

According to the New York Controlled Substances Act (hereinafter, the Act), “[i]t shall be unlawful for any person to manufacture, sell, prescribe, distribute, dispense, administer, possess, have under his control, abandon, or transport a controlled substance except as expressly allowed by this article.” N.Y. Pub. Health Law § 3304 (West 2020). The Act defines “practitioner,” as “a physician . . . or other person licensed, or otherwise permitted to dispense, administer, or conduct research with respect to a controlled substance in the course of a licensed professional practice. . . .” *Id.* at § 3302(29). Finally, New York regulations state that “[a] prescription for a controlled substance may be issued only by a practitioner who is . . . authorized to prescribe controlled substances pursuant to his licensed professional practice . . .” N.Y. Comp. Codes R. & Regs. Tit. 10, § 80.64 (West 2020).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in New York. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in New York. Thus, because Registrant lacks authority to practice medicine in New York and, therefore, is not authorized to handle controlled substances in New York, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant’s DEA registration be revoked.

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. BG6075875 issued to Irene G. Gurvits, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Irene G. Gurvits, M.D. to renew or modify this registration or for any other registrations in the State of New York. This Order is effective January 28, 2021.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–33]

Steven M. Kotsonis, M.D.; Order

On May 3, 2018, the Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC) to Steven M. Kotsonis, M.D. (hereinafter, Respondent), which sought to revoke Respondent’s DEA Certificate of Registration FK1584336 and to deny any pending applications for renewals or modifications of such registration, based on its contention that his continued registration is inconsistent with the public interest. Administrative Law Judge Exhibit (ALJX) 1 (OSC). In response to the OSC, Respondent submitted a timely request for a hearing, which was held from August 14–17, 2018. On October 23, 2018, Chief Administrative Law Judge John J. Mulrooney, II issued a Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision), which recommended that I revoke Respondent’s registration and that I deny any pending application for renewal. Respondent filed Exceptions to the Recommended Decision, and the record was forwarded to me for final Agency action on November 26, 2018.

After reviewing the record, I learned that Respondent had surrendered his DEA registration on December 23, 2019. I issued an Order on September 25, 2020, requiring the Government to produce documentation of Respondent’s surrender of his registration. The Order further instructed the parties to file a Request for Dismissal “if it is the intent of [the] party to rely on Respondent’s voluntary surrender of his registration to terminate this proceeding” or a brief on the issue “if [the] party opposes the dismissal of this proceeding prior to the issuance of my Decision on the Government’s allegation in the OSC.” Both parties filed timely responses.

Respondent filed a Request for Dismissal on October 15, 2020. As grounds for the dismissal, Respondent stated that, “upon DEA request, he voluntarily surrendered his DEA registration on December 23, 2019.” Respondent Request for Dismissal.

The Government submitted a response to my September 25 Order on October 23, 2020 (hereinafter, the Government Response). As required by my September 25 Order, the

Government submitted a copy of the Voluntary Surrender of Controlled Substances Privileges form, DEA–104, signed by Respondent surrendering DEA Registration No. FK1584336. The Government stated that Respondent voluntarily surrendered his DEA registration following a guilty plea to felony criminal drug charges in a criminal matter concurrent to the instant matter. Government Response at 2. The Government Response neither requested that I dismiss this matter nor that I file a final Decision on the allegations it made in the OSC. Rather, the Government provided legal arguments regarding why Respondent’s voluntary surrender of his registration did not preclude me from issuing a final Decision. *Id.* at 2–3. The Government then concluded its Response stating that I “should issue whatever order is appropriate in light of the administrative record presented.” *Id.* at 3.

Based upon my review of the parties’ submissions, the record, and public documents from Respondent’s criminal case, I am granting Respondent’s Request for Dismissal.

Facts

Respondent was registered with DEA as a practitioner in schedules II through V under Certificate of Registration No. FK1584336, at the registered address of 347 Park Ave., Pewaukee, Wisconsin 53702. OSC at 1. In its OSC, the Government contended that Respondent’s registration was inconsistent with the public interest and should be revoked because Respondent failed to comply with applicable federal law relating to controlled substances. *Id.* at 1–2. Specifically, the OSC alleged that Respondent issued prescriptions for controlled substances outside the usual course of professional practice and not for a legitimate medical purpose, in violation of 21 CFR 1306.04(a). *Id.* at 2.

