Waiver No. XR0869719 issued to Craig S. Rosenblum, M.D. I further hereby deny any pending application(s) of Craig S. Rosenblum, M.D., to renew or modify these registrations, as well as any other pending application(s) of Craig S. Rosenblum, M.D., or Aurora Surgery Center LP for registration in California. This Order is effective May 9, 2022.

Anne Milgram,

Administrator.

[FR Doc. 2022–07727 Filed 4–8–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Christopher King, C.N.P.; Decision and Order

On December 18, 2019, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Christopher C. King, N.P. (hereinafter, Applicant) of Manchester, Maine. Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 2 (OSC), at 1. The OSC proposed to deny Applicant's DEA Certificate of Registration application, Number W19022896M, as well as to deny any pending applications for renewal or modification of such registration and any applications for any other registrations pursuant to 21 U.S.C. 824(a)(4) and 823(f), because ''[Applicant's] registration is inconsistent with the public interest.'' *Id.*

The OSC alleged that Applicant had ''exhibited negative experience in handling controlled substances . . . and [had] failed to comply with applicable federal and state laws relating to controlled substances.'' *Id.* at 2. Specifically, the OSC alleged that, while employed at Mercy Hospital from April 10, 2013, to June 13, 2013, Applicant diverted controlled substances on at least two different occasions in violation of federal and state law. *Id.* at 4–6. The OSC also alleged that, while employed at St. Mary's Regional Medical Center (hereinafter, St. Mary's Hospital) from August 25, 2014, until November 1, 2016, Applicant diverted controlled substances on at least five different occasions in violation of federal and state law. *Id.* at 2–3.

The OSC notified Respondent of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 3 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 6–7 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a Declaration dated August 23, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the Manchester District Office stated that on December 18, 2019, she sent a copy of the OSC to ''both [Applicant's] registered and mailing address via First Class Mail'' and ''sent the [OSC] via certified mail on the following day.'' DI's Declaration, at 2. The DI stated that on December 19, 2019, she ''contacted [Applicant] by phone at the mobile number listed on his application.'' *Id.* According to the DI, she ''explained what an [OSC] was, and requested that [Applicant] contact [her] when he received a copy of the [OSC].'' *Id.* The DI stated that on December 26, 2019, she received an email from Applicant that read, '' 'I have received the hard copy of the [OSC] in the mail. I do not want to pursue this matter and do not feel it is necessary to meet and discuss.' '' *Id.; see also* RFAAX 3 (email from Applicant).

The Government forwarded its RFAA, along with the evidentiary record, to this office on August 26, 2021. In its RFAA, the Government represents that Applicant did not request a hearing. RFAA, at 1. The Government requests that ''the Administrator issue a final order denying the DEA Certificate of Registration application for [Applicant]'' because ''Applicant's [r]egistration is not in the public interest.'' *Id.*

Based on the DI's Declaration, the Government's written representations, and my review of the record, I find that the Government accomplished service of the OSC on Applicant on or before December 26, 2019. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the DI's Declaration, the Government's written representations, and my review of the record, I find that neither Applicant, nor anyone purporting to represent Applicant, requested a hearing, submitted a written statement while waiving Applicant's right to a hearing, or submitted a corrective action plan. Accordingly, I find that Applicant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.43(e).

I. Findings of Fact

A. Application for DEA Registration

On March 12, 2019, Applicant applied for a DEA Certificate of Registration as a practitioner in Schedules II through V with a proposed registered address of 29 Bowdoin St, Manchester, ME 04351. RFAAX 1, at 1. Applicant's application was assigned Control No. W19022896M. *Id.*

B. Government's Case

The Government's RFAA includes the DI's Declaration and 10 attached Exhibits, including a copy of Applicant's application for DEA registration, various documents pertaining to the drug diversion allegations against Applicant at both St. Mary's Hospital and Mercy Hospital, and a copy of a Consent Agreement between Applicant and the Maine Board of Nursing in which Applicant's license to practice nursing was suspended. *See* RFAAX 1–10.

