(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3574'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: November 1, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–24173 Filed 11–4–21; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 20–29]

George Roussis, M.D.; Decision and Order

On August 10, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to George Roussis, M.D. (hereinafter, Respondent), of Staten Island, New York. Order to Show Cause (hereinafter, OSC), at 1 and 3. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration, Control No. W20041078C, because Respondent was excluded from ''participation in Medicare, Medicaid, and all Federal health care programs pursuant to section 1320a–7(a) of Title 42'' and such exclusion ''warrants denial of [Respondent's] application for a DEA registration pursuant to 21 U.S.C. 824(a)(5).'' *Id.* at 1–2 (citing *Narciso A. Reyes, M.D.,* 83 FR 61,678 (2018)).

Specifically, the OSC alleged that, on or about October 16, 2017, a judgment was entered against Respondent based on his conviction on one count of ''Racketeering-Transporting In Aid of Travel Act-Acceptance of Bribes'' in violation of 18 U.S.C. 1952(a)(3) and 2. *Id.* at 1 (citing *U.S.* v. *George Roussis,* No. 2:17–CR–00232–SRC–1 (D.N.J. Oct. 16, 2017)). The OSC further alleged that ''[b]ased on [Respondent's] conviction, the U.S. Department of Health and Human Services, Office of [the] Inspector General (''HHS/OIG''), mandatorily excluded [Respondent] from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. § 1320a–7(a).'' *Id.* at 2. According to the OSC, the exclusion was effective on April 19, 2018, and runs for 13 years. *Id.*

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.* (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated September 2, 2020, Respondent timely requested a hearing. Administrative Law Judge Exhibit (hereinafter, ALJX) 2. The matter was placed on the docket of the Office of Administrative Law Judges and was assigned to Administrative Law Judge John J. Mulrooney, II (hereinafter, the Chief ALJ). On September 11, 2020, the Chief ALJ issued an Order for Prehearing Statements. ALJX 3. The Government timely filed its prehearing statement on September 25, 2020. ALJX 4. Respondent timely filed his prehearing statement on October 1, 2020. ALJX 5. On October 19, 2020, the Chief ALJ issued a prehearing ruling that, among other things, established the schedules and procedures for the remaining prehearing activities and for the hearing. ALJX 6 (Prehearing Ruling, at 1–7).

The hearing in this matter took place via video teleconference on December 16, 2020. Following the hearing, both the Government and Respondent filed their post-hearing briefs on January 22, 2021. On January 26, 2021, the Chief ALJ issued the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, RD). Neither party filed exceptions to the RD. *See generally* Transmittal Letter. I have reviewed and agree with the procedural rulings of the Chief ALJ during the administration of the hearing.

Having considered the record in its entirety, I agree with the Chief ALJ and find that the record established by substantial evidence a *prima facie* case supporting the denial of Respondent's application. RD, at 12. I also agree with the Chief ALJ that Respondent failed to fully accept responsibility for his misconduct, failed to demonstrate that the Agency can entrust him to maintain his registration, and that denial of his application is appropriate. *Id.* at 12–15. I make the following findings of fact.

I. Findings of Fact

A. Respondent's Application for DEA Registration

Agency records show that on April 30, 2020, Respondent applied for DEA registration No. W20041078C as a practitioner authorized to handle controlled substances in Schedules II–V at the proposed registered location of 4735 Hylan Blvd., Staten Island, New York 10312. GX 1, at 1; *see also* RD, at 3 (Stipulation 1). Respondent previously held DEA registration No. BR7710999. GX 2, at 2. Respondent's previous DEA registration was the subject of an OSC issued on February 19, 2019, based on the sole allegation that Respondent was without authority to handle controlled substances in New York, the state in which he was registered with the DEA, because his New York medical license had been suspended. *Id.* at 1–2. The OSC was dismissed when the suspension of Respondent's New York medical license was lifted subject to probation and other conditions on August 16, 2019. *Id.* at 2. The expiration date of Respondent's previous DEA registration was April 30, 2020, and it is in retired status. *Id.*

B. Respondent's Criminal Conviction

The evidence in the record demonstrates that on June 21, 2017, an Information was filed in the United States District Court for the District of New Jersey against Respondent. GX 3. The Information charged that from October 2010 through April 2013, Respondent engaged in commercial bribery in violation of N.J.S.A. § 2C:21–10, 18 U.S.C. 1952(a)(3). *Id.* at 4. The Information charged that from October 2010 through April 2013, Biodiagnostic Laboratory Services, LLC (hereinafter, BLS), a clinical blood laboratory, paid Respondent and his brother bribes of approximately $175,000 in the aggregate to refer patient blood specimens to BLS. *Id.* at 1 and 4. The Information charged that BLS used the patient blood specimens from Respondent to submit claims to Medicare and private insurers to collect approximately $1,450,000. *Id.* at 4. Further, the Information charged that between October 2010 and April 2013, ''in addition to cash payments'' and ''at the request of [Respondent], on multiple occasions,'' BLS paid bribes to Respondent and his brother in the form of trips to strip clubs where ''BLS paid for women to perform lap dances on, and engage in sex acts with, [Respondent] and [Respondent's brother], in order to induce [Respondent] to refer the blood specimens of [Respondent's] patients to BLS for testing and related services.'' *Id.* On June 21, 2017, Respondent pled guilty to the charge of Racketeering-Transporting in Aid of Travel Act-Acceptance of Bribes in violation of 18 U.S.C. 1952(a)(3) & 18 U.S.C. 2. GX 5, at 1. Judgment was entered on October 16, 2017, and as a result of his guilty plea, Respondent was sentenced to serve 37 months in prison, pay a fine of $7,500, and forfeit $175,000 ''jointly and severally with [his brother].'' GX 3, at 6; GX 4, at 4; GX 5, at 1–2, 7, and 8; *see also* RD, at 3 (Stipulation 2).

