appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before noon on Tuesday, April 15, 2025. Please provide an email address for each conference participant in the email. Information on conference procedures, format, and participation, including guidance for requests to appear as a witness via videoconference, will be available on the Commission's Public Calendar (Calendar (USITC) | United States International Trade Commission). A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

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.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before 5:15 p.m. on April 22, 2025, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written testimony and supplementary material in connection with their presentation at the conference no later than 4:00 p.m. on April 16, 2025. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also 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 investigations must be served on all other parties to the investigations (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.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations 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 these or related investigations or reviews, 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, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.12 of the Commission's rules.

By order of the Commission.

Issued: March 28, 2025.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2025–05617 Filed 4–1–25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 24–21]

Prescript Pharmaceuticals; Decision and Order

On November 17, 2023, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) to Prescript Pharmaceuticals of Pleasonton, California (Respondent). OSC/ISO, at 1. The OSC/ISO informed Respondent of the immediate suspension of its DEA registration, No. RP0177798, pursuant to 21 U.S.C. 824(d), alleging that Respondent's continued registration constitutes '' 'an imminent danger to the public health or safety.' '' *Id.* (quoting 21 U.S.C. 824(d)). The OSC/ISO also proposed the revocation of Respondent's registration, alleging that Respondent's continued registration is inconsistent with the public interest. *Id.* (citing 21 U.S.C. 824(a)(4), 823(a)(1)).

More specifically, the OSC/ISO alleges that between 2020 and 2023, Respondent, who is registered as a manufacturer engaged in repackaging and relabeling activities, ordered Schedule II opioids from a supplier without having requested or received any procurement quota from DEA, in violation of 21 CFR 1303.12(b).[1] *Id.* at 2; Tr. 99.

A hearing was held before DEA Chief Administrative Law Judge John J. Mulrooney, II (the Chief ALJ),[2] who, on October 31, 2024, issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (Recommended Decision or RD), recommending that Respondent's registration be revoked. RD, at 37. The Government filed timely exceptions to the RD.[3] Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the Chief

[1] The Government also alleged that Respondent ordered pseudoephedrine-guaifenesin, a List I chemical, from a supplier without having requested or received any procurement quota, in violation of 21 CFR 1315.32(a). The Chief ALJ did not sustain this allegation because, while pseudoephedrine is a List I chemical subject to quotas, *see* 21 CFR 1315.32(a), 21 U.S.C. 802(34)(K), the Chief ALJ found that the Government did not preponderantly establish that pseudoephedrine is still a List I chemical when combined with guaifenesin. RD, at 30 n.75. The Chief ALJ noted that the only pertinent evidence on this subject was the testimony of a DEA Diversion Investigator (DI), who equivocated on the stand about whether pseudoephedrine-guaifenesin is a List I chemical. RD, at 9; *compare* Tr. 140, 182 (''[T]he mix of the pseudoephedrine is a List I chemical, which is contained within the Pseudoephedrine-Guaifenesin.'') *with* Tr. 183 (''I don't know if the fact that it's mixed would change the fact that it contains a Listed I chemical'').

In its post-hearing brief and Exceptions, the Government observes that the CSA's implementing regulations (21 CFR 1315.11(a)) provide that among the Administrator's quota-related duties is the duty to make an annual assessment regarding the maximum amount of pseudoephedrine—*including any chemicals that contain pseudoephedrine*—that may be manufactured or imported. ALJX 37, at 13; RD, at 30 n.75; Government's Exceptions, at 4–5. Furthermore, there is no limiting language in DEA's regulations suggesting that quota would not be required for pseudoephedrine when it is combined with another chemical. DEA's regulations state that quota is required for ''any person . . . who desires to use during the next calendar year *any* . . . pseudoephedrine . . . for purposes of manufacturing.'' 21 CFR 1315.32(a) (emphasis added). Respondent apparently understood that pseudoephedrine-guaifenesin was a chemical for which quota is required, because Respondent requested quota from DEA for this chemical in 2017. GX 10, at 1 (requesting quota for pseudoephedrine and pseudoephedrine/guaifenesin).

However, given the overwhelming nature of the evidence establishing that Respondent's registration is inconsistent with the public interest, the Agency need not make any findings related to this allegation.

[2] On January 10, 2024, the Chief ALJ issued an order terminating proceedings, which Respondent successfully appealed to the Agency. RD, at 2; ALJX 10, 11, 12.

[3] The Agency has reviewed and considered the Government's exceptions and addresses them herein.

ALJ's rulings,[4] credibility findings,[5] findings of fact, conclusions of law, sanctions analysis, and recommended revocation sanction as found in the RD, and summarizes and clarifies portions thereof herein.