On December 23, 2019, Respondent voluntarily surrendered his DEA registration. Government Response, Attachment 1 (DEA Form 104 signed by Respondent). In his surrender form, Respondent affirmed that he was voluntarily surrendering his registration for cause “[i]n view of [his] alleged failure to comply with the Federal requirements pertaining to controlled substances.” *Id.* Respondent also acknowledged that submitting the form to DEA would result in the immediate termination of his registration. *Id.*

The Government stated in its Response that Respondent surrendered his DEA registration “following a guilty plea to felony criminal drug charges in [a] concurrent criminal matter.”

Government Response, at 1–2. According to the publicly available records from the Respondent’s concurrent criminal matter, *U.S. v. Steven M. Kotsonis*, No. 2:16–CR–92 (E.D. Wis. filed July 21, 2016), Respondent was criminally indicted on June 21, 2016, on twenty counts alleging violations of the Controlled Substances Act, specifically 21 U.S.C. 841(a)(1), (b)(1)(C), and 846.¹ Respondent pled guilty to one count, Count 17, of the indictment for “dispensing unlawfully a controlled substance outside a professional medical practice and not for a legitimate medical purpose” in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C). Judgment, at 1, *Kotsonis*, No. 2:16–cr–92.

Attachment A of the Plea Agreement, which I have attached to this Order, provides a narrative of the factual basis for Respondent’s guilty plea.² Plea Agreement, at 13–15, *Kotsonis*, No. 2:16–cr–92. In brief summary, Respondent admitted that the clinic he co-owned, and at which he was the exclusive health care provider, only accepted cash, that individuals paid \$200 to \$350 in cash to obtain a prescription, that “[p]rescriptions were written for large quantities of Oxycodone, particularly Oxycodone 30 mg (average of 150–180 tablets per month), along with other narcotic medications commonly prescribed for pain relief such as amphetamine and morphine,”³ and that “[i]ndividuals frequently obtain[ed] prescriptions at [his clinic] without being examined or having their vitals (height, weight, blood pressure) taken during the visit.” *Id.* at 13. Respondent also admitted to signing

controlled substance prescriptions prepared by his office manager, who was not a licensed health care provider, without examining the patients or reviewing the patients’ files. *Id.* at 13 and 15. In regard to the specific count to which Respondent pled guilty, Count 17 of the indictment, Respondent admitted that on January 31, 2013, he signed a prescription for 90 tablets of Oxycodone 30 mg for “Patient D” that the clinic’s office manager prepared and that he did so without seeing Patient D. *Id.* at 14. When Patient D was interviewed regarding Respondent’s clinic, she stated that, despite having visited the clinic and received prescriptions for Oxycodone on four prior occasions, “she did not see [Respondent], did not have vitals taken, did not receive any type of medical exam, and did not submit a urine screening.” *Id.* at 13.

Discussion

DEA regulations promulgated pursuant to the authority delegated by the Controlled Substances Act (CSA) provide that “the registration of any person . . . shall terminate, without any further action by the Administration, if and when such person . . . surrenders a registration.” 21 CFR 1301.52. As Respondent surrendered his DEA registration on December 23, 2019, pursuant to the regulation, his registration terminated on the day of his surrender, and Respondent is no longer authorized to dispense controlled substances under federal law.

The termination of Respondent’s registration, however, does not automatically terminate this proceeding. Although factually distinct from registrations terminated through a voluntary surrender, DEA has issued final decisions revoking registrations subsequent to their expirations, and the legal reasoning for the Agency’s ability to issue decisions in those matters is applicable here. As my predecessor explained in *Jeffrey Olsen, M.D.*, in which he ordered the revocation of an expired registration, “mootness does not play the same role in administrative agency adjudications as it plays in Article III court proceedings” and “[t]he agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.” 84 FR 68,474, 68,478 (2019) (quoting *Tennessee Gas Pipeline v. Federal Power Comm’n*, 606 F.2d 1373, 1380 (D.C. Cir. 1979); 5 U.S.C. 554(e)); see also *Climax Molybdenum Co. v. Sec’y of Labor, Mine Safety and Health Admin.*, 703 F.2d 447, 451 (10th Cir. 1983) (“At the outset, we note that

an administrative agency is not bound by the constitutional requirement of a ‘case or controversy’ that limits the authority of [A]rticle III courts to rule on moot issues.”). DEA is therefore not precluded from issuing a final decision revoking a registration that was voluntarily surrendered even though that registration is terminated.

As my predecessor identified in *Olsen*,

[F]inal adjudications are particularly helpful in supporting the purposes of the CSA and my responsibilities to enforce the CSA because nothing in the CSA prohibits an individual or an entity from applying for a registration even when there is a history of being denied a registration, or a history of having a registration suspended or revoked. As such, having a final, official record of allegations, evidence, and the Administrator’s decisions regarding those allegations and evidence, assists and supports future interactions between the Agency and the registrant or applicant.