C. Respondent's Exclusion

Based on Respondent's guilty plea and conviction, on March 30, 2018, HHS/OIG excluded Respondent from participation in Medicare, Medicaid, and all federal health care programs for a minimum period of 13 years pursuant to 42 U.S.C § 1320a–7(a). GX 7, at 1; *see also* RD, at 3 (Stipulation 4).

D. Respondent's State Medical License

Respondent was authorized to practice medicine in the State of New York by issuance of license number 224106. GX 2, at 2. Following Respondent's guilty plea and conviction, Respondent's New York medical license was suspended for 15 months starting from May 16, 2018. *Id.* On August 16, 2019, Respondent's state medical license was reinstated subject to probation for five years. *Id.* According to the State of New York's online records, the status of Respondent's state medical license is currently listed as ''Registered.'' *http://www.op.nysed.gov/opsearches.htm* (last visited date of signature of this Order). Following his conviction, Respondent was also excluded from participation in the New York State Medicaid program, effective November 5, 2017. GX 6, at 1–2.

E. The Parties' Positions

1. Government's Position

The OSC's sole allegation is that Respondent's exclusion from federal health care programs pursuant to 42 U.S.C. 1320a–7(a) warrants denying his application under 21 U.S.C. 824(a)(5). OSC, at 2. The Government alleges that Respondent's exclusion was based on his conviction on one count of Racketeering-Transporting In Aid of Travel Act-Acceptance of Bribes, in violation of 18 U.S.C. 1952(a)(3) & 18 U.S.C. 2. *Id.* at 1–2.

The Government's documentary evidence includes a copy of Respondent's application for DEA registration No. W20041078C as well as a copy of the Certification of Non Registration for DEA registration No. W20041078C. *See* GX 1 and 2. The Government's documentary evidence also includes a copy of the Information filed in the United States District Court for the District of New Jersey against Respondent as well as Respondent's Plea Agreement and the Judgment following Respondent's conviction. *See* GX 3–5. Additionally, the Government's documentary evidence includes a copy of Respondent's exclusion letter from HHS/OIG as well as a website screen print from the HHS/OIG exclusions database showing that Respondent is excluded. *See* GX 7 and 8. Finally, the Government's documentary evidence includes a copy of Respondent's exclusion letter from the New York State Medicaid program. *See* GX 6.

The Government called one witness to testify at the hearing, a Group Supervisor (GS) who works for the DEA New York Field Division. The GS testified about her career experience, including her previous encounter with Respondent when Respondent's prior DEA registration was the subject of an OSC because Respondent's New York medical license had been suspended. Tr. 15–21; *see also* RD, at 3; GX 2, at 1–2. The GS also authenticated the Government's documentary evidence and testified about her investigation-related actions, including obtaining the Government's documentary evidence and confirming that Respondent's exclusion from federal health care programs was still in effect. Tr. 15–37; *see also* RD, at 3–4.

Having read and analyzed all of the record evidence, I agree with the Chief ALJ that the testimony from the GS was

''sufficiently detailed, plausible, and internally consistent,'' and that the GS ''presented as an objective regulator and investigator with no discernable motive to fabricate or exaggerate.'' RD, at 4.

2. Respondent's Position

Respondent requested a hearing in response to the Government's OSC, asserting that although his medical license had been restored, without a DEA registration, he was not able to effectively practice. Request for a Hearing (hereinafter, Hearing Request).

The Respondent's documentary evidence includes various orders from the New York State Department of Health regarding the status of Respondent's medical license following his conviction. *See* RX 1–3. The Respondent's documentary evidence also includes a collection of support letters from patients, colleagues, and friends that had been previously submitted to the District of New Jersey as part of Respondent's criminal case. *See* RX 4. Respondent was the sole witness to testify for his case.

Respondent explained his educational background, including both his undergraduate and medical education. Tr. 71–73. Respondent also described his career in pediatrics. *Id.* at 75–78. Respondent testified that he is currently married with two eleven-year-old children and that they are a ''very loving family.'' *Id.* at 48. Respondent also confirmed that he committed the crime to which he pled guilty. *Id.* Respondent testified that he had been having financial difficulties as a solo practitioner at the time but that it was not an excuse for what he did. *Id.* at 97. Respondent testified that a friend who worked for BLS as a representative introduced him to BLS and initiated Respondent's arrangement with BLS. *Id.* at 64. Respondent stated that he referred his laboratory specimens to BLS and in exchange he would receive $2,000–$4,000 [1] in cash on a monthly basis and trips to a strip club with his brother a few times a year.[2] *Id.* at 48–49, 60–61, 63, and 65. Regarding his non-monetary remuneration, he testified, ''So what I received was of course we would eat there. I mean they had typical—it was a restaurant in there. And alongside that, it would be a lap dance.'' *Id.* at 60. Respondent's friend who introduced him to BLS was the one who brought Respondent the monthly payments at Respondent's office. *Id.* at 64–66. The monthly payments varied but did not depend on anything in particular like how much lab work Respondent sent to BLS. *Id.* at 65. Respondent testified that his wife did not know about his arrangement with BLS, however, his wife knew that he was going out with the owners of BLS to a strip club and Respondent and his wife have nonetheless maintained a good and trusting relationship. *Id.* at 62–63 and 66. Respondent also testified that he was ''not exclusive to BLS.'' *Id.* at 49. Respondent sent approximately 40% of his lab work to BLS and Respondent and his brother received a combined total of $175,000, of which Respondent received half. *Id.* at 49 and 99. Respondent stated that he knew that referring the blood samples to BLS was wrong at the time that he was doing it. *Id.* As far as his protocol for deciding whether to send blood samples to BLS or other laboratories, Respondent testified that he rotated laboratories to compare the blood results amongst the different laboratories. *Id.* at 49–50. On cross examination, Respondent testified that the arrangement with BLS ended when BLS was arrested by the federal government and that he did not know the approximate number of patients that he had referred to BLS throughout the duration of the arrangement. *Id.* at 95.

