CHART I—Continued

Supplier	Product name	Form	Application date
o2si Smart Solutions	Oxycodone Solution, 2,000 mg/L—Parent Stock Solution—Not For Sale	Glass cryule: 2 mL	5/28/2021
o2si Smart Solutions	Pentazocine Solution, 2,000 mg/L—Parent Stock Solution	Glass cryule: 2 mL	5/28/2021
Restek Corporation	Custom D-Methamphetamine Standard	Glass Ampule: 1.3 mL	4/15/2021
UTAK Laboratories, Inc	DAU High Cutoff 1 Urine Control	Kit: 4 bottles, 10 mL each	4/16/2021
UTAK Laboratories, Inc	DAU High Cutoff 2 Urine Control	Kit: 4 bottles, 10 mL each	4/16/2021
UTAK Laboratories, Inc	DAU Low Cutoff 1 Urine Control	Kit: 4 bottles, 10 mL each	4/16/2021
UTAK Laboratories, Inc	DAU Low Cutoff 2 Urine Control	Kit: 4 bottles, 10 mL each	4/16/2021
UTAK Laboratories, Inc	Drugs of Abuse Level 1 Whole Blood Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	Fentanyl Analogues 2 NG/ML Whole Blood Control	Kit: 5 bottles, 3 mL each	4/16/2021
UTAK Laboratories, Inc	Fentanyl Analogues 5 NG/ML Urine Control	Kit: 5 bottles, 3 mL each	4/16/2021
UTAK Laboratories, Inc	PM 100 Urine Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	PM 100 Whole Blood Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	PM Plus High Urine Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	PM Plus Low Urine Control	Kit: 5 bottles, 5 mL each	4/16/2021
UTAK Laboratories, Inc	SAMHSA Confirm Level 1 SMX Oral Fluid Control	Kit: 5 bottles, 3 mL each	4/16/2021
UTAK Laboratories, Inc	SAMHSA Confirm Level 2 SMX Oral Fluid Control	Kit: 5 bottles, 3 mL each	4/16/2021

The Assistant Administrator has found that each of the compounds, mixtures, and preparations described in Chart II below is not consistent with the criteria stated in 21 U.S.C. 811(g)(3)(B) and in 21 CFR 1308.23. Accordingly, the Assistant Administrator has determined that the chemical preparations or mixtures generally described in Chart II below and specifically described in the application materials received by DEA, are not exempt from application of any part of the CSA or from application of any part of the CFR, with regard to the requested exemption pursuant to 21 CFR 1308.23, as of the date that was provided in the determination letters to the individual requesters.

CHART II

Supplier	Product name	Form	Application date
Aalto Scientific, Ltd	Immunoassy Base (Level A–E)	Glass vial, bottle, or flask: 500 mL–1L.	4/1/2021
Aalto Scientific, Ltd	Immunoassy Base (Level A–E)	Glass vial, bottle, or flask: 100mL–500 mL.	4/1/2021
Aalto Scientific, Ltd	Immunoassy Base (Level A–E)	Glass vial, bottle, or flask: 100 mL ..	4/1/2021

Opportunity for Comment

Pursuant to 21 CFR 1308.23(e), any interested person may submit written comments on or objections to any chemical preparation in this order that has been approved or denied as exempt. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Assistant Administrator will immediately suspend the effectiveness of any applicable part of this order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Assistant Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

Approved Exempt Chemical Preparations Are Posted on the DEA's Website

A list of all current exemptions, including those listed in this order, is available on the DEA's website at *http://www.DEAdiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf.* The dates of applications of all current exemptions are posted for easy reference.

* * * * *

Brian S. Besser,

Acting Assistant Administrator.

[FR Doc. 2022–01125 Filed 1–20–22; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Daniel R. Nevarre, M.D.; Decision and Order

On June 7, 2021, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Daniel R. Nevarre, M.D., (hereinafter, Applicant), of South Jordan, Utah. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the denial of Applicant's application No. H21079595C for a DEA Certificate of Registration, because the United States Department of Health and Human Services, Office of Inspector General (hereinafter, HHS/OIG) mandatorily excluded Applicant from participation in Medicare, Medicaid, and all Federal health care programs for a minimum period of 10 years pursuant to 42 U.S.C. 1320a–7(a); and such exclusion ''warrants denial of [Applicant's] application for DEA registration pursuant to 21 U.S.C. 824(a)(5).'' *Id.* at 2. The OSC also alleged that Applicant's application ''contains material false statements'' and thus forms an independent ground for denial. *Id.* at 2 (citing 21 U.S.C. 824(a)(1)).