84 FR at 68,479. As additionally noted in *Olsen*, “a final adjudication is a public record of the Agency’s expectations for current and prospective members of that community.” *Id.* Final adjudications also provide continuing education for all DEA personnel and help coordinate law enforcement efforts. *Id.* Finally, final adjudications inform stakeholders, such as legislators and the public, about the Agency’s work and allows them to provide feedback to the Agency, thereby helping shape how the Agency carries out its responsibilities under the CSA. *Id.*

Since *Olsen* was decided, the Agency has universally issued final adjudications in cases where a registration expired while a proceeding to revoke the registration was pending before the Administrator. See, e.g., *Salvatore Cavaliere, D.O.*, 85 FR 45,657 (2020); *Jaime C. David, M.D.*, 85 FR 10,462 (2020); *Jeanne E. Germeil, M.D.*, 85 FR 73,786 (2020). I recognize, however, that a voluntary surrender for cause of a registration that is executed while the matter is pending before the Administrator can be distinct from the expiration of a registration, depending on the circumstances particular to a matter, and that the aforementioned benefits obtained by a final Agency adjudication could be diminished by those circumstances. I also recognize that the voluntary surrender for cause is an essential tool in preserving Agency enforcement resources and in preventing the misuse of a registration during the pending enforcement action. However, it would be contrary to my duties under the CSA to allow the usurpation of the Agency’s enforcement mission by permitting the unilateral

¹ I am taking official notice of the docket and two documents from Respondent’s criminal matter, the Plea Agreement and the Judgment. *Kotsonis*, No. 2:16–cr–92. 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 fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.” Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Respondent files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (dea.addo.attorneys@dea.usdoj.gov).

² Respondent admitted that the facts in Attachment A are true and “establish his guilt beyond a reasonable doubt.” Plea Agreement, at 2, *Kotsonis*, No. 2:16–cr–92.

³ Oxycodone is a schedule II controlled substance. 21 CFR 1308.12(1).

execution of a voluntary surrender for cause by a registrant after the registrant has availed himself of the hearing process and, particularly where he obtained an unfavorable recommendation from an Administrative Law Judge; and therefore, I find that it is most reasonable to assess whether to adjudicate particular matters to finality based on the particular circumstances presented by the matters.

Based on my evaluation of the record in this matter, I have decided that the benefits to issuing a final adjudication in this matter are diminished by the particular circumstances, and as such, I am dismissing this matter. Here, Respondent voluntarily surrendered his registration for cause concurrent with his guilty plea to a felony, thereby acknowledging that the surrender was “[i]n view of [his] alleged failure to comply with the Federal requirements pertaining to controlled substances.” Government Response, Attach. 1. The Judgment from Respondent’s concurrent criminal case provides a record of Respondent’s criminal violation of the CSA for issuing a prescription for a controlled substance outside the usual course of professional practice and without a legitimate medical purpose, and the Plea Agreement provides an official record of the details of Respondent’s criminal violation. I find that these records provide many of the same benefits that a final Decision would provide in this matter—they will assist and support any future interactions between the Agency and Respondent including by providing the Agency with facts that may be relevant should Respondent re-apply for a registration in the future; they provide a public record regarding the Agency’s expectations of registrants; they inform stakeholders about the Agency’s work; and they enable me to allocate Agency resources efficiently and effectively. Accordingly, I find that it is in the Agency’s interest to dismiss this matter without my issuing a final Decision on the Government’s request to revoke Respondent’s registration, and I will grant Respondent’s Request for Dismissal.

My decision to dismiss this matter should not be interpreted as applying unilaterally to all matters seeking revocation of a registration in which a registrant surrenders their license while the matter is pending before me. The Agency expends considerable resources investigating and adjudicating these matters, not every matter will have such a robust record absent a final adjudication, and each matter is unique. I will, therefore, continue to evaluate

such matters on a case-by-case basis to determine if a final adjudication is warranted.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824, I hereby dismiss the Order to Show Cause issued to Steven M. Kotsonis, M.D. This Order is effective immediately.

Timothy J. Shea,
Acting Administrator.