I. Applicable Law

As already discussed, the OSC/ISO alleges that Respondent violated multiple provisions of the Controlled Substances Act (CSA) and its implementing regulations. As the Supreme Court stated in *Gonzales* v. *Raich,* ''the main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. . . . To effectuate these goals, Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.'' 545 U.S. 1, at 12–13 (2005). In maintaining this closed regulatory system, ''[t]he CSA and its implementing regulations set forth strict requirements regarding registration, labeling and packaging, production quotas, drug security, and recordkeeping.'' *Id.* at 14. The OSC/ISO's allegations concern the CSA's ''strict requirements regarding . . . labeling and packaging [and] production quotas'' and, therefore, go to the heart of the CSA's ''closed regulatory system'' specifically designed ''to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances.'' *Id.* at 12–14.

The Allegation That Respondent Purchased Controlled Substances Without Requesting or Obtaining Procurement Quota, in Violation of 21 CFR 1303.12(b)

The CSA requires manufacturers to obtain a registration from DEA prior to procuring controlled substances or engaging in manufacturing activities, 21 U.S.C. 823(a), (e), and authorizes DEA to place restrictions on registrants' manufacturing activities. Congress has provided the following definition of the term ''manufacture'':

> [T]he production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container . . . .''

21 U.S.C. 802(15); RD, at 21. The CSA's implementing regulations similarly define manufacturing to include ''the producing, preparation . . . or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance . . . .'' 21 CFR 1300.01; RD, at 21.

Under the CSA and DEA's implementing regulations, the Attorney General is authorized to establish an annual aggregate production quota, which is defined as ''the total quantity . . . [of] each basic class of controlled substances in schedules I and II . . . to be manufactured each calendar year . . . .'' 21 U.S.C. 826(a); 21 CFR 1303.03(a); RD, at 21–22. The Attorney General is further authorized to establish individual procurement quotas restricting the quantity of controlled substances that manufacturers may procure each year for purposes of engaging in manufacturing activities. 21 U.S.C. 826; 21 CFR 1303. DEA's implementing regulations create five subcategories of manufacturing and procurement quotas, including one category for ''packaging/repackaging and labeling/relabeling'' activities. 21 CFR 1303.04(e). The regulations specify that this subcategory is limited to manufacturers that package/repackage or label/relabel controlled substances, without engaging in any other commercial production activities:

> This is the quota for the amount of material moved to a registrant to undergo packaging and labeling activities. This quota is limited to that activity only and only for the packaging/repackaging and labeling/relabeling noted in the application; it may not be used or substituted for commercial production.

Id.; see also 21 CFR 1315.30(b)(3) (''A procurement quota authorizes a registered manufacturer to procure and use quantities of each chemical for . . . [r]epackaging or labeling the chemical or dosage forms.''); 21 CFR 1303.03(c) (defining ''procurement quota'' as ''the maximum quantity of each basic class of schedules I and II controlled substances that a registered manufacturer may procure during a calendar year for the purpose of manufacturing into dosage-forms or other substances'').

DEA's regulations expressly delineate the obligations of manufacturer registrants with respect to quotas, stating:

> *Any person who is registered to manufacture controlled substances* listed in any schedule and who desires to use during the next calendar year any basic class of controlled substances listed in Schedule I or II . . . *for purposes of manufacturing, shall apply* . . . *for a procurement quota* for such basic class.

21 CFR 1303.12(b)[6] (emphasis added); RD, at 22. In other words, any entity that is registered with DEA to manufacture controlled substances *must apply for and obtain* a procurement quota before purchasing a Schedule I or Schedule II controlled substance for any manufacturing activity, including repackaging and labeling. 21 U.S.C. 842(b)(2); 21 CFR 1303.12(b); *see also* Tr. 192, 272 (DEA Drug Science Specialist testifying that manufacturer registrants engaged in packaging/repackaging and labeling/relabeling of controlled substances must apply for and obtain a procurement quota from DEA). The CSA prohibits a registrant from ''manufactur[ing] a controlled substance in schedule II . . . not expressly authorized . . . by a quota assigned to him . . . or in excess of a quota assigned to him.'' 21 U.S.C. 842(b)(2);[7] *Gonzales* v. *Raich,* 545 U.S. at 27; RD, at 27.

II. Findings of Fact

The Allegation That Respondent Purchased Controlled Substances Without Requesting or Obtaining Procurement Quota, in Violation of and 21 CFR 1303.12(b)

Respondent is a manufacturer of controlled substances in Pleasanton, California, primarily engaged in pharmaceutical repackaging and

[4] The Agency does not adopt the Chief ALJ's mootness analysis. The Agency has repeatedly held since 2019 that the fact that a registrant allows a registration to expire during the pendency of an OSC does not impact the Agency's jurisdiction or prerogative under the Controlled Substances Act to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68474, 68476–79 (2019). See also *infra* n.20.

