recurrence of material injury within a reasonably foreseeable time.

DATES: October 6, 2023.

FOR FURTHER INFORMATION CONTACT: Alexis Yim (202–708–1446), 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 October 6, 2023, the Commission determined that the domestic interested party group response to its notice of institution (88 FR 42753, July 3, 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)).[2]

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 November 21, 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,[3] 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 5:15 p.m. on November 30, 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 November 30, 2023. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. 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: October 27, 2023.

Katherine Hiner,

Supervisory Attorney.

[FR Doc. 2023–24183 Filed 11–1–23; 8:45 am]

BILLING CODE 7020–02–P

[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] Commissioner Stayin did not participate in the vote on these reviews.

[3] The Commission has found the response submitted on behalf of the Cast Iron Soil Pipe Institute and its two individual members to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 22–36]

Osmin A. Morales, M.D.; Decision and Order

On May 25, 2022, the Drug Enforcement Administration (DEA or Government) issued an Order to Show Cause (OSC) to Osmin A. Morales, M.D., (Respondent) of Florida seeking to deny his application for a DEA Certificate of Registration, Control No. W20125906C, and alleging that his registration ''would be inconsistent with the public interest.'' OSC, at 1 (citing 21 U.S.C. 823(g)(1)[1]).

A hearing was held before DEA Chief Administrative Law Judge John J. Mulrooney, II (the Chief ALJ). On February 8, 2023, the Chief ALJ issued his Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (RD), which recommended that the Agency deny Respondent's application. RD, at 22. Respondent did not file exceptions to the RD. Having reviewed the entire record, the Agency adopts and hereby incorporates by reference the entirety[2] of the Chief ALJ's rulings, credibility findings,[3] findings of fact,

[1] Effective December 2, 2022, the Medical Marijuana and Cannabidiol Research Expansion Act, Pub. L. 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.

[2] See footnotes 4 and 6, *infra.*

[3] The Agency adopts the Chief ALJ's summary of each of the witnesses' testimonies as well as the Chief ALJ's assessment of each of the witnesses' credibility. *See* RD, at 3–10. The Agency agrees with the Chief ALJ that the Diversion Investigator's (DI) testimony, which focused on the investigative steps completed in the case and establishing the foundations for exhibits received into the record, was sufficiently detailed, plausible, and internally consistent to be afforded full credibility. *See id.* at 3–4. The Agency also agrees with the Chief ALJ's assessment of the testimony provided by a Task Force Agent (TFA) on investigative assistance provided to DEA and non-controversial introduction of documentary evidence. *See id.* at 4. The testimony was sufficiently detailed, plausible, and internally consistent to be afforded full credibility. *Id.* M.L., mother of Patient K.L, primarily testified about her observations of K.L. during the time period in which Respondent issued K.L. controlled substance prescriptions, as well as an interaction with Respondent at his medical office. *Id.* at 5–6. Despite M.L.'s apparent anger toward Respondent for the role that she believed he played in her daughter's addiction to pain medication, the Agency agrees with the Chief ALJ that M.L.'s testimony was sufficiently consistent, plausible, and detailed to be afforded credibility. *See id.* at 6. Further, the Agency agrees with the Chief ALJ that Dr. Mark Rubenstein, M.D., the Government's expert witness, provided opinions on

Continued

conclusions of law, and recommended sanction in the RD and summarizes and expands upon portions thereof herein.

I. Findings of Fact

The Agency finds from clear, unequivocal, convincing, and unrebutted evidence that Respondent committed numerous failures in his prescribing conduct that fell below the standard of care in Florida. Overall, the Agency finds that Respondent issued at least 252 prescriptions [4] to patients from September 27, 2017, through November 25, 2020, without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida. *See* RD, at 18–19.

Florida Standard of Care

Dr. Rubenstein provided expert testimony on the applicable standard of care for prescribing controlled substances in Florida.[5] RD, at 7–8; Tr. 637. According to Dr. Rubenstein, a physician is required to conduct ''an appropriate history and physical examination to establish an appropriate medical diagnosis, [and] review appropriate medical records,'' prior to prescribing a controlled substance. RD, at 7 (quoting Tr. 638). Dr. Rubenstein further explained that while the nature and depth of the physical examination may vary depending on the location of the pain, it should include an assessment tailored to the patient's particular complaints. RD, at 7; Tr. 639–40. He clarified that while the physical examination at the initial visit is usually the most thorough, physicians must still conduct additional physical examinations at subsequent visits. RD, at 7; Tr. 641. Dr. Rubenstein emphasized that ''[t]o prescribe controlled substances, you must establish an appropriate and valid medical diagnosis.'' RD, at 7 (quoting Tr. 646).