The OSC alleged that on May 25, 2018, Applicant ''pled guilty to one count of medical assistance fraud in violation of 62 P.S. § 1407(a)(1), and to one count of insurance fraud, in violation of 18 Pa.C.S. § 4117(a)(2).'' *Id.* at 1–2 (citing *Commonwealth of Pa.* v. *Daniel Raymond Nevarre,* No. CP–11–CR–0000717–2018 (Pa. Ct. Comm. Pl. May 25, 2018)). The OSC further alleged that, based on such conviction, HHS/OIG ''mandatorily excluded [Applicant] from participation in Medicare, Medicaid, and all Federal health care programs'' for a minimum period of 10 years pursuant to 42 U.S.C. 1320a–7(a), effective November 20, 2018. *Id.* The OSC therefore proposed denial of Applicant's application based on 21 U.S.C. 824(a)(5).

The OSC also proposed denial of Applicant's application based on 21 U.S.C. 824(a)(1), because Applicant responded ''no'' to Liability Question 1 on his DEA application, which asks whether Applicant has ever been excluded from participation in a medicare program. *Id.* The OSC therefore proposed denial of Applicant's application because his ''failure to disclose [his] exclusion from Medicare constitutes material falsification of [his] application for a DEA [registration].'' *Id.*

The Show Cause Order notified 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 2–3 (citing 21 CFR 1301.43). The OSC also notified Applicant of the opportunity to submit a corrective action plan. OSC, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

Adequacy of Service

In a signed and sworn Declaration, a Diversion Investigator (hereinafter, DI 2) assigned to the Pittsburg District Office, Philadelphia Field Division, stated that, on June 21, 2021, after receiving a request from the Salt Lake City District Office to assist with service of the OSC, he and a Narcotics Agent from the Pennsylvania Office of the Attorney General traveled to Applicant's residential address in Johnstown, Pennsylvania, where he ''personally served [the Applicant] with a copy of the [OSC].'' Request for Final Agency Action, dated November 9, 2021 (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) 3 (DI 2 Declaration), at 1–2.

The Government forwarded its RFAA, along with the evidentiary record, to this office on November 9, 2021. In its RFAA, the Government represents that ''neither [Applicant] nor any attorney representing [Applicant] has requested a hearing'' or filed a written statement. RFAA, at 2; *see also* RFAAX 3, at 2 & RFAAX 1, at 4. The Government requests ''Final Agency Action denying the Application on the grounds that [Applicant] materially falsified his Application and has been excluded from participation in Medicare, Medicaid, and all Federal health care programs pursuant to 42 U.S.C. 1320a–7(a).'' *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 June 21, 2021. I also find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's written representations, I find that neither Applicant, nor anyone purporting to represent the 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).

A. Findings of Fact

1. Applicant's DEA Application and Former Registrations

On February 1, 2021, DEA received an application from Applicant for a DEA Certificate of Registration as a practitioner in Schedules IIN [1] through V with a proposed registered address of 881 Baxter Drive, Suite 100, South Jordan, Utah 84095. RFAAX 1 (DI 1 Declaration) (Appendix, hereinafter, App.) 1 (Applicant's Application). Applicant's application was assigned Control No. H21079595C. RFAAX 1, at 1.

DI 1 submitted a Declaration, dated September 13, 2021, which stated that Applicant had previously surrendered for cause DEA Certificates of Registration numbered FN7029487 and BN5130290 on September 5, 2018, and October 15, 2018, respectively, after losing his state authority to practice medicine in Pennsylvania. RFAAX 1 (DI 1 Declaration) at 2. DI 1 further stated that Applicant's third previous DEA Certificate of Registration numbered FN5716420 in New York expired on October 31, 2018. *Id.* at 2–3.

2. Applicant's Exclusion (21 U.S.C. 824(a)(5))

The Government's uncontroverted evidence demonstrates that Applicant pled guilty to false information/claims and insurance fraud on or about May 25, 2018, in the Court of County Pleas in Cambria County, Pennsylvania. RFAAX 1, at App. C (Applicant's Guilty plea). In a letter from the HHS/OIG, dated October 31, 2018, HHS excluded Applicant from Medicare, Medicaid, and all federal health care programs under 42 U.S.C. 1320a–7(a) for a minimum period 10 years based on Applicant's conviction. RFAAX 1, App. E (hereinafter, HHS Exclusion), at 1. The HHS Exclusion stated that the exclusion would become effective twenty days from the date of the letter. *Id.* at 1.

