

Rules of Practice and Procedure (19 CFR 210.8(b)).

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 EDIS,¹ 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 at United States International Trade Commission (USITC) at USITC.² The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.³ 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 ResMed Corp; ResMed Inc. and ResMed Ltd. on April 14, 2016. 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 sleep-disordered breathing treatment systems and components thereof. The complaint names as respondents BMC Medical Co., Ltd. of China; 3B Medical, Inc. of Lake Wales, FL; and 3B Products, L.L.C. of Lake Wales, FL. 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, 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. 3140") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures⁴). 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.⁵

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: April 15, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016-09212 Filed 4-20-16; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Ibem R. Borges, M.D.; Decision and Order

On October 14, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Ibem R. Borges, M.D. (Respondent), of Orlando, Florida. GX 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration BB3166053, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, and the denial of any application to renew or modify this registration, as well as any application for any other DEA registration, on the ground that Respondent does "not have authority to handle controlled substances in Florida, the State in which [he is] registered with the DEA." *Id.* at 1.

The Show Cause Order specifically alleged that effective November 8, 2013, the Florida Department of Health issued an "Order of Emergency Restriction of License" to Respondent, which prohibits him from prescribing controlled substances in schedules II through IV. *Id.* The Show Cause Order also alleged that Respondent "do[es] not have a Florida dispensing license, which is an additional license required [by the State] before a physician is authorized to order and directly

¹ Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

² United States International Trade Commission (USITC): <http://edis.usitc.gov>.

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

⁴ Handbook for Electronic Filing Procedures: http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.

⁵ Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

dispense or administer controlled substances.” *Id.* The Show Cause Order thus alleged that Respondent “do[es] not have authority in Florida to order, dispense, prescribe or administer any controlled substances in Schedules II through IV,” and that the Agency “must revoke [his] DEA registrations [sic] based upon [his] lack of authority to handle controlled substances in the State of Florida for Schedules II through IV.” *Id.* (citing 21 U.S.C. 802(21), 823(f) and 824(a)(3)).

The Show Cause Order also notified Respondent of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43).

On October 22, 2015, a DEA Diversion Investigator (DI) served the Order to Show Cause by certified mail, return receipt requested, addressed to Respondent at his personal residence. GX 3, at 1 (Declaration of DI). On November 6, 2015, the DI received back the USPS return receipt card; however, while the card bore Respondent’s signature, it was dated “2/29/15.” *Id.*; see also GX 4, at 1. The DI then obtained the USPS tracking record for the delivery, which revealed that the Show Cause Order was delivered on October 29, 2015. GX 3, at 1; GX 4, at 2.

On November 9, 2015, the DEA Office of Administrative Law Judges received a letter from an attorney stating that he represented Respondent; the letter was addressed to the Deputy Assistant Administrator, care of the Hearing Clerk, and used the mailing address of the Office of Administrative Law Judges. GXs 5 and 6. Thereafter, the Chief Administrative Law Judge (CALJ) sent a letter to Respondent’s attorney stating that because the latter had not requested a hearing, his Office was not authorized to take any further action. GX 6.

The Government subsequently filed a Request for Final Agency Action along with various documents submitted as the Investigative Record, including the letter from Respondent’s attorney. Based on Respondent’s failure to request a hearing in his letter, I find that Respondent has waived his right to a hearing on the allegations of the Show Cause Order. 21 CFR 1301.43(d). However, I have treated the letter of Respondent’s Counsel as his written statement of position and made it a part of the record. *Id.* § 1301.43(c). Having considered the entire record, I issue this Decision and Final Order, *id.* § 1301.43(e), and make the following findings of fact.

Findings

Respondent is the holder of DEA Certificate of Registration BB3166053, pursuant to which he is authorized to dispense controlled substances in schedules II through V, at the registered address of Pain Free Clinic & More, 1800 W. Oakridge Rd., Orlando, Florida. GX 2. Respondent’s registration does not expire until July 31, 2016. *Id.*

