treatment. [*Id.*]. Further, the Order alleged that on October 11, 2011, the Respondent prescribed the same patient sixty dosage units of alprazolam without documenting any findings of anxiety symptoms in the patient's file. [*Id.*].

The Administrator then gave the Respondent the opportunity to show cause as to why his registration should not be revoked on the basis of those allegations. [*Id.* at 3].

On February 3, 2012, Respondent filed a request for a hearing in the above-captioned matter. [ALJ Exh. 3].

On March 1, 2012, a Protective Order was issued to protect patient names and medical files used in this proceeding. [ALJ Exh. 6].

The hearing was conducted on March 6-7, 2012, in Beaufort, South Carolina. [ALJ Exh. 5]. At the hearing, counsel for the DEA called three witnesses to testify and introduced documentary evidence. [Transcript ("Tr.") Volume I-II]. The Respondent called one witness to testify and testified on behalf of himself. [*Id.*].

After the hearing, the Government submitted Proposed Findings of Fact, Conclusions of Law and Argument ("Govt. Brief"). The Respondent did not submit a post-hearing brief.

#### II. ISSUE

The issue in this proceeding is whether or not the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration should revoke the DEA Certificate of Registration Number BE9655284 of Cleveland J. Enmon, Jr., M.D., as a practitioner, pursuant to 21 U.S.C. 824(a) (2006), and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. 823(f), because his continued registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f). [Tr. 5; ALJ Exh. 4].

#### III. FINDINGS OF FACT

##### A. Dr. Enmon's Registration History

The Agency first issued a certificate of registration as a practitioner to Dr. Enmon on March 9, 2006. [Govt. Exh. 3 at 4]. On September 4, 2008, Dr. Enmon requested to