

2017 aggregate production quota for controlled substances in schedules I and II and establishing an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, 21 CFR 1303.11(c) and 1315.11(f).

Dated: July 14, 2016.

Chuck Rosenberg,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Mikhayl Soliman, M.D.: Decision and Order

On March 27, 2015, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Mikhayl Soliman, M.D. (hereinafter, Applicant), of both Wayne, Michigan and Los Angeles, California. The Show Cause Order proposed the denial of Applicant's applications for DEA Certificates of Registration in the States of Michigan and California on multiple grounds. GX 7, at 1.

First, the Show Cause Order alleged that Applicant had previously been registered to handle controlled substances in only Schedule III and IIIN, at the registered address of 3152 South Wayne Road, Wayne, Michigan. *Id.* The Show Cause Order alleged that on September 14, 2012, Applicant was issued an Order to Show Cause and Immediate Suspension of Registration and that he subsequently voluntarily surrendered his registration.

The Show Cause Order alleged that on September 24, 2012, Applicant applied for a new DEA practitioner's registration at his previous registered location in Wayne, Michigan, and that on October 2, 2012, he applied for a new practitioner's registration at a proposed location in Los Angeles, California. *Id.* The Order then alleged that on both applications, Applicant had failed to disclose that he had voluntarily surrendered his registration and had materially falsified both applications. *Id.* at 1-2 (citing 21 U.S.C. 843(a)(4)(A)).

Second, the Show Cause Order alleged that as a result of actions taken by the medical boards of California and Michigan, Applicant is "without authority to practice in the States . . . in which [he] applied for" DEA registrations. *Id.* at 2. Specifically, the Show Cause Order alleged that on January 15, 2014, the Michigan Board of Medicine issued a Consent Order which

found that he "had prescribed controlled substances . . . in a manner which demonstrated negligence, incompetence, and a lack of good moral character" and that he "prescribed, gave away or administered drugs for other than lawful diagnostic or therapeutic purposes." *Id.* The Order also alleged that the Michigan Board had suspended his medical license for six months and one day and required that he petition the Board for reinstatement; the Order then alleged that Applicant's Michigan medical license remains suspended. *Id.* The Order further alleged that based on the Michigan Board's findings, the Medical Board of California revoked his California license effective October 10, 2014. *Id.*

Finally, the Show Cause Order alleged that on May 16, 2012, DEA Investigators had seized 323 patient files which Applicant had discarded in the trash at his residence, and that the files showed that Applicant had prescribed both hydrocodone (then a Schedule III controlled substance) and alprazolam (a Schedule IV drug) "to the majority of these patients." *Id.* The Order then alleged that DEA Investigators obtained information from the Michigan Automated Prescriptions System which showed that "between January 1, 2007 and August 20, 2012, [Applicant] prescribed at least 19,409 dosage units of [s]chedule II [drugs], 725,760 dosage units of [s]chedule IV [drugs], and 246,397 dosage units of [s]chedule V [drugs], without the registered authority to do so." *Id.*¹

Thereafter, the Government attempted to serve the Show Cause Order by FedEx delivered to the proposed business address Applicant used when he applied for a registration in Los Angeles. GX 9, at 1. The Government did not, however, require a signature. *Id.* at 1-2. Moreover, the Government does not point to any precedent of either the courts or this Agency which allows for the use of FedEx to serve a charging document or complaint (as opposed to post-service filings) on a person.² Thus, this attempt was deemed inadequate to accomplish service.

The Government also noted that it emailed a lawyer who was representing Applicant "in a pending criminal matter" and asked him if he could

¹ The Show Cause Order also notified Applicant of his right to either request a hearing on the allegations of the Order to Show Cause or to submit a written statement while waiving his right to a hearing, the procedure for electing either option, and the consequence of failing to elect either option. GX 7, at 3.

² Nor am I aware of any rules of procedure which allow for a charging document or complaint to be served in this manner.

confirm Applicant's current address or accept service on Applicant's behalf. GX 10. The lawyer, however, did not respond. Request for Final Agency Action, at 3. Moreover, according to the Government, a Supervisory Diversion Investigator phoned the attorney and asked for Applicant's address in order to serve the Show Cause Order. *Id.* According to the Government, while the attorney stated that he would contact the Government's counsel, he did not.³ *Id.*

The Government then mailed the Show Cause Order by certified mail, return receipt requested, addressed to Applicant at his proposed business address in Wayne, Michigan. GX 11, 12, and 13. Several weeks later the mailing was returned unclaimed, with the Post Office indicating that it was "unable to forward" the mailing. GX 13. The Government did not, however, send the Show Cause Order to Applicant by First Class Mail. *See Jones v. Flowers*, 547 U.S. 220 (2006).