On November 8, 2013, the Florida Department of Health (DOH) issued an Order of Emergency Restriction of License (Order) to Respondent. The Order restricted Respondent’s medical license by prohibiting him from prescribing any medications listed in schedules II, III or IV, as set forth in section 893.03 of the Florida Statutes.¹ GX 8, at 28. In its Order, the DOH found that Respondent: (1) “prescribed, dispensed, administered, mixed or otherwise prepared a legend drug, other than in the course of his professional practice” to an undercover officer, by excessively and inappropriately prescribing controlled substances; (2) “failed to keep legible medical records that justifi[ed] the course of treatment of” the undercover officer, by “[f]ailing to document a complete medical history; and/or . . . [f]ailing to document a complete physical examination results”; and (3) “failed to comply with the applicable standards for the use of controlled substances for pain control.” GX 8, at 23–27 (citing Fla. Stat. §§ 458.331(1)(q); 458.331(1)(m); 458.331(1)(nn) (2012–2013); Fla. Admin. Code. r. 64B8–9.013(3)).

Under Florida law, physicians are required to be registered as “a dispensing practitioner” in order to directly dispense a controlled substance.² Fla. Stat. § 465.0276. The record includes a letter from the Florida Department of Health which states that Respondent is not registered as a dispensing practitioner. GX 9.

A review of the Department of Health Web site shows that while Respondent’s license is in an active status, the emergency prohibition against his prescribing of any medications listed in

¹ The factual basis of the DOH’s Order was Respondent’s prescribing of oxycodone 30 mg and morphine sulfate 30 mg to an undercover officer on multiple occasions, ignoring “the most basic standards for the use of controlled substances for the treatment of pain as directed by the Board of Medicine’s written standards found in Rule 64B8–9.013 [of] the Florida Administrative Code.” GX 8, at 18 (int. quotations omitted).

² This provision, however, prohibits even a properly registered practitioner from dispensing a schedule II or III controlled substance except for in limited situations. Fla. Stat. 465.027(1)(b).

schedules II, III, or IV of Fla. Stat. § 893.03 remains in effect.³

Based on the above, I find that the only authority Respondent currently possesses under Florida law is the authority to prescribe controlled substances in schedule V.

In his written statement of position, Respondent does not dispute this. Indeed, he “recognizes that his DEA registration for the prescription of [s]chedules II, III, and IV [c]ontrolled [s]ubstances is subject to revocation in the immediate future.” GX 5, at 1. However, he “reserves his right to prescribe [s]chedule V [c]ontrolled [s]ubstances.” *Id.* He further requests that he be “permitted to retain and renew his basic DEA registration and his ability to prescribe Class V pharmaceuticals as this would permit him to renew or expand the scope of his prescribing should he be acquitted of the pending criminal charges and otherwise fulfil [sic] the DEA requirements for registration.” GX 5, at 1.

In addition to the foregoing, I take official notice that court records from the Osceola County Circuit Court indicate that Respondent has been charged with racketeering, conspiracy to engage in racketeering, three counts of trafficking oxycodone, and manslaughter, and faces a jury trial on June 6, 2016.

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, “upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” Moreover, Congress has defined “the term ‘practitioner’ [to] mean[] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional

³ Under the Administrative Procedure Act (APA), an agency “may take official notice of facts at any stage in a proceeding—even in the final decision.” U.S. Dept. of Justice, *Attorney General’s Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA’s regulations, Respondent is “entitled on timely request to an opportunity to show to the contrary.” 5 U.S.C. 556(e); see also 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within ten calendar days of service of this order which shall commence on the date this order is mailed.

practice.” 21 U.S.C. 802(21). Likewise, the CSA conditions the granting of a practitioner’s application on his/her possession of authority to dispense controlled substances under state law. See 21 U.S.C. 823(f) (“The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.”). Of further note, the CSA defines the term “dispense” as meaning “to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner.” *Id.* § 802(10) (emphasis added).

Thus, the Agency has repeatedly 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*, 76 FR 71371 (2011), *pet. for rev. denied*, 481 Fed Appx. 826 (4th Cir. 2012). And because a practitioner’s authority under the CSA is based on his/her authority to dispense controlled substances under the laws of the State in which he practices, the Agency has further held that “to the extent a practitioner is not authorized under state law to dispense certain categories or schedules of controlled substances, he can no longer lawfully dispense them under federal law.” *Kenneth Harold Bull*, 78 FR 62666, 62672 (2013).