[5] The Agency adopts the Chief ALJ's summary of each witness's testimony, as well as the Chief ALJ's assessment of each witness's credibility. *See* RD, at 8–17.

[6] On November 28, 2023, substantive modifications were made to 21 CFR 1303.12(b), and it was redesignated as 21 CFR 1303.15. *See Mgmt. of Quotas for Controlled Substances and List I Chems.,* 88 FR 60117–02, 60128 (2023). This Decision cites to the original version at 21 CFR 1303.12(b), which was in place when the relevant misconduct occurred.

Respondent argues that the November 28, 2023 modifications *added* the requirement for packagers/repackagers to request quota, and that prior to this modification, packaging and repackaging activities did not require quota. Tr. 413, 482. Not only is Respondent's argument directly contradicted by the plain language of the statutes and regulations discussed herein, but it is directly contradicted by the order summarizing the modifications to 21 CFR 1303.12(b), which states that ''packaging and repackaging are manufacturing activities defined in the CSA and CFR and already require quota,'' and that ''[q]uota for Packaging/Repackaging and Labeling/Relabeling are already being utilized by DEA with full cooperation from all registrants.'' 88 FR at 60126, 60133.

[7] The Agency need not adjudicate the criminal violations alleged in the instant OSC/ISO. *Ruan* v. *United States,* 597 U.S. 450 (2022) (decided in the context of criminal proceedings).

relabeling. GX 1; RD, at 8, 13–14. William Hartig is the founder and president of Respondent. Tr. 112–13, 144–46, 340–41; RD, at 8, 13–14. Respondent first obtained authority to handle Schedule II controlled substances in 2010. Tr. 379.

Respondent has a long history of refusing to obtain procurement quota from DEA prior to purchasing Schedule II controlled substances, despite repeated encounters with DEA employees who cautioned Mr. Hartig that quota was required. *See infra* Section IV.A. These encounters included email communications with a DEA General Supervisor (GS) and other DOJ employees in 2013, 2017, and 2020; a Letter of Admonition (LOA) from DEA in 2014, and additional conversations with DEA employees during scheduled inspections. *See infra* Section IV.A.

The Government's allegations involve Respondent's failure to obtain procurement quota for Schedule II opioids in 2020 through 2023. ALJX 1, at 2–4.

In October 2021 and August 2023, DEA issued administrative subpoenas to obtain details about Respondent's purchases of controlled substances from a drug distributor. GX 2, 3; Tr. 102–06, 174; RD, at 9. The distributor's invoices showed that Respondent had ordered hydrocodone and oxycodone every year from 2020 through 2023. GX 4; Tr. 133–35, 155; RD, at 9–10. Hydrocodone and oxycodone are Schedule II controlled substances for which registered manufacturers must obtain procurement quota from DEA. 21 CFR 1308.12(b)(1) (identifying hydrocodone and oxycodone as Schedule II controlled substances); *id.* § 1303.12(b) (requiring registered manufacturers who ''desire[ ] to use during the next calendar year any basic class of controlled substances listed in Schedule I or II for purposes of manufacturing'' to apply for procurement quota).

DEA queried internal databases[8] and confirmed that Respondent had not requested or received any procurement quota from DEA for hydrocodone or oxycodone, and Mr. Hartig testified that Respondent did not apply for procurement quota from 2020 to 2023. Tr. 107–08, 115, 132–34, 157, 243–45, 439–40; Stipulations (Stips.) 6–10; RD, at 9.

On August 11, 2022, DEA conducted a scheduled inspection at Respondent. Tr. 98, 107, 143–44; RD, at 8. At the inspection, DEA investigators told Mr. Hartig that they had not found any paperwork indicating that Mr. Hartig had requested quotas from DEA for the controlled substances that Respondent had purchased. Tr. 156–58; RD, at 9. Mr. Hartig told DEA investigators that, in his opinion, Respondent was not required to request quota, and that he had no intention of requesting quota in the future unless DEA convinced him that the quota rules applied to Respondent's business activities. Tr. 157–58, 166; RD, at 9. The inspection team informed Mr. Hartig that Respondent was in violation of the regulations. Tr. 166–67; RD, at 9.

Based on the factual findings above, the Agency agrees with the Chief ALJ and finds substantial record evidence that: (1) Respondent was registered as a manufacturer during all times relevant to the charged misconduct, GX 1; RD, at 8, 13–14; (2) Respondent was engaged in packaging/repackaging or labeling/relabeling of controlled substances, which is activity that fits squarely within the statutory[9] and regulatory[10] definitions of manufacturing,[11] ALJX 1, at 2 ¶ 1; GX 1, 7, 8, 11, 15, 16, 18, 20, 23; RD, at 21–22; and (3) Respondent did not request procurement quota from DEA for the hydrocodone or oxycodone that it purchased in 2020 through 2023. Stips. 6–10; *see also* ALJX 2, at 2–3 ¶¶ 8, 11, 14, 17, 18; GX 4, 5; RD, at 5–6, 29.