Subsequently, the Government submitted a Request for Final Agency Action along with the Investigative File. Upon review of the record, I found that service was inadequate and directed that the Request for Final Agency Action be returned.

On November 9, 2015, the Government again mailed the Show Cause Order by certified mail, return receipt requested, addressed to Applicant at his proposed registered location. Here again, several weeks later the mailing was returned by the Post Office as undeliverable. GX 18.

Also on November 9, 2015, the same day the Government had re-mailed the Show Cause Order, it emailed the Order to Applicant at the email address he had provided to the Agency on his applications. According to an affidavit submitted by the Government, it "did not receive any bounce-back email or other indication that the email . . . was undeliverable or otherwise not received." GX 19.

Upon re-submission of its Request for Final Agency Action, the Government advised that on September 24, 2015, Applicant was found guilty in the United States District Court for the Eastern District of Michigan on multiple counts of health care fraud and aiding and abetting the unlawful distribution of controlled substances. Request for Final Agency Action, at 4; *see also* GX 15, at 5). The Government further advised that on October 5, 2015,

³ Given that Applicant had been criminally charged and released on bond, the Pre-Trial Services Office would likely have been a more fruitful source for obtaining his residence address.

Applicant failed to appear for a bond hearing leading the District Court to issue a bench warrant for his arrest.

Based on the above, I find that the Government has satisfied its obligation under the Due Process Clause “to provide ‘notice reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.’” *Jones*, 547 U.S. at 226 (quoting *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950)). Due process does not, however, require actual notice, *Jones*, 547 U.S. at 226 (quoting *Dusenbery v. United States*, 534 U.S. 161, 170 (2002)), but rather, only “‘notice reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.’” *Id.* (quoting *Mullane*, 339 U.S. at 314). Moreover, the Government is not required to undertake “heroic efforts” to find an applicant. *Dusenbery*, 534 U.S. at 170 (2002).

Here, I conclude that Applicant’s secreting himself rendered the Government’s use of the traditional means of service futile, and that therefore, the Government was entitled to attempt to serve the Show Cause Order by emailing it to him at the email address he had previously provided to the Agency. See *Rio Properties, Inc. v. Rio Int’l Interlink*, 284 F.3d 1007, 1017–18 (9th Cir. 2002); see also *Snyder, et al. v. Alternate Energy Inc.*, 857 N.Y.S. 2d 442, 447–449 (N.Y. Civ. Ct. 2008); *In re International Telemedia Associates, Inc.*, 245 B.R. 713, 721–22 (Bankr. N.D. Ga. 2000).

To be sure, courts have recognized that the use of email to serve process has “its limitations,” including that “[i]n most instances, there is no way to confirm receipt of an email message.” *Rio Properties*, 284 F.3d at 1018. Here, however, I conclude that the use of email to serve Applicant satisfied due process because service was made to an email address he had previously provided to the Agency and the Government did not receive back either an error or undeliverable message. See *Richard C. Quigley, D.O.*, 79 FR 50945 (2014); *Emilio Luna, M.D.*, 77 FR 4829 (2012), see also *Robert Leigh Kale*, 76 FR 48898, 48899–900 (2011). Thus, I am satisfied that the Government has provided Applicant with notice “reasonably calculated . . . to apprise [him] of the pendency of the action” and to present his objections.⁴ *Jones*, 547

U.S. at 226 (quoting *Mullane*, 339 U.S. at 314).

Having found that the service of the Show Cause Order was constitutionally adequate, I turn to whether Applicant has waived his right to a hearing or to submit a written statement in lieu of a hearing. According to the Government, since the re-service of the Show Cause Order, neither Applicant, nor anyone purporting to represent him, has requested a hearing or submitted a written statement of position. Accordingly, as more than 30 days have now passed since the date of service, I find that Applicant has waived his right to a hearing or to submit a written statement. 21 CFR 1301.43(d). I therefore issue this Decision and Final Order based on relevant evidence contained in the Investigative Record submitted by the Government. *Id.* 1301.43(d) & (e). I make the following additional findings of fact.