Respondent testified that he was never charged with doing any unnecessary testing and that there was no additional expense to the patients, insurance companies, or the government. *Id.* at 50 and 80. Respondent also testified that although BLS was not a reputable company and what they did was ''terrible'' their blood testing was normal and comparable with other laboratories. *Id.* at 95–96. Other than the present case, Respondent has never been in trouble with the law. *Id.* at 50. Additionally, Respondent has made all of the payments required as part of his plea agreement. *Id.* at 82. During cross examination, Respondent confirmed that he appealed his exclusion ''with regards to [his] extent of the blame for the exclusion'' and described his attempt to lessen the time period of the exclusion. *Id.* at 84 and 87. Respondent also confirmed that he was aware of the aggravating factors that contributed to his long exclusion period, including the financial loss to government agencies of $50,000 or more, his conviction lasting more than two years, and his sentence including a period of incarceration. *Id.* at 88. Respondent stated that he didn't believe it was unreasonable to receive an exclusion, but that he thought it was an ''excessive'' exclusion. *Id.* at 88–89.

Respondent is currently licensed without restriction but is subject to probation for five years and has to have a practice monitor for 24 months. *Id.* The practice monitor is board-certified in internal medicine. *Id.* at 75. Before he was convicted and excluded from federal health care programs, Respondent had a pediatric practice. *Id.* at 51. Respondent stated that he wants to return to pediatrics but that because of his exclusion from federal health care programs, he is having issues being credentialed by private insurance companies, which insure the majority of his patients. *Id.* at 66–68. Respondent has also lost his previous hospital admitting privileges. *Id.* at 77. Additionally, Respondent was previously certified by the American Board of Pediatrics but because of his felony conviction, was suspended. *Id.* at 73–74. Respondent stated that he petitioned to be reinstated but because of the condition on his license that he has to have a practice monitor, he was unsuccessful. *Id.* at 74. Respondent confirmed that his petition was unsuccessful only because of the practice monitor requirement and not because of any issues with his level of practice. *Id.* Respondent also mentioned that he receives ''many phone calls'' asking him to return to pediatric practice. *Id.* at 79.

In the time since his medical license was reinstated in August 2019, Respondent has only been actively practicing medicine as of October 2020. *Id.* at 92. Respondent currently has an aesthetics wellness practice with his brother that offers aesthetic services, hormone replacement, and medical weight loss and Respondent has ''trained in many courses'' regarding aesthetics wellness. *Id.* at 51–53. Respondent testified that he would need a DEA registration to keep the practice running because he needs to prescribe

[1] The RD noted that Respondent's testimony in which Respondent first stated that the cash payments were ''always the same amount'' but then went on to state that the cash payments ranged from $2,000–$4,000 as an example of Respondent's lack of candor. RD, at 5; Tr. 65. It is difficult to tell from the record whether Respondent was just clarifying that the payments were not based on a particular factor when he stated that they were ''always the same amount,'' but the Chief ALJ then asked him on what the range depended and he stated, ''There was nothing—it would vary. That's all I would say.'' Tr. 65. I agree with the Chief ALJ that these statements do not appear to be fully forthcoming and should be considered as relevant to Respondent's acceptance of responsibility.

[2] On cross examination, Respondent was questioned regarding the specific services he and his brother were given during the trips to strip clubs provided by BLS because while in his testimony he had indicated that they were only given lap dances, in the plea agreement that he had signed, it was indicated that they had received lap dances and sexual acts. *Id.* 110–114. During this line of questioning, Respondent testified that they had only received lap dances, that ''sex acts'' referred only to lap dances, and that regarding the ambiguity of the wording involved with the plea agreement, he had simply signed what he was told to sign by his attorney. *Id.*

testosterone for hormone replacement and because it's ''very difficult to earn a living without [the] DEA license.'' *Id.* at 53–55. On cross examination, Respondent testified that he has not partnered with any other medical professionals in situations where his patients need controlled substances, so if a patient needs a controlled substance, Respondent will deny them service. *Id.* at 92–93. Respondent also confirmed that he would not have a need to prescribe opioid drugs or benzodiazepine drugs. *Id.* at 94. When questioned by the Chief ALJ if he would need the DEA registration for other reasons like malpractice insurance or credentialing, Respondent said he would not and that he did not have any issues with malpractice insurance. *Id.* at 54.