III. Discussion

A. The Controlled Substances Act (CSA)

Under Section 304 of the CSA, ''[a] registration . . . to . . . manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under [21 U.S.C. 823] . . . inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). In the case of a ''manufacturer,'' Congress directed the Attorney General to consider six factors in making the public interest determination. *Id.* Sec. 823(a)(1–6).[12] The six factors are considered in the disjunctive. *Gonzales* v. *Oregon,* 546 U.S. 243, 292–93 (2006) (Scalia, J., dissenting) (''It is well established that these factors are to be considered in the disjunctive,'' citing *In re Arora,* 60 FR 4447, 4448 (1995)); *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003); *Direct Wholesale Denial of Application,* 69 FR 11654, 11655 (2004) (''As with the public interest analysis for practitioners and pharmacies pursuant to subsection [(g)(1)[13]] of section 823, these factors are to be considered in the disjunctive.''); *Alra Laboratories, Inc.,* 59 FR 50620, 50621 (1994), *aff'd Alra Labs.* v. *DEA,* 54 F.3d 450 (7th Cir. 1995). 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. *Penick Corp.* v. *Drug Enf't Admin.,* 491 F.3d 483, 490 (D.C. Cir. 2007); *Morall,* 412 F.3d. at n.2; *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993).

According to DEA regulations, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. 824(a) . . .

[8] The internal database was queried by a DEA Drug Science Specialist (DSS), who testified at the hearing about the Agency's process for reviewing and issuing procurement quotas to registrants. Tr. 243–45; RD, at 10. DSS testified that the internal ''quota management system'' has been operational since 2011 and records a registrant's application history, such as when the registrant applied, how much quota the registrant requested, and the result of the agency's adjudication of the application. Tr. 222, 227; RD, at 11.

[9] 21 U.S.C. 802(15).

[10] 21 CFR 1300.01.

[11] At the hearing, Respondent argued that it was not required to request quota because the activities that Respondent engaged in did not constitute manufacturing. RD, at 22–29. The Chief ALJ comprehensively addressed this argument in the RD, and the Agency hereby incorporates that analysis. *Id.* The Agency agrees that Respondent's arguments are contradicted by the plain language of the CSA and DEA's implementing regulations, as well as by DEA's *Quota User Manual* (*see infra* Section IV.A) and the consistent guidance that Respondent received from numerous DEA officials over several years. *Id.* As the Chief ALJ correctly observes, ''every relevant definition of manufacturing in the CSA and regulations include packaging/repackaging-labeling/relabeling activity. 21 U.S.C. 802(15); 21 CFR 1300.01. . . . The manufacturer registrant's obligation is clear: if an entity intends to engage in *any form of Schedule I and II manufacturing,* it must apply for quota, irrespective of whether the Administrator will grant one or not.'' RD, at 23, 25.

[12] The six factors of 21 U.S.C. 823(a) are:

(1) maintenance of effective controls against diversion of particular controlled substances . . . into other than legitimate medical, scientific, research, or industrial channels . . .;

(2) compliance with applicable state and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

These six factors are applicable to manufacturers of controlled substances in schedules I and II. The factors applicable to manufacturers of controlled substances in schedules III through IV are substantially similar. *See id.* Sec. 823(e).

[13] 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 here, as 21 U.S.C. 823(g)(1).

are satisfied.'' 21 CFR 1301.44(e); *see also Morall,* 412 F.3d. at 174.

In this matter, while all of the 21 U.S.C. 823(a) factors have been considered, the Agency finds that the Government's evidence in support of its *prima facie* case is confined to factor five (past experience in the manufacture of controlled substances).[14] RD, at 19, 27, 30–31.

Having reviewed the record and the RD, the Agency agrees with the Chief ALJ, adopts the Chief ALJ's analysis, and finds substantial record evidence that the Government satisfied its *prima facie* burden of showing that Respondent's continued registration is ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4); RD, at 37.

B. Allegation That Respondent's Registration Is Inconsistent With the Public Interest

Factor Five—Respondent's Past Experience in the Manufacture of Controlled Substances

As found above, Respondent repeatedly failed to request procurement quota prior to purchasing hydrocodone and oxycodone to engage in manufacturing activities. 21 CFR 1303.12(b); *Gonzales* v. *Raich,* 545 U.S. at 27; RD, at 22–29. The Agency agrees with the Chief ALJ and finds substantial record evidence that the CSA and its implementing regulations required Respondent to request and obtain procurement quota from DEA prior to purchasing hydrocodone and oxycodone to engage in manufacturing activities. RD, at 22–29; 21 CFR 1303.12(b); *Gonzales* v. *Raich,* 545 U.S. at 27. The Agency finds substantial record evidence that Applicant violated 21 CFR 1303.12(b), and therefore finds that Factor Five weighs in favor of revoking Respondent's registration.