Attachment A

This investigation began in 2012 and arose in connection with the investigation of Dr. Beaver who operated Beaver Medical Clinic. In April of 2012, Dr. Beaver voluntarily surrendered his DEA registration for cause based upon allegations of improper prescribing of controlled substances and Dr. Beaver’s Wisconsin medical license was limited to preclude him from prescribing controlled substances. In May of 2012, Dr. Kotsonis began working at Beaver Medical Clinic and DEA Investigators met with Kotsonis to notify him of DEA’s concerns that narcotics prescribed at Beaver Medical Clinic were frequently being sold by patients. During this meeting, Kotsonis acknowledged that Moyer, who was the office manager at Beaver Medical Clinic at the time, sometimes prepared prescriptions for him, and he agreed with Investigators when they suggested that Kotsonis himself should prepare the prescriptions.

Sometime prior to December of 2012, Kotsonis relocated his practice to 10721 W Capitol Drive, Office G103, Wauwatosa, Wisconsin, and changed the name of the practice to Compassionate Care Clinic. Moyer continued to work for Kotsonis as the officer manager of the Compassionate Care Clinic (“Compassionate”) and also, at some point, became the co-owner of Compassionate. Moyer is not a licensed health care provider and there are no other licensed physicians, nurses, or other health care providers working at Compassionate aside from Kotsonis.

The investigation of Compassionate has revealed that only cash is accepted and individuals pay \$200 to \$350 in cash to obtain a prescription. Prescriptions are written for large quantities of Oxycodone, particularly Oxycodone 30mg (average of 150–180 tablets per month), along with other narcotic medications commonly prescribed for pain relief such as amphetamine and morphine. Moyer typically fills out the prescriptions and

has Kotsonis sign the prescriptions without Kotsonis actually seeing the individual patient. Individuals frequently obtain prescriptions at Compassionate without being examined or having their vitals (height, weight, blood pressure) taken during their visit.

For example, in January 2013, CS #1 a/k/a Patient “D,” was interviewed regarding Compassionate. CS #1 stated that she was brought to Compassionate by her friend, who was addicted to Oxycodone, and CS #1 was introduced to Moyer by her friend as a new patient. CS #1 stated that she visited Compassionate on approximately 4 occasions and CS #1’s friend went with her on every occasion but one. CS #1’s friend paid for the appointment fee and in return received a portion of CS #1’s pills. CS #1’s friend also brought other individuals to Compassionate to obtain Oxycodone prescriptions. CS #1 provided MRI’s regarding back issues from 2006 to 2008 to Moyer and was accepted as a patient. CS #1 stated that she received prescriptions ranging from 150–210 tablets of Oxycodone 30 mg at each of her visits to Compassionate. During the visits CS #1 did not see Kotsonis, did not have vitals taken, did not receive any type of medical exam, and did not submit a urine screening. CS #1 received prescriptions from Moyer, who prepared the prescriptions and took the prescriptions to Kotsonis for signature. During the visits, Moyer asked CS #1 a few questions about pain and CS #1 stated she had back pain. CS #1 filled out a form regarding pain during each visit. On one occasion CS #1 and her friend went to a visit early and said they were driving to Florida. Moyer asked what they were prescribed last time and CS #1 said 180 tablets of Oxycodone 30mg. Moyer told CS #1 that she would write the prescription for 210 tablets because of the long drive to Florida. Moyer wrote the prescriptions out in the waiting room because they were already signed by Kotsonis. CS #1 stated that during the visits she witnessed Moyer take the patient sign-in sheet, write the individuals’ names and dates of birth on the prescriptions (sometimes written in the waiting room) and take the stack of prescriptions to Kotsonis’s office for signature. Moyer then saw the individuals and wrote the quantities on the prescription. The waiting room was always full with approximately 15 individuals in the waiting room and approximately 5 individuals waiting outside the waiting room in the hallway.

Count Seventeen: On January 31, 2013, CS #1 and an undercover agent (UC #1) visited Compassionate and this visit is audio and video recorded.

During the visit, CS #1 filled out a two-page pain form and CS #1 and UC #1 signed in on the patient sign-in sheet. During the visit, Moyer stood next to the patient sign-in sheet and wrote down names on a prescription pad from the sign-in sheet and she asked some of the individuals for their date of birth and which drug they were prescribed. Moyer entered Kotsonis's office carrying the handwritten prescriptions and exited minutes later. The individuals were provided prescriptions and many did not see Kotsonis. During the visit, Moyer called CS #1 and UC #1 into her office. UC #1 did not see any medical equipment in the office. Moyer asked CS #1 to tell the truth about her current criminal charges. Moyer said she would have to cut CS #1 loose but would give CS #1 a prescription. Moyer said DEA would say what kind of people CS #1 was hanging out with and then "bye bye clinic, bye bye license, bye bye Dr. Steve's career" because DEA would go after the doctor. Moyer said if CS #1's criminal charges were dropped she could come back to the clinic. Moyer said CS #1's friend (who referred CS #1 to the clinic) was dumb because he sold pills to an undercover cop. Moyer asked CS #1 for her name and date of birth and wrote CS #1 a prescription for 90 tablets of Oxycodone 30mg, which Moyer took to Kotsonis to sign. CS #1 paid Moyer \$200 cash for the visit. Moyer asked CS #1 if she knew what people called Moyer. CS #1 said no and Moyer responded "The Oxy Czar." "They call me the gestapo because if you screw up the world will stop, so don't screw up." Moyer then continued to fill out additional prescriptions.