Prior to his sentencing, Respondent spoke to the Richmond County Medical Society, which, although he was embarrassed, he felt was ''absolutely necessary'' to express how sorry he was to have ''betrayed them and . . . the profession.'' *Id.* at 69–70. Respondent stated that they all knew about his situation because it was all public and that they accepted and understood that he was trying to ''educate them not to fall into the same trap.'' *Id.* Respondent also stated that if he could ''do anything to take it back [he] would.'' *Id.* at 70. Respondent testified that while he was in prison for 18 months, his wife would send him weekly journals regarding ''pretty much all disciplines of medicine which [he] would actually keep up with.'' *Id.* at 55–56 and 98. Respondent also testified that there were other physicians with him in prison and that they formed a club and had discussions regarding medicine on a weekly basis. *Id.* at 56. Since his release from prison, Respondent has taken about 60 CME credits, received his opiate certificate, and taken a 12-week ethics course, the latter two of which were required by the Office of Professional Medical Conduct (OPMC). *Id.* at 56–59. Respondent stated that he brought shame to his family, friends, and patients and that ''there wasn't anybody that wasn't the victim both directly [and] indirectly.'' *Id.* at 81. Respondent said that he was ''not looking to go back in prison'' and that ''[o]ne day in prison is enough to teach anybody a lesson.'' *Id.* Respondent's father passed away while he was in prison and Respondent described the remorse he feels for not being able to tell his father how sorry he was for what he did. *Id.* Respondent stated that it's been very difficult for him to start his practice and that he's ''tried everything [he] can to feed [his] family.'' *Id.* Respondent stated that he will ''never compromise [his] position as long as [he has] been given this last chance to do the right thing'' and that ''[he] will do the right thing.'' *Id.* at 82. On cross examination, Respondent testified that even if he had financial difficulties in the future, ''[a]fter being in prison for [so] long'' he would not take another ''opportunity for financial enrichment.'' *Id.* at 98.

Respondent's testimony also included the authentication of Respondent's exhibits. *Id.* at 40–44. Regarding a determination order from the New York State Department of Health State Board for Professional Medical Conduct, Respondent testified that the Board referred to Respondent's ''special remorse for which [he] suffered financially.'' *Id.* at 70–71. Regarding Respondent's collection of support letters, Respondent testified that he had not solicited patients for the letters but that because his case was in the news and everyone found out about it, patients had come in and asked what they could do to help him. *Id.* at 44–45. Respondent also testified that, in regard to glaring similarities between the letters, he had only told his patients to ''speak the truth and how [they] [felt] about [him]'' and ''what [their] [experiences were] with [Respondent] treating [them] as patients.'' *Id.* at 45–46. Finally, Respondent testified that he had received ''many more character letters'' than those included in the collection submitted for this case. *Id.* at 47–48. On cross examination, Respondent confirmed that all of the letters were written in 2017 in response to his criminal conviction and that none of the letters were addressed to the court of the current matter. *Id.* at 106–107.

Having read and analyzed all of the record evidence, I agree with the RD that while Respondent was candid and credible in discussing his background and his personal remorse, Respondent's testimony in other areas raises concerns regarding Respondent's candor and thus reduces his credibility and the weight this decision gives to his testimony. RD, at 8. In particular, I find that Respondent's testimony regarding his reasons for seeking a DEA registration was confusing and ambiguous as to whether he intends to return to pediatrics or to continue with the aesthetics practice that he currently operates with his brother. Tr. 51–55 and 66–68; *see also* RD, at 7.[3] I also agree with the Chief ALJ that ''[Respondent's] own admission that he signed his plea agreement, not because it was all true, but because his attorney told him to, raises significant doubts as to the credibility of his testimony.'' [4] RD, at 8; *see also* Tr. 110–114. Finally, and as will be discussed in more detail below, the stark similarities between Respondent's patient support letters combined with Respondent's testimony that there was no coaching or even solicitation involved in their acquisition further raises concerns regarding Respondent's candor and thus further damages Respondent's credibility. RX 4; RD, at 6–7; Tr. 44–46.

II. Discussion

A. The Government's Position

In its Post-Hearing Brief, the Government argues that ''[a] respondent's mandatory exclusion from federal health care programs under 42 U.S.C. 1320a–7(a) provides grounds for denial under 21 U.S.C. § 824(a)(5)'' and notes that ''[i]t is undisputed that Respondent has been excluded from participation in Medicare, Medicaid, and all [f]ederal health programs pursuant to 42 U.S.C. 1320a–7(a) for a period of 13 years.'' Government's Post-Hearing Brief, at 6. Additionally, the Government argues that the denial of Respondent's application is the appropriate sanction and that even if Respondent's application were granted, it should be restricted because ''Respondent has not unequivocally accepted responsibility, but has instead attempted to downplay his misconduct'' and ''Respondent's misconduct is so egregious, that denial of his application is warranted notwithstanding any purported acceptance of responsibility.'' *Id.* at 6–7. Specifically, the Government alleges that Respondent failed to acknowledge a portion of the bribes he received (namely, that he received both lap dances and additional sex acts) and that Respondent downplayed his role in the bribery scheme by characterizing it as ''nothing more than an informal arrangement between old friends.'' *Id.* at 7–9. Moreover, the Government contends that ''[a]lthough Respondent's crimes are not related to the controlled substances act, his crimes are of a nature that should concern the Agency'' because ''[w]ere Respondent to accept

[3] I am not considering the purpose of his application for a DEA registration for any other reason than his inconsistent statements.