Dr. Rubenstein also testified that prior to issuing a controlled substance prescription, a physician should query the state prescription monitoring program (PMP), which, in Florida, is the Electronic-Florida Online Reporting of Controlled Substance Evaluation Program (E–FORCSE). RD, at 7–8; Tr. 638, 650, 835–36. The physician should also assess and document signs of misuse or noncompliance. RD, at 8; Tr. 647, 651–52. Notably, Dr. Rubenstein stressed the importance of maintaining ''full and appropriate records'' that include patient history, physical examinations, medical records, diagnostic studies, and controlled substance prescriptions. RD, at 8 (quoting Tr. 646); Tr. 650, 813.

The Patients

Patient K.L.

Regarding Patient K.L., the Agency finds that Respondent issued at least 110 controlled substance prescriptions from July 9, 2018, through November 25, 2020, without a legitimate medical purpose, outside the usual course of professional practice, and beneath the applicable standard of care.[6] *See* RD, at 18–19; GX 7, 12; Tr. 670–71, 852–54. Based on Dr. Rubenstein's testimony and the record as a whole, these prescriptions were issued without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care because Respondent failed to appropriately establish or document a medical indication (RD, at 8; GX 11; Tr. 689–90, 705, 708–10, 714, 719, 722, 725, 736–37, 853), altered prescriptions without any documented justification (RD, at 8; GX 11; Tr. 825–34), maintained Patient K.L. on high doses and high-risk combinations of controlled substances without any established or documented medical indication (RD, at 8–9; GX 11; Tr. 671, 687, 706, 710, 712–13, 717–19, 725–26, 729, 737, 853), issued prescriptions on dates prior to correlating patient visits (RD, at 9; GX 11–12; Tr. 758–61, 801–810), failed to resolve or adequately address signs of potential diversion prior to issuing prescriptions (RD, at 9; GX 11; Tr. 825–27, 839, 841, 843–48, 853–54), failed to document and maintain copies of certain prescriptions (RD, at 9; GX 11–12; Tr. 814–19) created patient records with inconsistent information (RD, at 9; GX 11–12; Tr. 745–50, 756–58, 851–52, 957–58), and/or failed to conduct in-person examinations of the patient, including a purported office visit noted in Patient K.L.'s file when evidence indicated that Respondent was not in the country (RD, at 9; GX 11–12, 20; Tr. 542, 745–50, 756–58, 851–52, 957–58).

Patient R.J.

Regarding Patient R.J., the Agency finds that Respondent issued at least 83 controlled substance prescriptions from August 2, 2018, to October 26, 2020, without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida. *See* RD, at 18–19; GX 14; 857, 925–26. Based on Dr. Rubenstein's testimony and the record as a whole, these prescriptions were issued beneath the standard of care and outside the usual course of professional practice because Respondent failed to appropriately establish or document a medical indication (RD, at 8; GX 13; Tr. 863, 868–69, 885, 896–97, 904–06), maintained Patient R.J. on high doses and high-risk combinations of controlled substances without any established or documented medical indication (RD, at 8–9; GX 13; Tr. 866–67, 898, 905–06, 925), issued prescriptions on dates prior to correlating patient visits (RD, at 9; GX 13–14; Tr. 914–17), failed to resolve or adequately address signs of potential diversion prior to issuing prescriptions (RD, at 9; GX 13; Tr. 920–23, 925), failed to document and maintain copies of certain prescriptions (RD, at 9; GX 13–14; Tr. 917–20), and/or created patient records with inconsistent information (RD, at 9; GX 13–14; Tr. 882, 911, 914).

Patient A.H.

Regarding Patient A.H., the Agency finds that Respondent issued at least 19 controlled substance prescriptions from June 26, 2019, through November 11, 2020, without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida. *See* RD, at 18–19; GX 16; Tr. 927–28, 931. Based on Dr. Rubenstein's testimony and the record as a whole, these prescriptions were issued beneath the standard of care and outside the usual course of professional practice because Respondent failed to appropriately establish or document a medical indication (RD, at 8; GX 15; Tr. 927–29), maintained Patient A.H. on high doses and high-risk combinations of controlled substances without any established or documented medical indication (RD, at 8–9; GX 15; Tr. 927–

Florida's standard of care and Respondent's prescribing history that ''gave every appearance of being comprehensive and well-reasoned,'' were unrefuted and uncontroverted, and merited controlling weight. *Id.* at 10. Respondent did not present a case. *Id.* at 3; Tr. 1,124–25.