CS #1 asked Moyer if UC #1 could be accepted as a patient and she said everyone who came with CS #1 would have to be rescreened (because of CS #1's criminal charges). Moyer then looked over the MRIs provided by UC #1 and said the second MRI looked a little better than the first. Moyer said she would show the MRIs to the doctor. Moyer opened her desk drawer and pulled out a handful of prescriptions, papers, and cash, then put everything back in the drawer and said "This is a nasty little business we're in." Moyer then said "I own this clinic now, and I don't have to be nice. I don't have to let just anybody in neither. It's my clinic, me and the doctor's clinic, I don't have to let anybody in. And I won't, if I think they're a problem. No way, why would I? Are you kidding? This is a big business here." She told UC #1 that the first office visit was \$350 and UC #1 could come alone next time and asked him/her to bring prescription records.

UC #1 was given a longer version of the pain form provided to CS #1 earlier in the visit to bring back with her to the next visit. Moyer exited her office, called out CS #1's name along with five other names and said she would get the prescriptions signed. Moyer then entered Kotsonis's office and approximately four minutes later she exited Kotsonis's office and handed out the prescriptions. CS #1 and UC #1 then made their next appointment with the receptionist.

On July 23, 2013, a search warrant was executed at Compassionate Care Clinic and Kotsonis' patient files were seized along with other evidence. Patient files, computers, Moyer's cellphone and pre-signed prescriptions (containing the doctor's signature only), filled out prescriptions without signature and ripped up prescriptions were recovered from Moyer's office. Agents also recovered a letter from Costco refusing to fill Dr. Kotsonis' prescriptions and an Express Scripts letter regarding excessive medication prescribed to a patient as well as prefilled out monthly evaluation notes. Agents observed minimal medical equipment in the clinic. During the execution of the search warrant Kotsonis agreed to be interviewed and was advised he was not under arrest. Kotsonis admitted to allowing Moyer to prepare prescriptions that he subsequently signs and said she brings in prescriptions 3-4 patients at a time and that he trusts Moyer's advice on what medication should be prescribed and generally agrees with her. Kotsonis stated most of the time he verifies what prescription the patient is receiving. He stated that if Moyer does not bring the patient file to his office with the prescription to verify he trusts what she says the patient is receiving. Kotsonis estimated 20-25 patients per day are follow up patients and Moyer brings 10-12 patient charts to Kotsonis a day and Kotsonis actually sees and examines 1-2 patients per day. Moyer was also interviewed and stated she and Kotsonis discuss patients but he determines what to prescribe. She stated she writes out prescriptions before the patients are seen based upon their last prescription but does not write down a quantity.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Annamalai Ashokan, M.D.; Decision and Order

On June 1, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Annamalai Ashokan, M.D. (hereinafter, Registrant), OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. BA0859174. *Id.* It alleged that Registrant is without "authority to handle controlled substances in the State of California, the state in which [Registrant is] registered with the DEA." *Id.* at 1-2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that Registrant surrendered his medical license pursuant to an agreement he entered into with the Medical Board of California on November 12, 2019, and that his license remains surrendered. *Id.* at 1-2. The OSC further alleged that because Registrant surrendered his medical license, Registrant lacks the authority to handle controlled substances in the State of California. *Id.* at 2.

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

On June 4, 2020, a DEA Diversion Investigator placed a copy of the OSC addressed to the Registrant in his "office's outgoing mail pickup box for pickup by DEA mailroom staff that day. The letter would have been placed in the United States mail by DEA's mailroom staff no later than the following day, June 5, 2020." Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 4, at 1 (Declaration of Diversion Investigator). Registrant's attorney sent a letter, dated July 22, 2020, to the Assistant Administrator, Diversion Control Division, stating that Registrant had surrendered his medical license and that "he hereby waives his right to a hearing on this matter." RFAAX 5 (Letter from Registrant's Attorney), at 1. I find that more than thirty days have now passed since the Government accomplished service of the OSC.