[4] In the recent decision *Keith A Jenkins, N.P.,* which found in favor of the Respondent, a similar issue regarding the Respondent signing something because his attorney advised it was raised. *Keith A Jenkins, N.P.,* 86 FR 35,339 (2021). However, the present case can be distinguished from *Jenkins* in that in the present case, the issue pertains to a major fact of the underlying crime, while in *Jenkins,* the Respondent entered an Alford plea of guilty as a strategic decision at the advice of his attorney regarding a particular legal element of his offense. *Id.* at 35,344.

cash payments to prescribe unlawful prescriptions, it would be challenging for DEA to detect.'' *Id.* at 9–10. Finally, the Government concludes that for the protection of the public, even if granted, Respondent's registration should be limited to only what he claims that he needs it for, namely testosterone prescriptions. *Id.* at 10.

B. Respondent's Position

In Respondent's Post-Hearing Brief, Respondent highlighted a Determination and Order of the New York State Department of Health which, after a hearing was held to determine if Respondent's New York medical license should be revoked following his conviction, denied the Department's request to revoke Respondent's license and instead, opted to suspend Respondent's license until he was released from incarceration, followed by five years of probation, the first two years including a practice monitor. Respondent's Post-Hearing Brief, at 3–4. Respondent's Post-Hearing Brief included a quote from the Determination and Order stating that ''[t]he Committee based [its] determination on the Respondent's personal statement accepting full responsibility.'' *Id.* at 4. The included quote also noted that ''Respondent also offered in mitigation letters from colleagues and patients and the testimony of [colleagues] to show his commitment to his pediatric practice.'' *Id.* Finally, the quote concluded, ''[t]he Hearing Committee credited the Respondent's expressions of remorse for enriching himself financially while participating in such a scheme and his remedial efforts in appearing before the Richmond County Medical Society to candidly discuss his unlawful acts.'' *Id.*

Respondent's Post-Hearing Brief went on to argue that Respondent was truly remorseful, as evidenced in part by his lecturing to other doctors about the mistake he made and how they should avoid it. *Id.* at 4–5. Respondent's Post-Hearing Brief also noted that no patient's care was ever compromised, that Respondent never performed any unnecessary tests, that the payments made by Medicare and other insurance entities were exactly the same as they would have been from any other lab, and that BLS never provided anything but ''top quality work.'' *Id.* at 5. Respondent's Post-Hearing Brief emphasized that Respondent has never had any trouble with the law and described Respondent as ''an old-fashioned doctor who besides providing excellent medical care to his patients, listened to his patients and never rushed them out of his office.'' *Id.* Moreover, Respondent's Post-Hearing Brief included excerpts from some of the patient letters that Respondent submitted as Exhibit 4 in this case to demonstrate ''the type of care Respondent provided to his patients and how they reflect his following the Hippocratic Oath.'' *Id.* at 5–8.

Respondent's Post-Hearing Brief then went on to describe Respondent's remedial efforts, including keeping up with medical journals while incarcerated, forming a club with other physicians while incarcerated, and, since his release from prison, taking CME courses, an Opiate course, and an ethics course. *Id.* at 8–9. Respondent's Post-Hearing Brief concluded by emphasizing Respondent's remorse once again, describing how Respondent has suffered from being incarcerated, from paying fines and forfeiture, and from embarrassing and hurting his family, community, and patients. *Id.* at 9. Respondent's Post-Hearing Brief highlighted that Respondent ''is now trying to turn his life around and become a productive member of society'' and that to do this, he needs a DEA license for his aesthetics practice, because he is no longer able to practice pediatrics because he cannot get insurance. *Id.* Finally, Respondent's Post-Hearing Brief included an excerpt of Respondent's testimony in which Respondent reiterated his remorse, stated that he needed the DEA license to continue practicing medicine, and testified that even if he faced financial difficulties in the future, he would never again take similar actions because of the disgrace he brought to his family, friends, and patients and because he had learned his lesson by going to prison. *Id.* at 9–10.

C. Analysis of Respondent's Application for Registration

In this matter, the OSC calls for my adjudication of the application for registration based on the charge that Respondent was excluded from participation in a program pursuant to section 1320a–7(a) of Title 42, which is a basis for revocation or suspension under 21 U.S.C. 824(a)(5). OSC, at 1–2.

Prior Agency decisions have addressed whether it is appropriate to consider a provision of 21 U.S.C. 824(a) when determining whether or not to grant a practitioner registration application. For over forty-five years, Agency decisions have concluded that it is. *Robert Wayne Locklear, M.D.,* 86 FR at 33,744–45 (collecting cases); *see also, William Ralph Kincaid.* In the recent decision *Robert Wayne Locklear, M.D.,* the former Acting Administrator stated his agreement with the results of these past decisions and reaffirmed that a provision of section 824 may be the basis for the denial of a practitioner registration application. 86 FR at 33,745. He also clarified that allegations related to section 823 remain relevant to the adjudication of a practitioner registration application when a provision of section 824 is involved. *Id.*

Accordingly, when considering an application for a registration, I will consider any actionable allegations related to the grounds for denial of an application under 823 and will also consider any allegations that the applicant meets one of the five grounds for revocation or suspension of a registration under section 824. *Id. See also Dinorah Drug Store, Inc.,* 61 FR 15,972, 15,973–74 (1996).

1. 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).

In this case, it is undisputed that Respondent holds a valid state medical license and is authorized to dispense controlled substances in the State of New York where he practices. *See* GX 2.

Because the Government has not alleged that Respondent's registration is inconsistent with the public interest under section 823, and although I have considered 823, I will not analyze Respondent's application under the public interest factors. Therefore, in accordance with prior agency decisions,

I will move to assess whether the Government has proven by substantial evidence that a ground for revocation exists under 21 U.S.C. 824(a). *Supra* II.C.