In sum, the Agency finds substantial record evidence that the Government established a *prima facie* case that Respondent's continued registration is inconsistent with the public interest, that Respondent did not successfully rebut that *prima facie* case, and that there is substantial record evidence supporting the revocation of Respondent's registration. 21 U.S.C. 824(a)(4).

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration should be revoked due to its blatant violations of the CSA, the burden shifts to Respondent to show why it can be entrusted with a registration. *Morall,* 412 F.3d. at 174; *Jones Total Health Care Pharmacy,* 881 F.3d 823, 830 (11th Cir. 2018); *Garrett Howard Smith, M.D.,* 83 FR 18882 (2018); *supra* sections II and III.

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent. *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019); *see also Jones Total Health Care Pharmacy,* 881 F.3d at 833. Moreover, as past performance is the best predictor of future performance, DEA Administrators have required that a registrant who has committed acts inconsistent with the public interest must accept responsibility for those acts and demonstrate that it will not engage in future misconduct. *Jones Total Health Care Pharmacy,* 881 F.3d at 833. A registrant's acceptance of responsibility must be unequivocal. *Id.* at 830–31. In addition, a registrant's candor during the investigation and hearing has been an important factor in determining acceptance of responsibility and the appropriate sanction. *Id.* Further, DEA Administrators have found that the egregiousness and extent of the misconduct are significant factors in determining the appropriate sanction. *Id.* at 834 and n.4. DEA Administrators have also considered the need to deter similar acts by the respondent and by the community of registrants. *Jeffrey Stein,* 84 FR at 46972–73.

A. Acceptance of Responsibility

Here, the Chief ALJ found, and the Agency agrees, that there is substantial record evidence that Respondent failed to unequivocally accept responsibility for its repeated violations of federal law. RD, at 31–33. When given several opportunities to accept responsibility at the hearing, Mr. Hartig refused to concede that Respondent had done anything wrong. Tr. 442, 445. He maintained that it was ''a gray area,'' and that it is ''up for grabs'' whether he had violated the law. Tr. 442, 445; RD, at 17, 34. Respondent's position and Mr. Hartig's testimony are particularly problematic given the clarity of the laws and regulations and DEA's repeated communications regarding quotas. 21 U.S.C. 802(15); 21 CFR 1303.12(b), 1300.01.

Witnesses at the hearing—including Mr. Hartig—described a decade of communications between Respondent and numerous DEA employees regarding Respondent's refusal to obtain procurement quota. For example, Mr. Hartig testified that in 2013, a DEA General Supervisor (GS) notified him of the quota requirement and emailed him materials about quotas. Tr. 380–83; RD, at 13–14. The next year, after an inspection in 2014, DEA sent a Letter of Admonition (LOA) to Respondent explaining that Respondent was in violation of DEA's regulations due to its failure to obtain procurement quota for the controlled substances that it had purchased. Tr. 420, 431; RD, at 12, 14. Over the following years, DEA repeatedly told Mr. Hartig verbally and in writing that Respondent was required to request quota. *See, e.g.,* Tr. 166–67; 394–96; GX 19; RX 4; RX 9 (February 8, 2017 email), 10 (March 10, 2017 email), 17 (August 24, 2020 email). For example, GS sent Mr. Hartig an email on February 14, 2017 (three years after the formal LOA and four years after GS's initial email) with citations and attachments to the relevant statutes and regulations and a summary of Respondent's failure since 2010 to request quota. Despite DEA's repeated and explicit warnings, Respondent continued to assert that he did not believe that Respondent's activities constituted manufacturing—a position that was directly contradicted by the relevant statutes and regulations. *See e.g.,* RX 9, 10, 17.

At the hearing, Mr. Hartig expressed his frustration that the law is ''confusing,'' and ''doesn't seem to apply to what [he does].'' [15] Tr. 403. He

[14] Respondent introduced evidence that it has employed software and packaging that results in significant potential public benefit to those who choose to utilize its services. Tr. 354, 360–79; RX 27; RD, at 30. The Chief ALJ found that ''[t]his evidence reflects favorably on Public Interest Factor Three (promotion of technical advances in the art of manufacturing) in the Respondent's favor.'' RD, at 30 (citing 21 U.S.C. 823(a)(3)). However, the Chief ALJ also found that ''juxtaposed against this favorable evidence is the balance of the sustained allegations, which militate strongly and decisively in favor of the sanction sought by Government under Public Interest Factor Five (the Respondent's past experience in the manufacture (packaging/repackaging-labeling/relabeling) of controlled substances).'' RD, at 30. The Agency agrees with the Chief ALJ that any evidence of innovation is outweighed by the substantial evidence that Respondent disregarded federal laws relating to the manufacture of controlled substances.