The DI's Declaration described the investigation into Applicant, including the collection of the Government's Exhibits. DI's Declaration, at 1–3. On June 13, 2013, Mercy Hospital issued a letter to Applicant following an investigation regarding Applicant's ''suspicious behavior'' during his shift on June 4, 2013. RFAAX 9. According to the letter, on June 4, 2013, ''medical waste (wet bloody paper towel, open syringe wrapper, syringe cap, open band aid wrapper, and an open alcohol wipe wrapper) was found in the bathroom in the staff break room.'' *Id.* Applicant's nurse manager ''had noted that [Applicant] had recently come into the area and had been in the bathroom.'' *Id.* According to the letter, video footage of the Emergency Department area prior to the medical waste being found was reviewed, and Applicant was observed pulling Dilaudid from the Pyxis machine and then entering the patient area for several minutes. *Id.* The video footage showed Applicant going to a supply cart and putting supplies in his pants pocket, then exiting the Emergency Department and entering the staff break room around the same time that Applicant's nurse manager had seen Applicant enter the bathroom. *Id.* The video footage showed Applicant returning to the Emergency Department several minutes later and going immediately to a sharps disposal container, where he pulled something from his pants pocket to dispose of in that container. *Id.* Finally, the video footage showed Applicant requesting an

additional dose of Dilaudid from the ordering physician for the patient. *Id.*

According to the letter, after review of Applicant's other worked shifts since his start at Mercy Hospital, there was ''further concern that similar behavior occurred on another shift.'' *Id.* During a meeting with Applicant on June 4, 2013, Applicant ''indicated that the patient did receive both doses of Dilaudid on that day; however, [Applicant was] unable to provide a clear answer as to why [he] had put a sharp in [his] pocket and later disposed of it [ ] when there are sharps containers in every patient bay[ ].'' *Id.* Moreover, during a phone conversation on June 12, 2013, Applicant ''declined to return to Mercy [Hospital] to participate in a follow-up conversation to [the] investigation.'' *Id.* According to the letter, Applicant was told that because of his behavior, Mercy Hospital had concerns that he may have been diverting medication, and consequently, Applicant's employment at Mercy Hospital was terminated effective June 13, 2013. *Id.*

On November 1, 2016, a Risk Manager at St. Mary's Hospital issued a Memorandum to the HR department regarding an ''Investigation of Suspicion of Drug Diversion.'' RFAAX 6, at 1. According to the Memorandum, on September 24, 2016, Applicant ''was found to have pulled a medication for another Emergency Department nurse's patient.'' *Id.* Further, chart documentation ''notes the medication as 'contaminated' and another vial was pulled and given to the patient by the nurse assigned to that patient.'' *Id.* The medication pulled was ''Hydromorphone 1 mg/1 mL Syringe.'' *Id.* According to the Memorandum, ''[w]hen handed to the other nurse, she noticed that the vial had been accessed and reported it to the nursing supervisor who then contacted the Director of the Emergency Department.'' *Id.* Staff was then instructed to safeguard the vial so that it could be sent for testing, with the results of the testing showing that the vial was at half concentration, indicating that it had been tampered with. *Id.; see also* RFAAX 7.

According to the Memorandum, there had been other suspicious incidents involving Applicant and several sharps containers in the Emergency Department. RFAAX 6, at 1. ''On one occasion, [Applicant] lost his ring in a sharps container in the [Emergency Department].'' *Id.* ''On another occasion, [Applicant] was found to be bleeding from his hand,'' and although he told staff he had cut himself on the sink, ''no blood was found on the sink but blood was noted on the sharps container located in that area.'' *Id.* The Memorandum notes that ''[t]here was no confirmation that [Applicant] accessed this sharps container.'' *Id.*

The Memorandum further states that ''[a] chart audit was performed to determine Pyxis access by [Applicant]'' and ''[a] report of [Applicant's] Pyxis access from August 25, 2016 to September 24, 2016 was run and reviewed against patient charts for that time period.'' *Id.* Further, ''[i]t was also reviewed against a full Pyxis report for all users for the same time period.'' The Memorandum states that ''[s]everal missing waste documentation was found from this initial chart audit.'' *Id.* On September 3, 2016, a 1 mg/1 mL syringe of Hydromorphone was removed, but only 0.5 mg was documented to be given to the patient, with no waste documented for the excess controlled substance. *Id.* On September 5, 2016, a 100 mcg/2 mL vial of Fentanyl Citrate for another nurse's patient was removed, but only 50 mcg was documented to be given to the patient, with no waste documented for the excess medication. *Id.* at 2. On September 10, 2016, a 2 mg/1 mL vial of Lorazepam was removed, but only 0.5 mg was ordered and documented to be given to the patient, with no waste documented for the excess controlled substance. *Id.* Finally, on September 11, 2016, a 100 mcg/2 mL vial of Fentanyl Citrate was removed, but only 50 mcg was ordered and documented to be given to the patient, with no waste documented for the excess controlled substance. *Id.*