Accordingly, I find clear, unequivocal, and convincing record evidence that HHS excluded Applicant from Medicare, Medicaid, and all federal health care programs under 42 U.S.C. 1320a–7(a) for a minimum of 10 years, effective November 20, 2018.

3. Material Falsification of Applicant's Application (21 U.S.C. 824(a)(1))

I find clear, unequivocal, and convincing record evidence that Applicant answered ''N'' to the first Liability question on the registration renewal application that was received by DEA on or about February 1, 2021. RFAAX 1, App. 1, at 2. I find clear, unequivocal, and convincing record evidence that the text of the first Liability question on the registration renewal application that Applicant submitted on or about February 1, 2021, asked whether Applicant had ''ever been . . . excluded or directed to be excluded from participation in a medicare or state health care program, or is any such action pending.'' [2] *Id.* Accordingly, I find clear, unequivocal, and convincing record evidence that Applicant's ''N'' response to the first Liability question on his application that he submitted on or about February 1, 2021, was false, because the record evidence clearly establishes that on October 31, 2018, Applicant was excluded from Medicare, Medicaid and all federal healthcare programs by HHS. *See* RFAAX 1, App. E.

B. Discussion

In its OSC, the Government relied upon grounds Congress provided to support revocation/suspension, not denial of an application. 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 33,738 33,744–45 (2021) (collecting cases); *see also, William Ralph Kincaid, M.D.,* 86 FR 40,636, 40,641 (2021). A provision of section 824 may be the basis for the denial of a practitioner registration application and allegations related to section 823 remain relevant to the adjudication of a practitioner

[1] Applicant only applied for schedule II non-narcotic (IIN).

[2] Although Applicant submitted evidence in his application related to his conviction and the circumstances of his surrender for cause of his previous DEA registrations, he did not include any discernable information on the HHS/OIG exclusion. RFAAX 1, App. 1 (Application).

registration application when a provision of section 824 is involved. *See Robert Wayne Locklear, M.D.,* 86 FR at 33,744–45.

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 or more 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 Controlled Substances Act (hereinafter, 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 this case, there is no indication that Applicant does not hold a valid state medical license or is not authorized to dispense controlled substances in the State of Utah, where he has applied for a registration.

Because the Government has not alleged that Applicant's registration is inconsistent with the public interest under section 823, and although I have considered 823, I will not analyze Applicant'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* B.

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 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, the undisputed record evidence demonstrates that HHS mandatorily excluded Applicant from federal health care programs. RFAAX 6. Accordingly, I will sustain the Government's allegation that Applicant 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 for revocation exists pursuant to 21 U.S.C. 824(a)(5).[3] 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. *See 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 an application for 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''). Applicant'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.

3. 21 U.S.C. 824(a)(1): Material Falsification

As already discussed, I find clear, unequivocal, and convincing evidence that Applicant submitted a registration application containing a false answer to the first Liability question. *Supra* section A.3. Applicant's false submission implicated Applicant's ''exclu[sion] . . . from participation in a program pursuant to section 1320a–7(a) of Title 42.'' 21 U.S.C. 824(a)(5). As a result, Applicant's false response to the first Liability question directly implicated my analysis related to the CSA's statutory grounds for revocation of a controlled substances registration, which as explained in *supra* B.1 and B.2, the agency has consistently interpreted to be equally relevant to its assessment of an application for a controlled substances registration. *See Robert Wayne Locklear, M.D.,* 86 FR at 33,744–45 (collecting cases). Therefore, Applicant's false submission affected my decision by depriving me of legally relevant facts when I evaluated Applicant's registration application. RFAAX 2, at 1; *see also Frank Joseph Stirlacci, M.D.,* 85 FR 45,229, 45,235 (2020). Accordingly, I find, based on the CSA, agency decisions, and the analysis underlying multiple Supreme Court decisions explaining ''materiality,'' that the falsity Applicant submitted was material. *Frank Joseph Stirlacci, M.D.,* 85 FR at 45,235.