[15] As the Chief ALJ observed, it became clear during Mr. Hartig's testimony that his refusal to comply with quota regulations was a business decision, rather than a sincere belief that procurement quota was not required for Respondent's business activities. RD, at 16–17. Mr. Hartig believed that compliance with quota regulations might limit the potential growth of his company, because ''if you restrict how much product [he] can buy from a supplier, that restricts how much [he] can sell.'' Tr. 404, 446; RD, at 16. The Chief ALJ reminded Mr. Hartig that registrants may submit a request to DEA to increase their quota,[15] to which Mr. Hartig replied: ''I happened to talk to other repackagers, and one, in particular, said that they've applied for increases three years in a row and have been denied every time.'' Tr. 405; RD, at 16. In other words, Mr. Hartig's reticence to

Continued

criticized DEA for not releasing compliance guides for industry participants, like other agencies do, and testified that ''DEA has not put out a single compliance guide that [he's] aware of with respect to this policy.'' *Id.* at 403. Contrary to Respondent's testimony, DEA's 2017 *Quotas User Manual,* which is available online [16] and is cited in Respondent's Prehearing Statement, *see* ALJX 17, at 5 ¶ 11, reiterates what the regulations make clear: That ''[t]he procurement quota form DEA 250 is required for . . . labelers/relabelers, and packager/repackagers.'' *DEA Quotas User Man.* at 2 sec. 1.1; RD, at 16. Further, in its published final orders, the Agency has repeatedly and explicitly stated that: (1) manufacturing includes relabeling/repackaging activities; and (2) repackagers/relabelers of controlled substances and List I chemicals must apply for (and receive) a procurement quota before they conduct regulated activities under the CSA.[17]

Respondent also attempted to pass blame to DEA failing to officially reprimand Respondent sooner, stating through counsel, ''you see the Government repeatedly coming to him, hearing his explanation and shrugging its shoulders and saying maybe we'll get back to you and dropping the issue for many, many years.'' Tr. 495; *see also id.* at 494. Respondent's attempts to shift blame for Respondent's violations to DEA—especially where DEA has issued guidance regarding manufacturers' obligations and expended significant resources to bring Respondent into compliance—further detract from Respondent's acceptance of responsibility. *See, e.g., Ester Mark, M.D.,* 86 FR 16760, 16762 (2021) (finding that the respondent did not accept responsibility because she ''passe[d] blame on DEA for not telling her how to comply with recordkeeping requirements'').

Regarding these matters, there is no record evidence that Respondent takes responsibility, let alone unequivocal responsibility, for the founded violations. Instead, Respondent incredibly denies that it is engaged in manufacturing activities, denies that it is required to obtain quotas, and suggests that DEA's failure to issue an OSC sooner is evidence supporting his claims. It is simply not reasonable to believe that Respondent's future controlled substance-related actions will comply with legal requirements. Accordingly, Respondent did not convince the Agency that he can be entrusted with a registration.

B. Deterrence and Egregiousness

In addition to unequivocally accepting responsibility, the Agency considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick,* 80 FR at 74810. In this case, the Agency agrees with the Chief ALJ and finds substantial evidence that ''the interests of specific deterrence weigh powerfully in favor of the revocation sanction sought by the Government.'' RD, at 35. Respondent has repeatedly signaled to DEA for more than a decade that he has no intention of complying with federal law, and he has maintained this position throughout DEA's enforcement proceeding. RD, at 34–35. Based on Mr. Hartig's continued assertions that the law is ambiguous, and that DEA has not provided him with sufficient clarity, it is clear that DEA cannot trust Respondent to follow DEA's quota regulations, or any other federal laws that Mr. Hartig deems confusing or inconvenient.

The Agency further agrees with the Chief ALJ that the interests of general deterrence compel a similar result. RD, at 35. As the Chief ALJ states, ''[w]here the record demonstrates that the Respondent lacked motivation to invest even moderate efforts to file the modest paperwork required to seek quota authorization for dangerous controlled substances, and was unwilling, even after specific warnings on the subject, to come into compliance, the unmistakable message to the regulated community would be that such conduct can be tried once (or more than once) with little or no consequence.'' *Id.* (citing *Kaniz F. Khan-Jaffery, M.D.,* 85 FR 45667, 45690 (''The interests of general deterrence in discouraging practitioners from ignoring their legal obligations and not genuinely complying with important recordkeeping provisions . . . weigh in favor of a sanction of revocation.'')). If the Agency permitted Respondent to retain its registration, it would signal that registrants may selectively choose which rules apply to them, even when those rules are crucial to preventing the abuse and diversion of dangerous controlled substances.

