

Issued: March 16, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021-05836 Filed 3-19-21; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

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 Skin Rejuvenation Devices, Components Thereof, and Products Containing the Same, DN 3538*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, 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 Document Information System (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov.

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at <https://www.usitc.gov>. The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at <https://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 § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of InMode Ltd. and Invasix Inc. d/b/a InMode on March 16, 2021. 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 skin rejuvenation devices, components thereof, and products

containing the same. The complainant names as respondents: ILOODA Co., Ltd. of Korea; and Cutera, Inc. of Brisbane, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 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 on the public interest 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. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions

were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number ("Docket No. 3538") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures¹). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, <https://edis.usitc.gov>.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at EDIS3Help@usitc.gov.

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 information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,² solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.³

By order of the Commission.

¹ Handbook for Electronic Filing Procedures: https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.

² All contract personnel will sign appropriate nondisclosure agreements.

³ Electronic Document Information System (EDIS): <https://edis.usitc.gov>

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Secretary to the Commission.

[FR Doc. 2021-05867 Filed 3-19-21; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Lawrence E. Stewart; Decision and Order

On June 12, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Lawrence E. Stewart, M.D. (hereinafter, Respondent), of Summit, Mississippi. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the denial of Respondent's application for a DEA Certificate of Registration because Respondent had committed acts that rendered his registration with DEA inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(f) and 824(a)(2), (4)).

On July 27, 2017, Respondent submitted a timely written statement in response to the OSC waiving his right to a hearing. Request for Final Agency Action Exhibit (hereinafter, RFAAX) 3. In lieu of a hearing, Respondent submitted a Statement of Position on the Facts and Law (hereinafter, Statement) regarding the matters alleged in the OSC. *Id.*

The Government filed a Request for Final Agency Action (hereinafter, RFAA) on March 25, 2019. In its RFAA, the Government stated that Respondent is no longer licensed to practice medicine in Mississippi and provided documentation from the Mississippi State Board of Medical Licensure to support this claim. RFAA at 2; see RFAAX 7, Appendices A–C. The Government then requested that I deny Respondent's application for a DEA registration on the grounds that Respondent lacks authority to handle controlled substances in the State of Mississippi, the state where he seeks a DEA registration. RFAA at 5–6. The Government had not alleged that Respondent lacked state authority in the OSC. OSC at 2.

The Government is not required to issue an amended OSC to notice an allegation of a registrant's lack of state authority that arises during the pendency of a proceeding regarding a DEA registration. *Hatem M. Ataya, M.D.*, 81 FR 8221, 8244 (2016). Previous Agency decisions have stated that because the possession of state authority

is a prerequisite for obtaining and maintaining a registration, the issue of state authority can be raised at any stage of a proceeding, even *sua sponte* by the Administrator. See *Ataya*, 81 FR at 8244; *Joe M. Morgan, D.O.*, 78 FR 61,961, 61,973–74 (2013). I issued an Order on February 3, 2021, providing Respondent with notice of the Government's allegation that he currently lacks state authority to handle controlled substances in the State of Mississippi, and providing him with the opportunity to show the contrary. Respondent submitted a response to the Order on February 4, 2021, stating "I am not currently licensed to practice medicine."

I make the following findings of fact based on the record before me.

Findings of Fact

Respondent's Application for a DEA Registration

On January 25, 2017, Respondent filed an application (Application Control No. H17068500C) for a DEA Certificate of Registration as a practitioner in schedules II–V, with a proposed registered location at 1050 Daisy Lane, Summit, Mississippi 39666. RFAAX 1.

The Status of Respondent's State License

At the time Respondent applied for a DEA registration, he held a Mississippi medical license. RFAAX 7, Appendix A (Mississippi State Board of Medical Licensure Determination and Order). On May 18, 2017, the Mississippi State Board of Medical Licensure (hereinafter, the Board) issued a Decision and Order suspending Respondent's medical license. *Id.* The Board suspended Respondent's license after finding him guilty of (1) having been convicted of violating a federal law regulating the distribution of a narcotic drug; (2) prescribing a drug having addiction forming or addiction sustaining liability otherwise than in the course of legitimate professional practice; and (3) unprofessional conduct. *Id.* The Decision and Order stayed Respondent's suspension contingent on his completion of certain requirements, including compliance with the Mississippi Professional Health Program (hereinafter, MPHP). *Id.* at 3–4.

On March 19, 2018, the Board found that Respondent had failed to comply with an MPHP requirement to abstain from alcohol. RFAAX 7, Appendix B (Board Order of Prohibition). The Board, therefore, issued an Order of Prohibition prohibiting Respondent from practicing medicine in Mississippi "until such

time as the Board and MPHP determines that [Respondent] is able to return to the practice of medicine." *Id.*

According to Mississippi's online records, of which I take official notice, Respondent's license is expired.¹ Mississippi State Board of Medical Licensure, Licensee Lookup, <https://gateway.msbml.ms.gov/verification/search.aspx> (last visited date of signature of this Order). Respondent also confirmed in response to my Order that, as of February 4, 2021, he was not licensed to practice medicine.

Accordingly, I find that Registrant currently is not licensed to engage in the practice of medicine in Mississippi, the State in which Registrant is registered with the DEA.

Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) "upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. See, e.g., *James L. Hooper, M.D.*, 76 FR 71,371 (2011), *pet. for rev. denied*, 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term "practitioner" to mean "a physician . . . or other person licensed, registered, or otherwise

¹ Under the Administrative Procedure Act, an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), "[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary." Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (dea.addo.attorneys@dea.usdoj.gov).