Findings of Fact

Applicant previously held DEA Certificate of Registration BS9471309, pursuant to which he was authorized to dispense controlled substances in Schedules III and IIIN, at the registered address of Soliman Medical Center, 3152 South Wayne Road, Wayne, Michigan. GX 2, at 1. However, on September 14, 2012, the former Administrator issued an Order to Show Cause and Immediate Suspension of Registration to Applicant, based on allegations that he was prescribing controlled substances in Schedules II, IV, and V, for which he lacked authority, and that he also issued prescriptions for drug cocktails of hydrocodone (then Schedule III) and alprazolam (Schedule IV) which lacked a legitimate medical purpose. GX 3, at 1–2. The former Administrator also noted that of the 323 patient files DEA Investigators found in his trash, 143 of the patients had “criminal histories involving controlled substance violations.” *Id.* at 2. The same day, Applicant voluntarily surrendered his registration “in view of [his] alleged failure to comply with the Federal requirements pertaining to controlled substances.” GX 4, at 1.

Four days later, on September 21, 2012, Applicant submitted an application for a new registration as a practitioner in Schedules IIN, III, IIIN and IV at the registered address of 3152 South Wayne Road, Wayne, Michigan. The DEA Chief of Registration certified

that on his application, Applicant answered “No” to question 3, which asks: “[h]as the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?” GX 1, at 1, 3. This application remains pending before the Agency. *Id.* at 1.

On October 1, 2012, Applicant submitted a second application for registration as a practitioner in Schedules III, IIIN, IV, and V, at the registered address of 3844 Wasatch Ave #4, Los Angeles, California. GX 8. The DEA Chief of Registration certified that on his application, Applicant answered “No” to the question, “Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?” GX 8, at 2, 4.

On February 25, 2013, the Michigan Board of Medicine’s Disciplinary Subcommittee filed an Administrative Complaint against Applicant. GX 5, at 13. Based on a review of 20 patient charts, the Board alleged that his charting was lacking:

- (1) “information pertaining to past medical history or current treating clinicians”;
- (2) “any findings pertaining to pain assessment, level of dysfunction from pain, treatment plan, or diagnostic testing”;
- (3) “any documentation pertaining to patient informed consents, prescribing agreements, pain assessments, clinical documentation, drug analysis screens, lab test results, patient risk assessments, copies of previous medical records, or the implementation of a pain management program”; and
- (4) “any documentation that [he] monitored the patients’ use of the controlled substances for drug dependency or diversion, or that he verified the efficacy of the long term use of the controlled substances in treating the diagnoses of the patients.”

Id. at 10–11. The Board also alleged that the charts “lack[ed] documentation that [he] counselled the patients about the risk associated with being prescribed a combination of hydrocodone and alprazolam, or the long term effects of continued consumption of acetaminophen.” *Id.* Based on its findings, the Board alleged that Applicant had violated various provisions of Michigan law, and had engaged in “selling, prescribing, giving away, or administering drugs for other than lawful diagnostic or therapeutic purposes.” *Id.* at 12 (quoting Mich. Comp. Laws section 162221(c)(iv)).

On January 15, 2014, Applicant stipulated with the Board to the entry of a Consent Order, pursuant to which his medical license was suspended for six months and one day, effective February

⁴ Because Applicant is a fugitive, I need not decide whether the Government could have satisfied its constitutional obligation by simply re-

mailing the Show Cause Order to him by regular first class mail as the Supreme Court’s decision in *Jones v. Flowers* suggests. *Jones*, 547 U.S. at 234–35.

15, 2014.⁵ GX 5, at 1–3. However, the Consent Order also provided that the reinstatement of Applicant's medical license "is not automatic and that he will have to petition for reinstatement" and show that he is of "good moral character," that he has "the ability to practice . . . with reasonable skill and safety," that he has satisfied "the guidelines on reinstatement," and that the reinstatement of his license "is in the public interest." *Id.* at 2. *See also* M.C.L.A. 333.16221.

To date, Applicant has not been reinstated. I therefore find that Applicant is currently without authority to dispense controlled substances in Michigan, one of the States in which he seeks registration.