The Agency further agrees with the Chief ALJ that Respondent's actions were egregious. RD, at 36. The Agency has held that ''unlawful manufacturing is an egregious violation and warrants the revocation of registration.'' *Pronto Pharmacy, LLC,* 86 FR 64714, 64744 (2021) (noting the registration renewal interval is only one year long for manufactures as compared to the three-year interval for practitioners); RD, at 36. As the Chief ALJ observed, ''the Respondent's president understood the rules and consciously, and over a lengthy period of time, elected to disregard them intentionally.'' *Id.*

The Agency has held manufacturer registrants ''to higher standards than practitioners with respect to recordkeeping, reporting, security, and frequency of renewing registration'' [18] because Congress has found that ''[t]he illegal importation, *manufacture,* distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.'' 21 U.S.C. 801 (emphasis added); *Gonzales* v. *Raich,* 545 U.S. at 12 n.20 (2005) (citing 21 U.S.C. 801); RD, at 27–28. Respondent's actions fell far below the Agency's standards for all DEA registrants, and even further below the Agency's heightened standards for manufacturers.

abide by federal law was based on his concern that DEA might not grant an increase in quota and would thereby hinder his prospects at growing his business. RD, at 16, 30. Respondent also wrote in an email to DEA on February 8, 2017, that it would be ''incredibly anti-competitive'' for DEA to ''further restrict how much product can be distributed by any one registrant,'' suggesting that it would not make sense that ''[a] small business can only grow by a preset quota.'' RX 9, at 1.

[16] *https://www.deadiversion.usdoj.gov/quotas/quotas_userguide.pdf.*

[17] *See Technical Amendments and Corrections to DEA Regulations,* 77 FR 4228, 4233 (2012) (''Manufacture means the producing. . . or the packaging or repackaging of such substance, or the *labeling or relabeling of the commercial container of such substance*''); *Registration Requirements for Importers and Manufacturers of Prescription Drug Products Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine,* 75 FR 4973, 4974 (2010) (''[U]nder the CSA, 'manufacture' is defined to include all of the following . . .: The packaging or repackaging of the processed substances or chemicals or labeling or relabeling of containers holding the chemicals.''); *Import and Production Quotas for Certain List I Chemicals,* 73 FR 73549, 73551 (2008) (''[B]ecause repackagers and relabelers handle products that are covered by other procurement or import quotas, DEA may need more details on customers from those seeking procurement quotas to ensure that it is not double counting quantities. This issue may arise particularly in reference to OTC products, where a manufacturer may produce dosage units that are repackaged or relabeled to be sold under multiple store brand labels.''); *Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II,* 79 FR 49661, 49671 (2014) (''Procurement quotas are typically issued to dosage form manufacturers and repackagers or relabelers for manufacturing activities. As related to [Hydrocodone Containing Products], a procurement quota is required . . . for a company to receive bulk finished dosage units for relabeling or repackaging.''); RD, at 26.

[18] *See also Wedgewood Vill. Pharmacy,* 71 FR 16593, 16594 (2006); (''The requirements for registration of manufacturers and distributors of controlled substances are more stringent than for those registered as practitioners to dispense controlled substances. . . . Recordkeeping, reporting and security requirements are also more rigorous for those who manufacture and distribute controlled substances.''); RD, at 27.

Despite DEA's entreaties over more than a decade that Respondent follow the straightforward, inexpensive, and statutorily required process of requesting quota, Respondent refused to do so and instead violated the law year-after-year.[19] Mr. Hartig's decision to repeatedly assert frivolous and incorrect arguments reflects a lack of respect for Respondent's obligations as a manufacturer and a lack of appreciation for DEA's important mission to protect the public from dangerous controlled substances.

In sum, Respondent has not offered any credible evidence on the record that despite its violations it can be entrusted with the responsibility of registration. Accordingly, the Agency will order that Respondent's registration be revoked.[20]

[19] Respondent applied for and obtained procurement quota in 2017. *See* RX 13–15.

[20] Respondent's DEA registration expired on March 31, 2024, during prehearing proceedings. ALJX 1, at 2, 14, at 2, 17, at 3, 19 at n.2; GX 1; RD, at 2. As of the date of the RD, Respondent had not submitted a renewal application. RD, at 2. Accordingly, the Chief ALJ ''recommended that either the Agency render the case MOOT by virtue of the fact that the Respondent's [registration] has expired without a renewal application, or alternatively, that the Government's application to revoke the Respondent's [registration] be GRANTED.'' *Id.* at 37.

