

plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “skin resurfacing devices, punctile resurfacing systems, radio-frequency microneedling systems, and components of each”;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

InMode Ltd., Tavor Building Shaar
Yokneam, P.O. Box 533, Yokneam
2069206, Israel

Invasix Inc. d/b/a InMode, 20996 Bake
Parkway, Suite 106, Lake Forest, CA
92630

(b) The respondents are the following entities alleged to be in violation of section 337, and the parties upon which the complaint is to be served:

ILOODA Co., Ltd., 120 Jangan-ro
458beon-gil, Jangan-gu Suwon, 16200,
Republic of Korea

Cutera, Inc., 3240 Bayshore Boulevard,
Brisbane, CA 94005

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations is not a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the

issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: April 15, 2021.

Lisa Barton

Secretary to the Commission.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-823]

Bulk Manufacturer of Controlled Substances Application: Research Triangle Institute

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of application.

SUMMARY: Research Triangle Institute, has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before June 21, 2021. Such persons may also file a written request for a hearing on the application on or before June 21, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on March 18, 2021, Research Triangle Institute, 3040 East Cornwallis Road, Hermann Building, Room 106, Research Triangle Park, North Carolina 27709, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I

The company plans to bulk manufacture the listed controlled substance synthetically only for distribution to its customers for research and analytical reference standards. No

other activity for this drug code is authorized for this registration.

William T. McDermott,

Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17-11]

Mark A. Wimbley, M.D.; Decision and Order

I. Procedural History

On October 20, 2016, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Mark A. Wimbley, M.D. (hereinafter, Respondent), of Costa Mesa, California. Administrative Law Judge (hereinafter, ALJ) Exhibit (hereinafter, ALJX) 1, (OSC) at 1. The OSC proposed the revocation of and denial of any pending application to modify or renew Respondent's Certificate of Registration No. BW5359004 pursuant to 21 U.S.C. 823(f) and 824(a)(4) for the reason that “[his] continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).” *Id.*

The OSC alleged that Respondent issued prescriptions for controlled substances to four¹ individuals outside the usual course of the professional practice in violation of 21 CFR 1306.04(a) and in violation of California law and the minimum standards of medical practice in California. *Id.* at 2–8. Specifically, the OSC alleged that Respondent “issued these orders for controlled substances without meeting the minimal medical standards required under California law, including those listed in the ‘Guide to the Laws Governing the Practice of Medicine by Physicians and Surgeons,’ Medical Board of California, 7th Ed. 2013.” *Id.* at 7. Additionally, the OSC alleged that for the four listed patients, Respondent failed to do one or more of the following:

perform a physical examination; take appropriate medical history; assess pain, physical and psychological function; make an assessment of any underlying or coexisting diseases or conditions; confirm the patient was taking previously prescribed

¹ The Government withdrew allegations related to one of the patients in its Supplemental Prehearing Statement, so this matter is limited to three patients. ALJX 7, 7–8.