Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

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INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–585–586 and 731–TA–1383–1384 (Review)]

Stainless Steel Flanges From China and India; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping and countervailing duty orders on stainless steel flanges from China and India would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: August 4, 2023.

FOR FURTHER INFORMATION CONTACT: Nitin Joshi (202) 708–1669, Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On August 4, 2023, the Commission determined that the domestic interested party group response to its notice of institution (88 FR 26592, May 1, 2023) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the reviews has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for these reviews on September 19, 2023. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before September 27, 2023, and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by September 27, 2023. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: September 11, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–19873 Filed 9–13–23; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Green Wave Analytical Decision and Order

On August 10, 2022, the Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC) to Green Wave Analytical (hereinafter, Applicant) of San Diego, California. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 10, at 1, 6. The OSC proposed the denial of Applicant's application for a DEA Certificate of Registration (hereinafter, registration), Control No. W21055614H, alleging that Applicant has ''committed such acts as would render [its] registration inconsistent with the public interest.'' *Id.* at 1, 2 (citing 21 U.S.C. 824(a)(4),[1] 823(g)(1)[2]).

The Agency makes the following findings of fact based on the uncontroverted evidence submitted by the Government in its RFAA dated March 3, 2023.[3]

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the responses submitted on behalf of Ameriforge, Core Pipe Products, Inc., and Kerkau Manufacturing to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

[1] Prior Agency decisions have addressed whether it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *Robert Wayne Locklear, M.D.,* 86 FR 33738, 33744–45 (2021) (collecting cases); *see also Dinorah Drug Store, Inc.,* 61 FR 15972, 15973–74 (1996).

[2] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Public Law 117–215, 136 Stat. 2257 (2022) (Marijuana Research Amendments or MRA), amended the Controlled Substances Act (CSA) and other statutes. Relevant to this matter, the MRA redesignated 21 U.S.C. 823(f), cited in the OSC, as 21 U.S.C. 823(g)(1). Accordingly, this Decision cites to the current designation, 21 U.S.C. 823(g)(1), and to the MRA-amended CSA throughout.

[3] Based on the Declaration from a DEA Diversion Investigator, the Agency finds that the

I. Findings of Fact

According to the DEA Diversion Investigator assigned to investigate Applicant (hereinafter, the DI), on May 18, 2021, Applicant applied, through its owner (hereinafter, J.P.), for a DEA registration as an analytical lab. RFAAX 1, at 2; *see also* RFAAX 3. Applicant's previous DEA registration, Control No. RG0546359, expired on September 30, 2020, and since then, Applicant has not held an active DEA registration. RFAAX 1, at 3; *see also* RFAAX 4. As part of her investigation of the application, the DI exchanged emails with J.P. regarding Applicant's possession of controlled substances. RFAAX 1, at 3; *see also* RFAAX 5. The DI asked J.P. if Applicant continued to possess controlled substances at its facility, and J.P. stated that Applicant had old samples of phenobarbital injection (Schedule IV) and ''a very small amount'' of opium suppositories (Schedule II) stored. RFAAX 1, at 3; RFAAX 5, at 4–5. Further, J.P. added that Applicant was uncertain of the proper disposal procedure for such substances. RFAAX 1, at 3; RFAAX 5, at 4.

The DI attempted to schedule with J.P. an onsite preregistration inspection of Applicant and time to assist J.P. with disposal of the controlled substances that Applicant continued to unlawfully possess.[4] RFAAX 1, at 3; RFAAX 5, at 1–3. On August 3, 2021, the DI, along with another Diversion Investigator, traveled to Applicant's registered address ''for the purpose of [Applicant] voluntarily surrendering its controlled substances and with the understanding that the preregistration inspection would occur at a later date.'' RFAAX 1, at 4. According to the DI, J.P. showed her the area of the facility where controlled substances were kept locked in a cabinet, and the DI found that Applicant possessed greater quantities and more types of controlled substances than J.P. had previously claimed. *Id.* Further, only some portions of the substances possessed by Applicant were labeled as controlled substances, with other portions unlabeled and unidentified.[5] *Id.* Applicant surrendered all of the substances, which the DI took possession of, inventoried, and delivered to the DEA Southwest Laboratory. *Id.; see also* RFAAX 6.[6] While still at Applicant's location, the DI also asked J.P. for the accompanying receiving records, logs, and/or inventory documentation, to which J.P. indicated that ''he did not have any such records, except for a partially completed DEA Form 222 in which [Applicant] acquired powdered opium suppositories from Vitae Enim Vitae Scientific, Inc. (VEV).'' RFAAX 5, at 1; *see also* RFAAX 7.[7]