On November 1, 2016, St. Mary's Hospital issued a letter to Applicant notifying him of his immediate dismissal from employment. RFAAX 5. In addition to the incidents of potential drug diversion previously identified in the above-described Memorandum, the letter also stated that Applicant ''falsified and omitted pertinent facts from [his] St. Mary's [Hospital] Employment Application by indicating that [his] prior employment at CMMC was still 'present' and for omitting pertinent employment information for [his] work and termination from Mercy Hospital in 2013.'' *Id.*

On October 16, 2017, Applicant signed a Consent Agreement for Reprimand, Suspension, and Probation (hereinafter, Consent Agreement) issued by the State of Maine Board of Nursing (hereinafter, the Board). RFAAX 10, at 1 and 5. The Consent Agreement includes facts pertaining to Applicant's alleged diversion while employed at St. Mary's Hospital, along with additional facts, such as that Applicant ''has a March 31, 2014 letter of concern on file with the Board in which the Board communicates its concern regarding 'the importance of the proper administration, waste and disposal of scheduled drugs in any employment setting.' '' *Id.* at 1–2. By signing the Consent Agreement, Applicant agreed to accept a Reprimand and agreed that his license would be suspended for one year followed by at least two years of probation. *Id.* at 2–3. Applicant also agreed that during the period of suspension, he would not ''work in any capacity requiring a nursing license'' and that he would continue to participate in the Maine Medical Professionals Health Program (hereinafter, MPHP) and ''remain in compliance with all the terms of his current MPHP monitoring agreement.'' *Id.* at 2.

II. Discussion

A. 21 U.S.C. 823(f): The Five Public Interest Factors

Pursuant to section 303(f) of the CSA, ''[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(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 consideration of the following factors:

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

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

21 U.S.C. 823(f).

The DEA considers these public interest factors in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *Drug Enf't Admin.,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 FR 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Furthermore, there is no

requirement to consider a factor in any given level of detail. *Trawick* v. *Drug Enf't Admin.,* 861 F.2d 72, 76–77 (4th Cir. 1988). The balancing of the public interest factors ''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 registrant. Rather, it is an inquiry which focuses on protecting the public interest . . . .'' *Jayam Krishna-Iyer, M.D.,* 74 FR 459, 462 (2009). When deciding whether registration is in the public interest, the DEA must consider the totality of the circumstances. *See generally Joseph Gaudio, M.D.,* 74 FR 10083, 10094–95 (2009) (basing sanction on all evidence on record).

The Government does not dispute that Applicant holds a valid state nursing license and is authorized to dispense controlled substances in the State of Maine where he practices. *See* OSC, at 2. While I have considered all of the public interest factors [1] in 21 U.S.C. 823(f), the public interest factors that are most relevant to the Government's case for denial of Applicant's application are Public Interest Factors One, Two, and Four. *See* RFAA, at 5–6. Moreover, the Government has the burden of proof in this proceeding. 21 CFR 1301.44. I find that the Government's evidence with respect to Factors Two, and Four satisfies its *prima facie* burden of showing that Applicant's registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(f). Specifically, I find that the record contains substantial evidence that Applicant violated both Maine law and federal law when he diverted controlled substances from Mercy Hospital and St. Mary's Hospital. I further find that Applicant failed to provide evidence to rebut the Government's *prima facie* case.

1. Factor One

In determining the public interest under Factor One, the ''recommendation of the appropriate State licensing board or professional disciplinary authority'' shall be considered. 21 U.S.C. 823(f)(1). ''Two forms of recommendations appear in Agency decisions: (1) A recommendation to DEA directly from a state licensing board or professional disciplinary authority (hereinafter, appropriate state entity), which explicitly addresses the granting or retention of a DEA COR; and (2) the appropriate state entity's action regarding the licensure under its jurisdiction on the same matter that is the basis for the DEA OSC.'' *John O. Dimowo,* 85 FR 15800, 15809 (2020); see also *Vincent J. Scolaro,* D.O., 67 FR 42060, 42065 (2002) (''While the State Board did not affirmatively state that the Respondent could apply for a DEA registration, [the ALJ] found that the State Board by implication acquiesced to the Respondent's application because the State Board has given state authority to the Respondent to prescribe controlled substances.'').