[4] In addition to the misconduct discussed in this Decision, the Chief ALJ found misconduct related to 23 prescriptions Respondent issued to patients on November 18, 2020, that the Government alleged were either (a) signed and dated prior to their issuance date, (b) fraudulently written by Respondent's staff, and/or (c) issued after Respondent surrendered his prior DEA registration. RD, at 4, 18–19. Based on the overwhelming nature of the evidence establishing Respondent's other misconduct in his prescribing of controlled substances, the Agency need not reach a factual finding with regard to these 23 prescriptions.

[5] The Agency adopts and incorporates by reference the entirety of the Chief ALJ's findings regarding the standard of care in Florida and the related summary of Dr. Rubenstein's expert testimony.

[6] Based on the overwhelming evidence of misconduct related to Respondent's prescribing to K.L., the Agency need not issue findings regarding prescriptions issued to K.L. on July 5, 2016, and July 15, 2016.

29), and/or failed to conduct and document a physical examination, obtain and document a medical history, monitor and document compliance, and/or create and document a treatment plan (RD, at 9–10; GX 15; Tr. 928–31).

Patient R.H.

Regarding Patient R.H., the Agency finds that Respondent issued at least 37 controlled substance prescriptions from September 27, 2017, through November 4, 2020, without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida. *See* RD, at 18–19; GX 18; Tr. 934, 941. Based on Dr. Rubenstein's testimony and the record as a whole, these prescriptions were issued beneath the standard of care and outside the usual course of professional practice because Respondent failed to appropriately establish or document a medical indication (RD, at 8; GX 17; Tr. 939), maintained Patient R.H. on high doses and high-risk combinations of controlled substances without any established or documented medical indication (RD, at 8–9; GX 17; Tr. 712, 933–34), and/or failed to conduct and document a physical examination, obtain and document a medical history, monitor and document compliance, and/or create and document a treatment plan (RD, at 9–10; GX 17; Tr. 934–35, 939–41).

Patients M.P., C.C., and C.A.

The Agency finds that Respondent issued one controlled substance prescription each to Patients M.P., C.C., and C.A.—on January 3, 2019, January 2, 2019, and December 26, 2018, respectively—without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida.[7] *See* RD, at 18–19; Tr. 945–46, 949–50, 956, 959–60. Although office visit notes indicated that Respondent had conducted in-person examinations of these patients, testimony by the DI and TFA, as well as U.S. Customs and Border Protection records, established that Respondent was not in the United States when he issued these controlled substance prescriptions. RD, at 5; GX 20, 22–27; Tr. 141–48, 608–25. Based on this evidence and related testimony by Dr. Rubenstein, these controlled substance prescriptions were issued to M.P., C.C., and C.A. without a legitimate medical purpose, outside the usual course of professional practice, and beneath the standard of care in Florida. RD, at 9; Tr. 941–56, 960.

II. Discussion

According to the CSA, a practitioner's application for a DEA registration may be denied upon a determination that ''the issuance of such registration . . . would be inconsistent with the public interest.'' 21 U.S.C. 823(g)(1). In the case of a practitioner, the CSA requires that the Agency consider the following factors in determining whether an applicant's registration would be inconsistent with the public interest:

(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).

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).

The Government has the burden of proof in this proceeding. 21 CFR 1301.44. While the Agency has considered all of the public interest factors in 21 U.S.C. 823(g)(1), the Government's evidence in support of its *prima facie* case for denying Respondent's application is confined to Factors B and D. *See* RD, at 13, n.24 (finding that Factors A, C, and E do not weigh for or against the sanction sought by the Government).

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 Sualeh Ashraf, M.D.,* 88 FR 1095, 1097 (2023); *Kareem Hubbard, M.D.,* 87 FR 21156, 21162 (2022). DEA regulations require that for a prescription for a controlled substance to be effective, it must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a); *see also* 21 U.S.C. 829.

Based on Dr. Rubenstein's uncontroverted expert opinion, the Agency finds that Respondent issued more than 250 prescriptions outside of the usual course of professional practice and beneath the Florida standard of care in violation of Federal law. *See supra* I. Additionally, the Agency finds that Respondent violated Fla. Stat. section 456.44(3) with regard to patients K.L., R.J., A.H., and R.H., by failing to obtain and/or document a medical history, establish and/or document a medical indication for prescribing, conduct and/or document a physical examination, create and/or document a treatment plan, monitor and document compliance, and/or maintain accurate and complete medical records.