Thereafter, the DI requested administrative subpoenas for VEV's records ''[t]o determine whether [Applicant] received any controlled substance[s] as a DEA registrant, for which it lacked records of receipt, and whether [Applicant] received any controlled substances after its DEA registration expired, for which it lacked legal authorization.'' RFAAX 1, at 5–6. On August 9, 2021, DEA issued an administrative subpoena to VEV, pursuant to which VEV produced records of controlled substance distributions to Applicant and ''Order Information/Chain of Custody'' forms. *Id.* at 6; *see also* RFAAX 8. As noted by the DI, the records show that ''between on or about October 21, 2020, and July 15, 2021, on approximately 14 occasions—while [Applicant] was not registered—[Applicant] received approximately 7.958 [g] of powder phenobarbital sodium, and at least 21 [ml] of phenobarbital sodium at a concentration of 130 [mg/ml].'' *Id.*[8]

On July 6, 2022, DEA issued another administrative subpoena to VEV, pursuant to which VEV produced records of controlled substance distributions from VEV to Applicant between December 3, 2018, and September 30, 2020, ''Order Information/Chain of Custody'' forms, and DEA Forms 222. *Id.; see also* RFAAX 9. As noted by the DI, the records show that ''between on or about May 7, 2019, and September 29, 2020, on approximately 31 occasions—while [Applicant] was registered—[Applicant] received approximately 645 vials of 65 mg/ml phenobarbital sodium, 775 vials of 130 mg/ml phenobarbital sodium, 30.7 g of powder phenobarbital sodium, 3.9 g of powder opium, and 0.5 g of powder morphine sulfate, yet [Applicant] did not maintain any records of receipt.'' *Id.*

II. Discussion

Pursuant to Section 303(g)(1) of the CSA ''[t]he 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.'' 21 U.S.C. 823(g)(1). Section 303(g)(1) further provides that an application for a practitioner's registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' *Id.* In making the public interest determination, the CSA requires consideration of the following factors:

(A) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(C) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(E) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(g)(1).

The DEA considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993). While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1),[9] the Government's evidence

Government's service of the OSC on Applicant was adequate. RFAAX 1, at 7. Further, based on the Government's assertions in its RFAA, the Agency finds that more than thirty days have passed since Applicant was served with the OSC and Applicant has neither requested a hearing nor submitted a corrective action plan, and therefore, has waived any such rights. RFAA, at 6; *see also* 21 CFR 1301.43 and 21 U.S.C. 824(c)(2).

[4] Regarding the quantities of controlled substances possessed by Applicant, J.P. stated ''I guess there are about 250 to 400 × 2 mL small vials with septum caps. Most are variable amounts left as they were analyzed in most cases. I guess that is about 400 to 500 total mLs of Phenobarbital Sodium Injection Solution.'' RFAAX 1, at 3–4; RFAAX 5, at 1.

[5] The DI noted that ''in addition to quantities of phenobarbital injections and opium suppositories, [Applicant] also had quantities of morphine sulfate and tetrahydrocannabinol (THC) residue.'' *Id.*

[6] As listed by the DI, ''the controlled substances (as identified by label) that [Applicant] unlawfully possessed included suppositories of opium . . . approximately 500 milligrams (mg) of morphine sulfate . . . 200 mg of phenobarbital . . . 1,714 vials of phenobarbital of various concentrations; and one vial containing THC residue.'' RFAAX 1, at 5; *see also* RFAAX 6.

[7] The record purported to show that on March 3, 2020, Applicant ''ordered two packages of 180 mg powdered opium from VEV, and the supplier portions and [Applicant's] portions after delivery were not completed.'' RFAAX 1, at 5; RFAAX 7.

[8] The DI also noted that some of the ''Order Information/Chain of Custody'' forms stated the name ''Expert Chemical Analysis, Inc.'' as the purchaser. *Id.* Based on a review of DEA registration records and business entity records available online through the California Secretary of State, the DI found that ''Expert Chemical Analysis, Inc.'' was a non-registrant company controlled by J.P. at the same address as Applicant. RFAAX 1, at 6.

[9] As to Factor A, the record contains no evidence of a recommendation from any state licensing board or professional disciplinary authority. 21 U.S.C.

Continued

in support of its *prima facie* case for denial of Applicant's application is confined to Factors B and D. *See* RFAA, at 6–9. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44.