2. 21 U.S.C. 824(a)(5): Mandatory Exclusion From Federal Health Care Programs Pursuant to 42 U.S.C. 1320a–7(a)

Under Section 824(a) of the Controlled Substances Act (hereinafter, CSA), a registration ''may be suspended or revoked'' upon a finding of one or more of five grounds. 21 U.S.C. 824. The ground in 21 U.S.C. 824(a)(5) requires that the registrant ''has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' *Id.* Here, there is no dispute in the record that Respondent is mandatorily excluded from federal health care programs under 42 U.S.C. 1320a–7(a). The Government has presented substantial evidence of Respondent's exclusion and the underlying criminal conviction that led to that exclusion, and Respondent has admitted to the same. GX 5; GX 7–8; Respondent's Post-Hearing Brief, at 2–3. Accordingly, I will sustain the Government's allegation that Respondent has been excluded from participation in a program pursuant to section 1320a–7(a) of Title 42 and find that the Government has established that a ground exists upon which a registration could be revoked pursuant to 21 U.S.C. 824(a)(5).[5] Although the language of 21 U.S.C. 824(a)(5) discusses suspension and revocation of a registration, for the reasons discussed above, it may also serve as the basis for the denial of a DEA registration application. *Dinorah Drug Store, Inc.,* 61 FR at 15,973 (interpreting 21 U.S.C. 824(a)(5) to serve as a basis for the denial of a registration because it ''makes little sense . . . to grant the application for registration, only to possibly turn around and propose to revoke or suspend that registration based on the registrant's exclusion from a Medicare program''). Respondent's exclusion from participation in a program under 42 U.S.C. 1320a–7(a), therefore, serves as an independent basis for denying his application for DEA registration. 21 U.S.C. 824(a)(5).

Here, there is no dispute in the record that Respondent is mandatorily excluded pursuant to Section 1320a–7(a) of Title 42 and, therefore, that a ground for the revocation or suspension of Registrant's registration exists. 21 U.S.C. 824(a)(5).

Where, as here, the Government has met its *prima facie* burden of showing that a ground for revocation exists, the burden shifts to the Respondent to show why he can be entrusted with a registration. *See Jeffrey Stein, M.D.,* 84 FR 46,968, 46,972 (2019).

III. Sanction

The Government has established grounds to deny a registration; therefore, I will review any evidence and argument the Respondent submitted to determine whether or not the Respondent has presented ''sufficient mitigating evidence to assure the Administrator that [he] can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *Drug Enf't Admin.,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Samuel S. Jackson, D.D.S.,* 72 FR at 23,853; *John H. Kennnedy,* M.D., 71 FR 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

A. Acceptance of Responsibility

In evaluating the degree required of a respondent's acceptance of responsibility to entrust him with a registration, in *Mohammed Asgar, M.D.,* the Agency looked for ''unequivocal acceptance of responsibility when a respondent has committed knowing or intentional misconduct.'' 83 FR 29,569, 29,572 (2018) (citing *Lon F. Alexander, M.D.,* 82 FR 49,704, 49,728). Here, the Respondent stated that he knew at the time that he did it that it was wrong. Tr. 49. I will, therefore, look for a clear acceptance of responsibility from Respondent.

Respondent is clearly remorseful for his conduct, with Respondent emphasizing how he had brought shame to his family, friends, and patients and that ''there wasn't anybody that wasn't the victim both directly [and] indirectly.'' Tr. 81. He does seem to acknowledge that there are many victims, although his statements do not show any particular understanding of his crime or its impact. However, remorse and acceptance of responsibility are not the same thing, and although Respondent acknowledged that his patients had suffered, Respondent's focus on his own suffering does not suggest an unequivocal acceptance of responsibility, but rather, suggests that what he regrets most are the negative consequences that he has personally faced. As the Chief ALJ noted, Respondent ''freely admits that the ramifications of getting caught and punished has visited an extreme level of inconvenience and misfortune.'' RD, at 13. In particular, much of Respondent's testimony focused on how much of an impact his incarceration had had on him, with Respondent testifying that ''[o]ne day in prison is enough to teach anybody a lesson'' and describing the remorse he had felt about not being able to tell his father how sorry he was for what he did because his father had passed away while he was incarcerated. Tr. 81. Respondent also mentioned how difficult it has been for him to start a new practice following his incarceration. *Id.* Regarding whether, if faced with financial difficulties in the future, he would take another ''opportunity for financial enrichment'', Respondent testified that ''[a]fter being in prison for [so] long'' he would not, suggesting that the fear of incarceration, rather than genuine regret for the harm he has caused, is what would deter him from similar misconduct in the future. *Id.* at 98.

Additionally, there are points of Respondent's testimony and actions in the record that suggest attempts to downplay his mistakes. As the Chief ALJ pointed out, ''[t]he Respondent here essentially admitted to those things which he dared not deny. He admitted he was convicted and excluded from Medicare, but presented testimony that

[5] The Government correctly argues, and Respondent did not rebut, that the underlying conviction forming the basis for a registrant's mandatory exclusion from participation in federal health care programs need not involve controlled substances to provide the grounds for revocation or denial pursuant to section 824(a)(5). *Jeffrey Stein, M.D.,* 84 FR 46,968, 46,971–72 (2019); *see also Narciso Reyes, M.D.,* 83 FR 61,678, 61,681 (2018); *KK Pharmacy,* 64 FR 49,507, 49,510 (1999) (collecting cases); *Melvin N. Seglin, M.D.,* 63 FR 70,431, 70,433 (1998); *Stanley Dubin, D.D.S.,* 61 FR 60,727, 60,728 (1996).