The Agency finds that for each of the seven patients at issue, Respondent failed to maintain sufficiently detailed medical records that were accurate and complete and, among other things, justified the course of medical treatment, thereby violating Fla. Stat. section 456.44(3), Fla. Stat. section 458.331(1)(m), and Fla. Admin. Code r. 64B8–9.003. Lastly, the Agency finds that Respondent violated Fla. Stat. section 458.331(1)(k) by preparing office visit notes stating that he had conducted in-person examinations of patients K.L., M.P., C.C., and C.A., when in fact he was not in the United States. This conduct violated Florida law and further rendered Respondent's dispensing outside the usual course of professional practice.

In sum, and in agreement with the RD, the Agency finds that the record contains substantial evidence that Respondent prescribed and dispensed controlled substances in violation of both Federal and State law. RD, at 18; *see* 21 U.S.C. 829; 21 CFR 1306.04(a); Fla. Stat. sections 456.44(3), 458.331(1)(k), 458.331(1)(m); Fla. Admin. Code r. 64B8–9.003. In weighing Factors B and D, the Agency finds that the Government has established a *prima facie* case that Respondent committed acts that render his registration inconsistent with the public interest and support denial of his registration application. *See* 21 U.S.C. 823(g)(1).

III. Sanction

Where, as here, the Government has established grounds to deny Respondent's application, the burden shifts to the respondent to show why he can be entrusted with the responsibility carried by a registration. *Garret Howard Smith, M.D.,* 83 FR 18882, 18910 (2018). When a respondent has committed acts inconsistent with the public interest, he must both accept responsibility and

[7] Respondent also issued four controlled substance prescriptions to Patient K.L. when Respondent was not in the country. *See supra,* Patient K.L.

demonstrate that he 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 33738, 33746 (2021).

When a respondent declines to testify and ''neither [takes] responsibility for his misconduct nor provid[es] any assurances that he has implemented remedial measures to ensure such conduct is not repeated,'' the respondent's silence weighs against registration. *Zvi H. Perper, M.D.,* 77 FR 64131, 64142 (2012) (citing *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008)); *see also Jeanne E. Germeil,* M.D., 85 FR 73786, 73803 (2020). Such silence also warrants an adverse inference against the respondent. *MacKay* v. *Drug Enf't Admin,* 664 F.3d 808, 820 (10th Cir. 2011) (upholding the Agency's finding that a respondent's failure to testify warranted an adverse inference because there was ''no evidence that [respondent] recognized the extent of his misconduct and was prepared to remedy his prescribing practices''); *T.J. McNichol, M.D.,* 77 FR 57133, 57153–54 (2012) (stating that ''it is appropriate to draw an adverse inference from Respondent's failure to testify'').

Here, Respondent has failed to accept responsibility or offer any basis for the Agency to trust him, despite his past misconduct, with the responsibility of a registration. RD, at 21. In light of Respondent's silence, he has not sufficiently demonstrated that he can be entrusted with a DEA registration. *See id.; MacKay,* 664 F.3d at 820; *Jeanne E. Germeil, M.D.,* 85 FR at 73803; *Zvi H. Perper, M.D.,* 77 FR at 64142.

In addition to acceptance of responsibility, the Agency looks to the egregiousness and extent of the misconduct, *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases), and considers both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74800, 74810 (2015). Here, Respondent's blatant and repeated disregard for the laws relating to controlled substances warrants a sanction. Respondent's inappropriate and unlawful prescribing of controlled substances placed multiple patients, and the public, at risk of harm. In this case, the Agency believes that denial of Respondent's application would deter Respondent and the general registrant community from disregarding controlled substance laws and engaging in the pattern of misconduct that permeated Respondent's actions as a registrant. *See* RD, at 22. As the Chief ALJ noted, ''[t]he misconduct established was sufficiently egregious that a denial is strongly supported.'' RD, at 22. Further, there is no evidence that Respondent's behavior is unlikely to recur in the future such that the Agency can entrust him with a registration.

In sum, the public interest factors weigh in favor of denial as a sanction; accordingly, the Agency shall order the sanctions the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(g)(1), I hereby deny the DEA registration application of Osmin A. Morales, M.D. (Control No. W20125906C) and any other pending application of Osmin A. Morales, M.D., for a DEA registration in Florida. This Order is effective December 4, 2023.

Signing Authority

This document of the Drug Enforcement Administration was signed on October 25, 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**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–24151 Filed 11–1–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1228P]

Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2024

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2024 aggregate production quotas (APQ) for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs (AAN) for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. For the 2024 quota year, DEA intends to allocate procurement quotas to DEA-registered manufacturers of schedule II controlled substances on a quarterly basis. In order to address domestic drug shortages of controlled substances, procurement quota allocations will be divided between quantities authorized for domestic sales and quantities authorized for export sales.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before December 4, 2023. Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will publish in the **Federal Register** a final order establishing the 2024 aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.