As previously discussed, on October 16, 2017, Applicant entered into a Consent Agreement issued by the Board. RFAAX 10, at 1 and 5. The Board's Consent Agreement includes some of the allegations against Applicant that were addressed in the OSC and RFAA—namely, those pertaining to Applicant's alleged diversion while employed at St. Mary's Hospital. *Id.* at 1–2. Further, the Consent Agreement includes additional facts related to Applicant's alleged history of diversion such as that Applicant ''has a March 31, 2014 letter of concern on file with the Board in which the Board communicates its concern regarding 'the importance of the proper administration, waste and disposal of scheduled drugs in any employment setting.' '' *Id.* at 2. The Consent Agreement suspends Applicant's license for one year followed by at least two years of probation. *Id.* at 2–3. The Consent Agreement also prohibited Applicant from ''work[ing] in any capacity requiring a nursing license'' during the suspension and required him to ''continue to participate in the MPHP and remain in compliance with all the terms of his current MPHP monitoring agreement.'' *Id.* at 2.

While the Board's Consent Agreement is not a ''direct recommendation'' for purposes of Factor One, it does indicate a recommendation by the appropriate state entity regarding a large portion of the allegations and evidence before me. *John O. Dimowo,* 85 FR at 15180. The Consent Order makes clear that the Board was aware of Applicant's alleged diversion incidents from his time as an employee at St. Mary's Hospital. The Consent Order also makes clear that the Board was aware that Applicant had a history of diversion allegations against him by including in its factual findings that, in March 2014, Applicant received a letter of concern from the Board that alluded to possible diversion in an employment setting. The Consent Order does not, however, make clear whether the Board was aware of Applicant's alleged diversion incidents from his time as an employee at Mercy Hospital nor whether the 2014 letter of concern was in reference to those allegations or something else. Additionally, the Board implemented a multi-year disciplinary action that included a year of total suspension from practice followed by a probationary period in which Applicant's practice would be ''restricted to structured settings with on-site supervision.'' RFAAX 10, at 3. The Board also required that Applicant ''sign a monitoring agreement with the MPHP, to remain in effect for at least two (2) years of [his] employment in the practice of nursing.'' *Id.*

The Board's Consent Agreement is not dispositive of the public interest inquiry in this case. The Board's suspension of Applicant's nursing license, as well as its probationary conditions, do not indicate a substantial amount of trust in Applicant. Ultimately, I find the Board's Consent Agreement to weigh slightly in favor of Applicant, but its weight is also minimized by the ambiguity regarding the Board's awareness of the full extent of Applicant's history of diversion allegations, the sanctions imposed by the Board, and the fact that I have no information from Applicant to mitigate the circumstances. *See John O. Dimowo,* 85 FR 15810–11 (citing *Brian Thomas Nichol, M.D.,* 83 FR 47352, 47362–63 (2018)).

2. Factors Two and Four

The unrebutted record evidence demonstrates that Applicant has a history of diversion, which comprises multiple documented incidents from at least two different places of employment. Although Applicant has denied at least some of the allegations from his time as an employee at St. Mary's Hospital, (RFAAX 10, at 1–2), Applicant nonetheless signed the Board's Consent Agreement in which he agreed that there was ''sufficient admissible evidence for the Board to find that it [was] more likely than not'' that he engaged in the conduct described in the allegations. *Id.* at 2. Furthermore, Applicant provided no contrary evidence on the record. Accordingly, I find that Applicant's history of diverting controlled substances constitutes negative dispensing experience and weighs

[1] As to Factor Three, there is no evidence in the record that Applicant has been convicted of an offense under either federal or state law ''relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). Agency cases have therefore found that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

As to Factor Five, the Government's evidence fits squarely within the parameters of Factors One, Two, and Four and does not raise ''other conduct which may threaten the public health and safety.'' 21 U.S.C. 823(f)(5). Accordingly, Factor Five does not weigh for or against Applicant.

against granting Applicant's application for a registration.

Furthermore, the Government alleges that Applicant repeatedly violated state and federal laws related to controlled substances by diverting controlled substances on at least two different occasions while employed at Mercy Hospital and on at least five different occasions while employed at St. Mary's Hospital. OSC, at 2 and 4 (citing 21 U.S.C. 843(a)(3); 21 CFR 1301.22(c); 17–A Me. Rev. Stat. § 1107–A; 32 Me. Rev. Stat. § 2105–A(2)(F) and (H); and Maine State Board of Nursing Rule Ch. 4 § 3(P)).