Here, the Agency finds that the Government's evidence satisfies its *prima facie* burden of showing that Applicant's registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

1. Factors B and D

Evidence is considered under Public Interest Factors B and D when it reflects compliance (or non-compliance) with laws related to controlled substances and experience dispensing controlled substances. *See Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022). In the current matter, the Government has alleged that Applicant has violated both federal and California state law regulating controlled substances. RFAAX 10, at 1–5.[10]

Under federal law, those engaged in chemical analysis are required to be registered with the DEA. 21 CFR 1301.13(e)(1)(x). Regarding recordkeeping, the CSA requires that DEA registrants maintain complete and accurate records of the manufacture, receipt, sale, delivery, or disposal of controlled substances. 21 U.S.C. 827(a)(3). Additional relevant recordkeeping requirements can be found at 21 CFR 1304.03(a) (all registrants shall maintain required records), 1304.04(a) (records must be retained and available for DEA inspection for at least two years), 1304.21(a) (records must be complete and accurate), 1304.23(a) (registrants registered for chemical analysis with controlled substances must maintain records for each controlled substance).

Here, the record demonstrates that prior to the expiration of its previous registration on September 30, 2020, Applicant failed to maintain necessary records as required by the CSA despite receiving and possessing controlled substances. Further, the record demonstrates that following the expiration of its previous registration on September 30, 2020, Applicant unlawfully continued to receive and possess large quantities of controlled substances without maintaining necessary records for two years as required by the CSA. As Applicant's conduct displays clear violations of federal law relating to controlled substances, the Agency hereby finds that Applicant violated 21 U.S.C. 827(a)(3) and 21 CFR 1301.13(e)(1)(x), 1304.03(a), 1304.04(a), 1304.21(a), 1304.23(a).

Accordingly, the Agency finds that Factors B and D weigh in favor of denial of Applicant's application and thus finds Applicant's registration to be inconsistent with the public interest in balancing the factors of 21 U.S.C. 823(g)(1). The Agency further finds that Applicant failed to provide sufficient evidence to rebut the Government's *prima facie* case.

III. Sanction

Where, as here, the Government has established grounds to deny Applicant's application, the burden shifts to the registrant to show why it can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). When a registrant has committed acts inconsistent with the public interest, it must both accept responsibility and demonstrate that it has undertaken corrective measures. *Holiday CVS, L.L.C., dba CVS Pharmacy Nos 219 and 5195,* 77 FR 62316, 62339 (2012) (internal quotations omitted). Trust is necessarily a fact-dependent determination based on individual circumstances; therefore, the Agency looks at factors such as the acceptance of responsibility, the credibility of that acceptance as it relates to the probability of repeat violations or behavior, the nature of the misconduct that forms the basis for sanction, and the Agency's interest in deterring similar acts. *See, e.g., Robert Wayne Locklear, M.D.,* 86 FR 33746.

Here, Applicant did not request a hearing, submit a corrective action plan, respond to the OSC, or otherwise avail itself of the opportunity to refute the Government's case. As such, Applicant has made no representations as to its future compliance with the CSA nor demonstrated that it can be entrusted with registration. Moreover, the evidence presented by the Government clearly shows that Applicant violated the CSA and the Agency has found that Applicant is ineligible for DEA registration. S*ee supra* at II.1. Accordingly, the Agency will order the denial of Applicant's application.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1) and 21 U.S.C. 824(a), I hereby deny the pending application for a Certificate of Registration, Control No. W21055614H, submitted by Green Wave Analytical, as well as any other pending application of Green Wave Analytical for additional registration in California. This Order is effective October 16, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 5, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–19820 Filed 9–13–23; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 23–7]

Rachel Pittala, APRN; Decision and Order

On October 18, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Rachel Pittala, APRN (Respondent) of Orlando, Florida. OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of her DEA Certificate of Registration, Control No. MP4600791, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes '''an imminent danger to the public health or safety.' '' OSC/ISO, at 1 (quoting 21 U.S.C. 824(d)). The OSC/

823(g)(1)(A). Nonetheless, an absence of such evidence ''does not weigh for or against a determination as to whether continuation of [or granting of a] DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011). As to Factor C, there is no evidence in the record that Applicant has been convicted of an offense under either federal or state law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(g)(1)(C). Likewise to Factor A, Agency cases have found that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). Finally, as to Factor E, the Government's evidence fits squarely within the parameters of Factors B and D and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(g)(1)(E). Accordingly, Factor E does not weigh for or against Applicant.

[10] The Agency need not adjudicate the criminal violations alleged in the instant Order to Show Cause. *Ruan* v. *United States,* 142 S. Ct. 2370 (2022) (decided in the context of criminal proceedings).