was equivocal and confusing regarding the details.'' RD, at 13. Respondent testified that he was never charged with doing any unnecessary testing, that there was no additional expense to the patients, insurance companies, or the government, and that, although BLS was not a reputable company and what they did was ''terrible,'' their blood testing was normal and comparable with other laboratories.[6] *Id.* at 50, 80, 95–96. Respondent repeatedly minimized his characterization of the non-monetary remunerations he received and even when confronted with the plain language of his plea agreement. *See supra* n.2; Tr. 60, 62; RD, at 13. Also, Respondent confirmed that he had appealed his exclusion from federal healthcare programs because, although he had understood the aggravating factors, he had also thought his long exclusion period was ''excessive,'' but he did not explain further the rationale for this belief or why the exclusion period was so long initially. *Id.* at 84 and 87–89. I do credit Respondent for stating, ''I just did it. I mean, I have no excuse.'' *Id.* at 97. However, ''the degree of acceptance of responsibility that is required does not hinge on the respondent uttering 'magic words' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Stein,* 84 FR at 46,973.

Overall, Respondent's focus on himself and his minimization of his wrongdoings and the issues with his credibility suggest that he has not credibly and unequivocally accepted responsibility for his actions and the harm that he caused. *See id.* at 46,972 (finding that a registrant's attempts to minimize his misconduct weigh against a finding of unequivocal acceptance of responsibility).

Even if Respondent's acceptance of responsibility for his wrongdoing had been sufficient such that I would reach the matter of remedial measures, Respondent has not offered adequate remedial measures to assure me that I can entrust him with a registration. *See Carol Hippenmeyer, M.D.,* 86 FR 33,748, 33,773 (2021). Prior to his sentencing, Respondent spoke to the Richmond County Medical Society about his crime.[7] Tr. 69–70. While in prison, Respondent kept up with medical journals and formed a club with other physicians to discuss medicine. Tr. 55–56. Since his release, Respondent has taken about 60 hours in continuing medical educations courses (CME),[8] gotten his opiate certificate, and taken a 12-week ethics course.[9] *Id.* at 56–59. Given the circumstances and in comparison to the similar case in *Martinho,* I find that Respondent's remedial efforts have been minimal and thus insufficient to ensure that Respondent can be trusted with registration.

B. Specific and General Deterrence

In addition to acceptance of responsibility, the Agency gives consideration to both specific and general deterrence when determining an appropriate sanction. *Daniel A. Glick, D.D.S.,* 80 FR 74,800, 74,810 (2015). Specific deterrence is the DEA's interest in ensuring that a registrant complies with the laws and regulations governing controlled substances in the future. *Id.* General deterrence concerns the DEA's responsibility to deter conduct similar to the proven allegations against the respondent for the protection of the public at large. *Id.* Where a respondent has committed a crime with no nexus to controlled substances, it is sometimes difficult to demonstrate that a sanction will have a useful deterrent effect. In this case, I believe a sanction of denial of the application would deter Respondent and the general registrant community from unethical behavior and deceit, particularly involving the acceptance of money for unlawful and unethical acts. It is not difficult to imagine, as the Agency has repeatedly encountered, this situation repeating itself in the context of receiving money for controlled substance prescriptions. ''Deterring such deceit and knowing criminal behavior both in Respondent and the general registrant community is relevant to ensuring compliance with the CSA.'' *Ibrahim Al-Qawaqneh, D.D.S.,* 86 FR 10,354, 10,357 (2021).

C. Egregiousness

The Agency also looks to the egregiousness and the extent of the misconduct as significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18,910 (collecting cases). In this case, Respondent knew that his arrangement with BLS was wrong but accepted the arrangement anyway and kept it going from October 2010 to March of 2013, because he had been having financial difficulties as a solo practitioner. Tr. 95. The arrangement was a blatant kickback scheme involving substantial monetary payments.[10] In addition, the arrangement was both periodic and ongoing for multiple years, giving Respondent plenty of opportunity to correct course, but there is nothing in the record to indicate that he had any intention of ending the arrangement. *See also* RD, at 14. After receiving 2 to 4 thousand dollars per month, *Id.* at 65, there must have been a point at which he was no longer facing financial difficulties, and yet he continued until ''the laboratory got arrested by the federal government.'' Tr. 95. Furthermore, the exclusion letter notes that HHS/OIG deemed Respondent's criminal misconduct egregious enough to warrant an exclusion period in excess of the statutory minimum. GX 7, at 2. The exclusion letter explains that HHS/OIG excluded Respondent for thirteen years instead of the statutory minimum of five years because (1) Respondent's misconduct caused or was intended to cause financial loss of more than $50,000 to a government agency or program; (2) Respondent committed the misconduct over a period of at least a year; and (3) Respondent's sentence included incarceration. *Id. See Michael Jones, M.D.,* 86 FR 20,728, 20,732 (2021) (considering the length of the HHS

[6] It is also noted that Respondent provided no support for the statement that the testing was normal and comparable in the record.