Applicant also formerly held a Physician's and Surgeon's Certificate issued by the Medical Board of California. However, on October 10, 2014, the Medical Board revoked his Physician's and Surgeon's Certificate based on the Michigan Board of Medicine's suspension of his Michigan medical license.

In its Request for Final Agency Action, the Government notes that the Order to Show Cause also sought to deny Applicant's application for a DEA registration in California on the basis that the California Medical Board had revoked his medical license. Request for Final Agency Action, at 2 n.1. The Government, however, now advises that "subsequent to the issuance of the [Show Cause Order], the undersigned counsel learned that the . . . Los Angeles Field Division . . . withdrew [Applicant]'s application pursuant to 21 CFR 1301.16(b), which provides that 'failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.'" *Id.* (quoting 21 CFR 1301.16(b)). The Government further explains that in December 2014, the Los Angeles Field Division "attempted to reach [Applicant] via certified mail at his application addresses in California and Michigan, [but] the certified letters were returned as unclaimed and undeliverable, and consequently, [his] application for a DEA Registration in California was 'deemed' a withdrawal and terminated in the registration database." *Id.* at 2–3.

The Agency's registration records (of which I take official notice, *see* 5 U.S.C. 556(e)), show that on December 5, 2014, Applicant was sent a letter requesting that he provide a valid California

Medical Board license number in order to process his pending application for registration. According to the affidavit of the then-chief of the Agency's registration unit, on February 27, 2015, Applicant's October 1, 2012, application for his proposed Los Angeles, California address was deemed "withdrawn and retired from the DEA computer system." GX 8, at 1.

Discussion

Pursuant to section 303(f) of the Controlled Substances Act, "[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(f). Section 303(f) 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 the consideration of the following factors:

- (1) The recommendation of the appropriate State licensing board or appropriate disciplinary authority.
 - (2) The Applicant's experience in dispensing . . . controlled substances.
 - (3) The Applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
 - (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
 - (5) Such other conduct which may threaten the public health and safety.
- Id.*

"These factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether . . . an application for registration [should be] denied." *Id.* Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011) (quoting *Volkman*, 567 F.3d 215, 222 (6th Cir. 2009) (quoting *Hoxie*, 419 F.3d 477, 482 (6th Cir. 2005))).⁶

In this case, I conclude that the record supports two independent grounds for

denying Applicant's application for a DEA registration. First, Applicant does not possess authority under the laws of Michigan, the State in which he seeks registration with the Agency. Second, Applicant materially falsified his application for a DEA registration.

Applicant's Lack of State Authority

Under the Controlled Substances Act (CSA), a practitioner must be currently authorized to handle controlled substances in "the jurisdiction in which he practices" in order to obtain a DEA registration. *See* 21 U.S.C. 823(f) ("The Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices."). *See also* 21 U.S.C. 802(21) ("[t]he term 'practitioner' means a physician . . . licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice"). Moreover, the CSA authorizes the revocation of a registration "upon a finding that the registrant . . . has had his State license or registration suspended [or] revoked . . . and is no longer authorized by State law to engage in the . . . distribution [or] dispensing of controlled substances." *Id.* section 824(a)(3). As the Supreme Court has explained, "[i]n the case of a physician, this scheme contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice." *United States v. Moore*, 423 U.S. 122, 140–41 (1975).

Based on these provisions, DEA has long and repeatedly held that the possession of state authority is a prerequisite for obtaining and maintaining a practitioner's registration. *See Frederick Marsh Blanton, M.D.*, 43 FR 27616, 27617 (1978) ("State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration."). *See also Sheran Arden Yeates*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci*, 58 FR 51104, 51105 (1993); *Bobby Watts*, 53 FR 11919, 11920 (1988).

Here, the investigative file establishes that the Michigan Board suspended applicant's medical license on February 15, 2014. Moreover, as found above, Applicant's Michigan medical license remains suspended as of the date of this Decision and Order. I therefore find that Applicant is without authority to dispense controlled substances in

⁵ Applicant was not required to admit that the allegations were true. GX 5, at 3.

⁶ "In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the [applicant]. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the [applicant's] misconduct." *Jayam Krishna-Iyer*, 74 FR 459, 462 (2009).