I find that there is clear, convincing, and unequivocal evidence in the record supporting denial of Applicant's application based on his having ''materially falsified any application filed pursuant to or required by this subchapter or subchapter II.'' 21 U.S.C. 824(a)(1).[4]

4. Summary of Government's Prima Facie Case

Where, in section 824(a)(5) cases, the applicant offers no mitigating evidence upon which the Administrator can analyze the facts, the agency has consistently held that revocation/suspension/denial is warranted. *See, e.g., Sassan Bassiri, D.D.S.,* 82 FR 32,200, 32,201 (2017); *Richard Hauser, M.D.,* 83 FR 26,308, 26,310 (2018) (revocation was sought under Section 824(a)(5) and the registrant's certificate of registration was revoked ''based on the unchallenged basis for his mandatory exclusion''). Additionally, in this case, there is evidence on the record that Applicant materially falsified his application. When the basis for revocation/suspension/denial is clear and the registrant/applicant has had notice and the opportunity to present evidence, whether in a hearing or a written statement in accordance with 21 CFR 1301.43, but has chosen not to present any such evidence that could inform the Administrator's decision, it is reasonable that the Administrator should revoke or suspend, or deny. *See KK Pharmacy,* 64 FR 49,507, 49,510 (1999); *Orlando Ortega-Ortiz, M.D.* 70 FR 15,122 (2005); *Lazaro Guerra,* 68 FR 15,266 (2003) (basis for revocation was both (a)(3) and (a)(5)).

Accordingly, I find that there is clear, convincing, and unequivocal evidence in the record supporting denial of Applicant's application based on his exclusion from federal health care programs. 21 U.S.C. 824(a)(5). I further

[3] It is noted that this Agency has concluded repeatedly that the underlying crime requiring exclusion from federal health care programs under Section 1320a–7(a) of Title 42 does not require a nexus to controlled substances in order to be used as a ground for revocation or suspension of a registration or denial of an application. *Narciso Reyes, M.D.,* 83 FR 61,678, 61,681 (2018); *KK Pharmacy,* 64 FR at 49,510 (collecting cases); *Melvin N. Seglin, M.D.,* 63 Red. Reg. 70,431, 70,433 (1998); *Stanley Dubin, D.D.S.,* 61 FR 60,727, 60,728 (1996). In this case, the HHS ALJ applied aggravating factors to extend Applicant's exclusion period due to circumstances such as, the amount of restitution ($288,900) and the length of the criminal activity, which continued over a period of approximately seven years. RFAAX 1, App. E, at 3. Applicant's extensive unlawful activity over the course of seven years and his falsification on his application demonstrate a serious lack of honesty such that I cannot entrust him with a controlled substances registration.

[4] *See supra* B.1 finding that a ground for revocation can serve as a basis for denial of an application.

find that there is clear, convincing, and unequivocal evidence in the record supporting denial of Applicant's application based on his material falsification of his application. 21 U.S.C. 824(a)(1).

C. Sanction

Here, there is no dispute in the record that Applicant is mandatorily excluded pursuant to Section 1320a–7(a) of Title 42, and, further that Applicant materially falsified his application for a controlled substance registration, and therefore, that grounds for the denial of Applicant's application exist. 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 18,882, 18,910 (2018) (collecting cases).

In this case, Applicant failed to respond to the Government's Order to Show Cause and did not avail himself of the opportunity to refute the Government's case. *See* RFAA, at 2. Therefore, Applicant has not provided any remorse or assurances that he would implement remedial measures to ensure such conduct is not repeated. Such silence weighs against the Applicant's registration. *Zvi H. Perper, M.D.,* 77 FR at 64,142, citing *Medicine Shoppe,* 73 FR at 387; *see also Samuel S. Jackson,* 72 FR at 23,853. Further, due to the lack of a statement or testimony from Applicant, it is unclear whether Applicant can be entrusted with a DEA registration; and therefore, I find that sanction is appropriate to protect the public from a recurrence of Applicant's unlawful actions in the context of his CSA registration. *See Leo R. Miller, M.D.,* 53 FR 21,931, 21,932 (1988).

Consequently, I find that the factors weigh in favor of sanction and I shall order the sanctions the Government requested, as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f) and 21 U.S.C. 824(a), I hereby deny the pending application for a Certificate of Registration, Control Number H21079595C, submitted by Daniel R. Nevarre, M.D., as well as any other pending application of Daniel R. Nevarre, M.D. for additional registration in Utah. This Order is effective [insert Date Thirty Days From the Date of Publication in the **Federal Register**].

Anne Milgram,

Administrator.