[7] I commend Respondent on his attempts to have a deterrent effect on his colleagues and community. In *Martinho,* the former Acting Administrator considered this type of engagement in determining that a respondent who had been excluded from federal healthcare programs for accepting similar kickbacks for laboratory referrals could be entrusted with a registration; however, the facts of *Martinho* are very distinct from the facts on the present record. *Michele L. Martinho, M.D.,* 86 FR 24,012, 24,019 (2021). The respondent in that case had dedicated herself to self-described ''restorative justice'' well beyond what was required by her probation—engaging in sixty-nine speaking engagements, which were featured in major news outlets. *Id.* Although her misconduct occurred for a similar amount of time and money, HHS penalized her with the minimum timeframe for exclusion, she engaged in a methodological survey to verify for her own conscience that she did not increase her blood draws and did not overstate that survey's value, she admitted that the lab had created insurance problems for her patients and tried to correct it, and importantly, she also fully, sincerely and credibly accepted responsibility for her actions, such that the prosecutor at her criminal sentencing stated that she '' 'had demonstrated a level of contrition that has been unique among the many, many doctors that we've dealt with in this case.' '' *Id.*

[8] Though Respondent testified to completing CME courses, he did not provide evidence to the record confirming the completion of the courses.

[9] As previously mentioned, the latter two were required by the Office of Professional Medical Conduct (OPMC). *Id.*

[10] Also, I am concerned about repeat behavior in this case because the wrongdoing appears to be influenced by social interactions. The fact that Respondent was first approached about the bribes by a ''friend of [his],'' Tr. 64, participated in the arrangement with his brother, and they all engaged in social activities together during which payments were received, does not inspire confidence that Respondent will take his responsibility to his patients and his ethical obligations seriously in the future.

exclusion in assessing egregiousness). As the Chief ALJ noted, ''on the record, the interests of general deterrence, like the egregiousness of the established conduct, support the imposition of the application denial sought by the Government.'' RD, at 15.

D. Letters of Support

My final item of consideration is the collection of nineteen letters that Respondent submitted from patients, colleagues, and friends to demonstrate his high level of care as a physician and his commitment to the Hippocratic Oath. Respondent's Post-Hearing Brief, at 5–8; RX 4. Although I find the letters to be sincere, they can only be of limited weight in this proceeding because of the limited ability to assess the credibility of the letters given their written form. *See Michael S. Moore, M.D.,* 76 FR 45,867, 45,873 (2011) (evaluating the weight to be attached to letters provided by the respondent's hospital administrators and peers in light of the fact that the authors were not subjected to the rigors of cross examination). Furthermore, these letters were not written for the purposes of recommending that Respondent be granted a controlled substances registration and therefore offer little value in assessing the Respondent's suitability to discharge the duties of a DEA registrant. *William Ralph Kinkaid, M.D.,* 86 FR 40,636, 40,641 (2021). Instead, Respondent's letters were used by his criminal defense counsel prior to his sentencing, with most of the letters dated back to 2017. RX 4; Tr. 106–107. Additionally, as the Chief ALJ noted, the ''recognizable pattern'' of the patient letters, in combination with Respondent's insistence that there was no suggested format and Respondent's testimony that he had not solicited patients for the letters, does raise questions as to whether there was any ''coaching or importuning'' involved in their collection and thus damages their credibility. RD, at 6–7; RX 4Tr. 44–46. The Chief ALJ did note that ''it would be difficult (and unjust) to ignore the volume of support/correspondence from his patients, or the often poignant accounts enshrined within those letters.'' RD, at 14. I agree and I note that the letters say many positive things about Respondent, however, I find that because Respondent has not demonstrated credible and unequivocal acceptance of responsibility, I cannot place weight on letters written in a different context in demonstrating that Respondent can be entrusted with a DEA registration, when he, himself, has not credibly done so. *See Kinkaid, M.D.,* 86 FR at 40,641.

As discussed above, to receive a registration when grounds for denial exist, a respondent must convince the Administrator that his acceptance of responsibility is sufficiently credible to demonstrate that the misconduct will not occur and that he can be entrusted with a registration. Having reviewed the record in its entirety, I find that Respondent has not met this burden. Although Respondent expressed remorse and took some responsibility for his actions through his guilty plea and his efforts at remediation, his acceptance of responsibility was not unequivocal. Respondent's focus on his own consequences and his minimization of his wrongdoings both raise concerns that he does not truly understand the severity of his misconduct. Further, Respondent's remediation efforts have been minimal and unpersuasive. As such, I am not convinced that Respondent would not commit similar misconduct again in the future if he believed that it would not result in negative consequences. Accordingly, I will order the denial of Respondent's application for a certificate of registration.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823, I hereby deny the pending application for a Certificate of Registration, Control Number W20041078C, submitted by George Roussis, M.D., as well as any other pending application of George Roussis, M.D., for additional registration in New York. This Order is effective December 6, 2021.

Anne Milgram,

Administrator.

[FR Doc. 2021–24205 Filed 11–4–21; 8:45 am]

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DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Agency Information Collection Activities; Comment Request; Request for Electronic Service of Orders—Waiver of Certified Mail Requirement

AGENCY: Division of Federal Employees', Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs.

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Request for Electronic Service of Orders—Waiver of Certified Mail Requirement.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by January 4, 2022.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained for free by contacting Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

Submit written comments about this ICR by mail or courier to the U.S. Department of Labor, Office of Workers' Compensation Programs, Room S3323, 200 Constitution Avenue NW, Washington, DC 20210; or by email at *suggs.anjanette@dol.gov.* Please note that comments submitted after the comment period will not be considered.

FOR FURTHER INFORMATION CONTACT: Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The Office of Workers' Compensation Programs administers the Longshore and Harbor Workers' Compensation Act. The Act provides benefits to workers injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend the Longshore Act's coverage to certain other employees.

The Longshore and Harbor Workers' Compensation Act (LHWCA), at 33 U.S.C. 919(e), requires that any order rejecting or making an LHWCA award (the compensation order) be filed in the appropriate district director's office of