Michigan, the State in which he seeks registration. Because he does not meet this prerequisite for obtaining a DEA registration, I will deny his application on this basis.

Material Falsification

Pursuant to section 304(a)(1), the Attorney General is also authorized to suspend or revoke a registration “upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter.” 21 U.S.C. 824(a)(1). It is well established that the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered in deciding whether to grant or deny an application under section 303. *See The Lawsons, Inc.*, 72 FR 74334, 74337 (2007); *Anthony D. Funches*, 64 FR 14267, 14268 (1999); *Alan R. Schankman*, 63 FR 45260 (1998); *Kuen H. Chen*, 58 FR 65401, 65402 (1993).

Thus, the allegation that Applicant materially falsified his application is properly considered in this proceeding. *See Samuel S. Jackson*, 72 FR 23848, 23852 (2007). Moreover, just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application. *The Lawsons*, 72 FR 74338; *cf. Bobby Watts, M.D.*, 58 FR 46995 (1993).

Here, the Government’s evidence shows that upon being served with an Order to Show Cause and Immediate Suspension of Registration which alleged that he had prescribed controlled substances in violation of the CSA, Applicant surrendered his registration. GXs 3 & 4. Moreover, on the Voluntary Surrender form, Applicant acknowledged that he was doing so “[i]n view of my alleged failure to comply with the Federal requirements pertaining to controlled substances.” GX 4. Yet days later, Applicant applied for a new registration and provided a “no” answer to the question: “[h]as the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?” GX 1, at 1, 3.

Applicant’s answer was false as he had clearly surrendered his registration for cause. His false answer was also material as “it ‘ha[d] a natural tendency to influence, or was capable of influencing, the decision of the decisionmaking body to which it was addressed.” *Kungys v. United States*,

485 U.S. 759, 770 (1988) (quoting *Weinstock v. United States*, 231 F.2d 699, 701 (D.C. Cir. 1956)) (other citation omitted); *see also United States v. Wells*, 519 U.S. 482, 489 (1997) (quoting *Kungys*, 485 U.S. at 770). As the Supreme Court has further explained, “it has never been the test of materiality that the misrepresentation or concealment would *more likely than not* have produced an erroneous decision, or even that it would *more likely than not* have triggered an investigation, but rather, whether the misrepresentation or concealment was predictably capable of affecting, *i.e.*, had a natural tendency to affect, the official decision.” *Kungys*, 485 U.S. at 771. While the evidence must be “clear, unequivocal, and convincing,” the “ultimate finding of materiality turns on an interpretation of the substantive law.” *Id.* at 772 (int. quotations and citations omitted).

Applicant’s false answer to the question of whether he had ever surrendered his federal registration was clearly “capable of affecting” the decision of whether to grant his application. As the evidence shows, Applicant surrendered his registration in response to allegations that he violated the CSA and DEA regulations by prescribing controlled substances that were in schedules for which he lacked authorization, as well as allegations that he issued prescriptions that lacked a legitimate medical purpose. GX 3, at 2 (Sept. 24, 2012 Immediate Suspension Order) (citing 21 U.S.C. 822(b) and 841(a)(1); 21 CFR 1301.12(a) and 1306.04(a)). Notably, under the public interest standard, the Agency is required to consider both the Applicant’s “experience in dispensing . . . controlled substances” and his “[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.” 21 U.S.C. 823(f)(2) & (4). *See also Shannon L. Gallentine, D.P.M.*, 76 FR 45864, 45866 (2011).

Thus, notwithstanding that the Agency did not grant his application, his false answer was still material as it was capable of influencing the decision as to whether to grant his application. *See United States v. Alemany Rivera*, 781 F.2d 229, 234 (1st Cir. 1985) (“It makes no difference that a specific falsification did not exert influence so long as it had the capacity to do so.”); *United States v. Norris*, 749 F.2d 1116, 1121 (4th Cir. 1984) (“There is no requirement that the false statement influence or effect the decision making process of a department of the United States Government.”). Accordingly, I conclude that Applicant materially falsified his September 2012 application

for registration. This provides a further reason to deny his pending application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Mikhayl Soliman, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective immediately.

Dated: July 15, 2016.

Chuck Rosenberg,
Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-420P]

Proposed Adjustments to the 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 2016

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to adjust the 2016 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 22, 2016. 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 his 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