In *Bull*, a case in which the practitioner’s state board had prohibited him from prescribing narcotics, the Agency explained that “where a state board takes such action, at a minimum, a practitioner’s CSA registration must be limited to authorize the dispensing of only those controlled substances, which he can lawfully dispense under state law.” *Id.* at 62672. Here, the Florida Department of Health has suspended Respondent’s authority to prescribe any medications listed in schedules II, III, or IV of the Florida schedules of controlled substances, and under Florida law, Respondent is limited to prescribing only those controlled substances in schedule V.⁴ Accordingly, I will order

⁴ Have reviewed the schedules of controlled substances under Florida law, I conclude that they are coterminous with those of the CSA with the exception of buprenorphine, which under Florida law, is a schedule V controlled substance. While buprenorphine was formerly a schedule V drug under the CSA, in 2002, the drug was placed in schedule III following the Department of Health and Human Services’ reevaluation of the drug’s “abuse potential and dependence profile in light of numerous scientific studies and years of human experience with [the] drug.” *Schedules of*

that Respondent’s registration shall be restricted to prohibit him from dispensing controlled substances in schedules II through IV and to authorize only the prescribing of schedule V controlled substances.

The conduct giving rise to the criminal charges for racketeering activity, unlawful distribution of controlled prescription drugs, and manslaughter related to drug overdose deaths could serve as the basis for a request for total revocation based on public interest grounds (or, in the event of a conviction, based upon a conviction of a felony related to controlled substances). 21 U.S.C. 824(a)(2) and (4). The Order to Show Cause before me is based solely upon Respondent’s lack of state authority to handle certain controlled substances. This Order is constrained by the basis set forth in the Order to Show Cause, and I will only consider Respondent’s alleged criminal conduct if and when he is served with an Order to Show Cause why his registration should not be revoked in total based on public interest grounds, and he is given the opportunity to address that allegation.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BB3166053, issued to Ibem R. Borges, M.D., be, and it hereby is, restricted to prohibit the dispensing of controlled substance in schedules II through IV and to authorize only the prescribing of controlled substances in schedule V of the Controlled Substances Act (21 CFR 1308.15). This Order is effective immediately.

Controlled Substances: Rescheduling of Buprenorphine From Schedule V to Schedule III, 67 FR 62354 (2002) (final rule). Thus, this Agency has determined that the drug “has a potential for abuse less than the drugs or other substances in schedules I and II,” that it “has a currently accepted medical use in treatment in the United States,” and most importantly, that “[a]buse of the drug . . . may lead to moderate or low physical dependence or high psychological dependence.” 21 U.S.C. 812(b)(3); see also 67 FR at 62367.

Notably, Florida has adopted the same criteria for placing a drug in its schedule III as the CSA uses, see Fla. Stat. 893.03(3), and the State has determined that Respondent’s “continued, unrestricted practice of medicine poses an immediate serious danger to the public health, safety or welfare,” and concluded, *inter alia*, that he cannot safely prescribe controlled substances in schedule III. GX 8, at 20; see also *id.* at 28. I therefore hold that notwithstanding that buprenorphine remains a schedule V drug under Florida law and that the scope of his federal authority derives from his authority under state law, the placement of the drug in schedule III of the CSA precludes him from lawfully prescribing the drug under his DEA registration.

Dated: April 5, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–09274 Filed 4–20–16; 8:45 am]

BILLING CODE 4410–09–P

EXECUTIVE OFFICE OF THE PRESIDENT

Office of National Drug Control Policy

Designation of Two Counties as High Intensity Drug Trafficking Areas

AGENCY: Office of National Drug Control Policy, Executive Office of the President.

ACTION: Notice of HIDTA Designations.

SUMMARY: The Director of the Office of National Drug Control Policy designated two additional counties as High Intensity Drug Trafficking Areas (HIDTA) pursuant to 21 U.S.C. 1706. The new counties are Austin and Walker Counties in Texas as part of the Houston HIDTA.

FOR FURTHER INFORMATION CONTACT:

Questions regarding this notice should be directed to Michael K. Gottlieb, Associate Director, Programs Office, Office of National Drug Control Policy, Executive Office of the President, Washington, DC 20503; (202) 395–4868.

Dated: March 23, 2016.

Michael Passante,

Deputy General Counsel.

[FR Doc. 2016–09230 Filed 4–20–16; 8:45 am]

BILLING CODE 3280–F5–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by May 23, 2016. This