[FR Doc. 2022–01112 Filed 1–20–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 21–5]

Stephen E. Owusu, D.P.M.; Decision and Order

On October 22, 2020, a former Assistant Administrator, Diversion Control Division, of the Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Stephen E. Owusu, D.P.M. (hereinafter, Respondent) of Brooklyn, New York. Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (OSC), at 1. The OSC proposed the denial of Respondent's application for DEA Certificate of Registration No. W19061136C (hereinafter, COR or registration) and the denial of any applications for any other DEA registrations pursuant to 21 U.S.C. 824(a)(2) and 824(a)(5) because Respondent was convicted of a felony related to controlled substances and because Respondent has been excluded from participation in Medicare, Medicaid, and all federal health care programs pursuant to 42 U.S.C. 1320a–7(a). *Id.*

On November 23, 2020, the Respondent timely requested a hearing, which commenced (and ended) on February 17, 2021, at the DEA Hearing Facility in Arlington, Virginia with the parties, counsel, and witnesses participating via video teleconference (VTC). On April 9, 2021, Administrative Law Judge Teresa A. Wallbaum (hereinafter, the ALJ) issued her Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision or RD). By letter dated May 4, 2021, the ALJ certified and transmitted the record to me for final Agency action. In the letter, the ALJ advised that neither party filed exceptions. Having reviewed the entire record, I adopt the ALJ's rulings, findings of fact, as modified, conclusions of law and recommended sanction with minor modifications, where noted herein.*[A]

*[A] I have made minor modifications to the RD. I have substituted initials or titles for the names of witnesses and patients to protect their privacy and

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Teresa A. Wallbaum; Administrative Law Judge

April 9, 2021

*[B] Respondent proceeded *pro se* throughout the entire case.[1] Respondent timely filed a Request for Hearing. A Prehearing Conference was conducted on January 12, 2021, via VTC. [2]A hearing on the merits of the OSC allegations was conducted on February 17, 2021, via VTC at the DEA Hearing Facility in Arlington, Virginia. The Government filed a Post-Hearing Brief on March 26, 2021.

The issue to be ultimately decided by the Acting Administrator, with the assistance of this Recommended Decision, is whether Respondent's application should be denied based

I have made minor, nonsubstantive, grammatical changes and nonsubstantive, conforming edits. Where I have made substantive changes, omitted language for brevity or relevance, or where I have added to or modified the ALJ's opinion, I have noted the edits with an asterisk, and I have included specific descriptions of the modifications in brackets following the asterisk or in footnotes marked with a letter and an asterisk. Within those brackets and footnotes, the use of the personal pronoun ''I'' refers to myself—the Administrator.

*[B] I have omitted a section of the RD's discussion of the procedural history to avoid repetition with my introduction.

[1] Respondent was advised during the Prehearing Conference that, under 21 CFR 1316.50, he had the right to seek representation by a qualified attorney at his own expense. Respondent was also advised that, if he continued to represent himself, he would be held to the same standards and procedural requirements of an attorney, including adherence to the procedural orders and rulings of this tribunal and to the procedural rules set forth in 21 CFR 1316.41–1316.68. ALJ Ex. 13 at 2, n.3. During the merits hearing, Respondent acknowledged that he had been so advised and confirmed that he wanted to proceed *pro se.* Tr. 7–8.

[2] Respondent failed to submit a Prehearing Statement by the December 29, 2020, deadline set out in this tribunal's Order for Prehearing Statements. ALJ Ex. 3. The tribunal then issued an Order Directing Compliance, which gave Respondent until January 4, 2021, to show good cause as to why he did not comply with the Order for Prehearing Statements. ALJ Ex. 7. Respondent then filed a Prehearing Statement on January 4, 2021, but did not offer any attempt to show good cause for his late filing. ALJ Ex. 8. The tribunal issued a Second Order Directing Compliance on January 4, 2021, requiring Respondent to show good cause. ALJ Ex. 9. Respondent then filed a document styled ''Requisite Good Cause for Late Filing,'' in which he purported to show good cause. ALJ Ex. 10. Thereafter, the tribunal issued an Order Regarding Respondent's Late Filed Prehearing Statement, which set out several of Respondent's failures to comply with the Order for Prehearing Statements, including late filings and at least two failures to serve pleadings on opposing counsel. ALJ Ex. 11. The Order also directed Respondent to file a Prehearing Statement in compliance with the Order for Prehearing Statements by January 11, 2021. *Id.* Respondent finally did file a compliant Prehearing Statement on January 10, 2021. ALJ Ex. 12.