According to Maine law, ''a person is guilty of unlawful possession of a scheduled drug if the person intentionally or knowingly possesses what that person knows or believes to be a scheduled drug, which is in fact a scheduled drug'' [2] unless ''the person possessed a valid prescription for the scheduled drug or controlled substance that is the basis for the charge and[ ], at all times, the person intended the drug to be used only for legitimate medical use in conformity with the instructions provided by the prescriber and dispenser.'' Me. Rev. Stat. Ann. tit. 17–A, §§ 1107–A(1) and (4) (Westlaw, current with legislation through the 2021 First Regular Session and Second Special Session of the 130th Legislature). Further, Maine regulation states that nurses are prohibited from engaging in unprofessional conduct as well as from violating Board rules, including, ''[d]iverting drugs, supplies or property of patients or health care provider[s].'' 02–380 Me. Code R. Ch. 4, § 3(P) (Westlaw, current through the June 16, 2021 Maine Weekly Rule Notice).

Under federal law, it is unlawful ''to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.'' 21 U.S.C. 843(a)(3). Federal law also states that ''[a]n individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that . . . [s]uch dispensing, administering or prescribing is done in the usual course of his/her professional practice.'' 21 CFR 1301.22(c). Federal law defines an individual practitioner as an ''individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice.'' 21 CFR 1300.01.

In this case, the evidence supports a finding that Applicant diverted controlled substances on at least two different occasions while employed at Mercy Hospital and on at least five different occasions while employed at St. Mary's Hospital. In doing so, he clearly acted outside of the usual course of his professional practice and dispensed controlled substances in violation of state and federal law. Given the repeated nature of Applicant's violations of federal and state regulations related to controlled substances, I find that Factors Two and Four strongly weigh against Applicant's registration and I find Applicant's registration to be inconsistent with the public interest in balancing the factors in 21 U.S.C. 823(f).

III. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that grounds for denial exist, the burden shifts to the Applicant to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases). In this case, Applicant did not request a hearing and did not avail himself of the opportunity to refute the Government's case. *See* RFAA, at 1 and RFAAX 3. As such, Applicant has not expressed any remorse nor provided any assurances that he would implement remedial measures to ensure his misconduct is not repeated, and such silence weighs against his registration. *Zvi H. Perper, M.D.,* 77 FR 64131, 64142 (2012) (citing *Medicine Shoppe-Jonesborough,* 73 FR 363, 387 (2008)); *see also Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007). Further, due to the lack of a statement or testimony from Applicant, it is unclear whether Applicant can be entrusted with a DEA registration. Therefore, I find that sanction is appropriate to protect the public from a recurrence of Applicant's unlawful actions. *See Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988). Accordingly, I shall order the sanctions requested by the Government, 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(f) and 21 U.S.C. 824(a), I hereby deny the pending application for a Certificate of Registration, Control Number W19022896M, submitted by Christopher C. King, N.P., as well as any other pending application of Christopher C. King, N.P. for additional registration in Maine. This Order is effective May 9, 2022.

Anne Milgram,

Administrator.

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BILLING CODE 4410–09–P

[2] I am not including a finding on this particular state law, because the Government failed to provide any arguments related to these allegations in the RFAA or further information related to the Maine schedules. It is clear to me that Applicant's registration is not in the public interest due to his diversion in spite of the limited arguments in the RFAA.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Crosby Pharmacy and Wellness; Decision and Order

I. Introduction

On October 23, 2021, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Crosby Pharmacy and Wellness (hereinafter, Applicant) of Montgomery, Texas. OSC, at 1. The OSC proposes the denial of Applicant's registration application, Control No. W20008908A (hereinafter, registration application). It alleges that Applicant materially falsified its registration application and that Applicant's registration would be ''inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).'' *Id.*

Specifically, the OSC alleges that, during an onsite visit when Applicant was a registrant, the Government discovered ''serious recordkeeping violations,'' including not maintaining an initial inventory, not maintaining a biennial inventory, and not maintaining accurate records of all controlled substances received and sold. *Id.* at 1–2 (citing 21 CFR 1304.11(b), 1304.11(c), 1304.21(a)). The OSC also alleges that Applicant materially falsified its registration application by answering ''no'' to the question of whether it had ''ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending.'' *Id.* at 2.

The OSC notifies Applicant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing; the procedures for electing each option; and the consequences for failing to elect either option. *Id.* at 3 (citing 21 CFR 1301.43). The OSC also notifies