The Agency has determined that its jurisdiction to adjudicate a matter to finality is not dependent on whether the respondent has an active DEA registration. *Jeffrey D. Olsen,* 84 FR 68474, 68475–80 (2019). Instead, the Agency's jurisdiction in an administrative action is over the *registrant,* not the *registration. See Abdul Naushad, M.D.,* 89 FR 54059, 54060 (2024) (''[O]ne way that the Administrator carries out the CSA is by investigating and administratively adjudicating *a registrant's* CSA-relevant actions and inactions. When the registrant's actions or inactions call for it, the sanction may be suspension or revocation of the registrant's registration. 21 U.S.C. 824(a). While the sanction involves the registration, the sanction is levied on the *registrant* and remains in the record throughout the rest of the registrant-Agency relationship, regardless of whether that relationship is either continuous or intermittent'') (emphasis added). When it serves the Agency's and the registrant's interests to litigate an expired registration to finality—for example, when a respondent intends to engage in regulated activity in the future, and memorializing a registrant's compliance (or non-compliance) with the CSA will aid the Agency's future relationship with the registrant—the Agency has determined that issuing a final order may be done in a manner that is with the Constitution, the CSA, applicable legal authority, and sound law enforcement principles. *Jeffrey D. Olsen,* 84 FR at 68475–80.

In the instant case, Respondent's prehearing filings reflect an intent to continue to engage in regulated activity, ALJX 17, at 2 n.1; RD, at 4, and he requested a sanction of ''time served'' so that he could resume manufacturing, Tr. 468–69, which suggests that Respondent will likely reapply for a DEA registration in the future. *See also* Tr. 456–61 (Respondent's counsel offering to apply for renewal if necessary to cure the Chief ALJ's mootness concerns). Additionally, Respondent represented that controlled substances were seized by DEA when the OSC/ISO was served, ALJX 17, at 10–11; RD, at 4, and the disposition of these substances remains outstanding. 21 U.S.C. 824(f); *Brewster Drug, Inc.,* 85 FR 19020, 19021 (2020) (issuing a final order revoking an expired registration, pursuant to 21 U.S.C. 824(f), because the ''[d]isposition of Registrant's seized controlled substances inventory remains outstanding even though Registrant discontinued business, and, therefore, its registration is terminated.''). Thus, issuing a final order in this matter will clarify the disposition of those assets, memorialize the allegations and evidence in this matter, and communicate the Agency's expectations to other current and prospective registrants engaged in similar activities. *See Jeffrey D. Olsen,* 84 FR at 68479. The facts in this case, such as the status of Respondent's registration and Respondent's intent to continue with regulated activity, are consistent with the Agency's analyses in *Jeffrey D. Olsen. Id.* at 68475–79.

V. Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. RP0177798 issued to Prescript Pharmaceuticals. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(a), (e), I hereby deny any pending applications of Prescript Pharmaceuticals to renew or modify this registration, as well as any other pending application of Prescript Pharmaceuticals for additional registration in California. This Order is effective May 2, 2025.

Signing Authority

This document of the Drug Enforcement Administration was signed on March 25, 2025, by Acting Administrator Derek Maltz. 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**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jennifer Marie Lager-Fermon, D.O.; Decision and Order

On April 30, 2024, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Jennifer Marie Lager-Fermon, D.O., of Mason, Ohio. Request for Final Agency Action (RFAA), Exhibit (RFAAX) 1, at 1, 3. The OSC proposed the revocation of Registrant's Certificate of Registration No. BL7988960, alleging that Registrant's registration should be revoked because Registrant is ''currently without authority to prescribe, administer, dispense, or otherwise handle controlled substances in the State of Ohio, the state in which [she is] registered with DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

The OSC notified Registrant of her right to file a written request for hearing, and that if she failed to file such a request, she would be deemed to have waived her right to a hearing and be in default. *Id.* (citing 21 CFR 1301.43). Here, Registrant did not request a hearing. RFAA, at 1.[1] ''A default, unless excused, shall be deemed to constitute a waiver of the [registrant's] right to a hearing and an admission of the factual allegations of the [OSC].'' 21 CFR 1301.43(e).

Further, ''[i]n the event that a registrant . . . is deemed to be in default . . . DEA may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default final order pursuant to [21 CFR] § 1316.67.'' *Id.* § 1301.43(f)(1). Here, the Government has requested final agency action based on Registrant's default, pursuant to 21 CFR 1301.43(c), (f), 1301.46. RFAA, at 1; *see also* 21 CFR 1316.67.

Findings of Fact

The Agency finds that, in light of Registrant's default, the factual allegations in the OSC are admitted. According to the OSC, effective January 16, 2024, the State Medical Board of Ohio indefinitely suspended Registrant's Ohio medical license. RFAAX 1, at 2.

According to Ohio online records, of which the Agency takes official notice, Registrant's Ohio medical license remains suspended.[2] eLicense Ohio

[1] Based on the Government's submissions in its RFAA dated September 19, 2024, the Agency finds that service of the OSC on Registrant was adequate. Specifically, the included declaration from a DEA Diversion Investigator indicates that on May 21, 2024, Registrant was personally served with a copy of the OSC. RFAAX 3, at 1–2; *see also* RFAAX 4.

[2] 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

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