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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1309, and 1316

[Docket No. DEA–438]

RIN 1117-AB36

Default Provisions for Hearing Proceedings Relating to the Revocation, Suspension, or Denial of a DEA Registration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This proposed rulemaking would add provisions requiring a person served with an order to show cause issued pursuant to the Controlled Substances Act to file a request for a hearing no later than 15 days after the date of receipt of the order. The proposed rulemaking would also add provisions requiring that a person who requests a hearing file an answer to the order to show cause no later than 30 days after the date of receipt of the order; it also sets forth criteria for what the answer must contain. The proposed rule would add provisions allowing the entry of a default where a party served with an order to show cause fails to request a hearing, fails to file an answer to the order to show cause, or otherwise fails to defend against the order to show cause. The proposed rule provides that where a party defaults, the factual allegations of the order to show cause would be deemed admitted. The proposed rule would also provide for the dismissal of an order to show cause where the Administration fails to prosecute the proceeding. This proposed rule would also provide that a default may only be excused upon a party establishing good cause to excuse its default and sets forth the procedures a party must follow to

seek such relief. Further, the proposed rule would remove the current provisions allowing a recipient of an order to show cause to file a written statement while waiving his/her/its right to an administrative hearing.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–438" on all correspondence, including any attachments.

Electronic Comments: The Drug Enforcement Administration encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to http://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

Paper Comments: Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield,

Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received, including attachments and other supporting materials, are considered part of the public record. They will be made available by the Drug Enforcement Administration (DEA) for public inspection online at https://www.regulations.gov/. The Freedom of Information Act applies to all comments received. Confidential information or personal identifying information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information.

Comments with confidential information, which should not be made available for public inspection, should be submitted as written/paper submissions. Two written/paper copies should be submitted. One copy will include the confidential information with a heading or cover sheet that states "CONTAINS CONFIDENTIAL INFORMATION." DEA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy should have the claimed confidential information redacted/blacked out. DEA will make this copy available for public inspection online at https://www.regulations.gov/. Other information, such as name and contact information, that should not be made available, may be included on the cover sheet but not in the body of the comment, and must be clearly identified as "confidential." Any information clearly identified as "confidential" will not be disclosed.

An electronic copy of this document is available at https://www.regulations.gov/.

Statutory and Regulatory Background of Administrative Hearing Regulations

DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended, and referred to as the Controlled Substances Act (CSA or the Act).[1] The CSA is designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety. To this end, controlled substances are classified into one of five schedules based upon: the potential for abuse, currently accepted medical use, and the degree of dependence if abused. 21 U.S.C. 812. Listed chemicals are separately classified based on their use in and importance to the manufacture of controlled substances (List I or List II chemicals). 21 U.S.C. 802(33)–(35).

The CSA establishes a closed system of distribution that requires DEA to monitor and control the manufacture, distribution, dispensing, import, and export of controlled substances until they reach their final lawful destination. In order to maintain this closed system of distribution, persons that manufacture, distribute, dispense, import, export, or conduct research or chemical analysis with controlled substances are required to register with DEA at each principal place of business or professional practice. Persons registered with DEA are permitted to possess controlled substances as authorized by their registration and must comply with the applicable requirements associated with their registration. 21 U.S.C. 822. The CSA also

[1] The Attorney General's delegation of authority to DEA may be found at 28 CFR 0.100.

establishes a system to monitor and control the manufacture, distribution, import, and export of listed chemicals and requires that persons who seek to engage in these activities obtain a registration authorizing them to do so from DEA.

In carrying out its functions under the Act, DEA "may hold hearings, sign and issue subpoenas, administer oaths, examine witnesses, and receive evidence at any place in the United States." 21 U.S.C. 875(a). *See also* 21 U.S.C. 965. The Act requires that, except as otherwise provided, hearings involving the proposed denial of an application for a registration or the proposed suspension or revocation of a registration[2] are to be conducted "in accordance with subchapter II of chapter 5 of Title 5," which sets forth the procedures for adversary adjudications under the Administrative Procedure Act (APA).[3] 21 U.S.C. 824(c)(4).

In accordance with the Attorney General's authority to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions" under the Act, 21 U.S.C. 871(b), DEA's predecessor agency, the Department of Justice's Bureau of Narcotics and Dangerous Drugs, first issued regulations in 1971 to implement the Comprehensive Drug Abuse Prevention and Control Act of 1970. *See* 36 FR 7776 (Apr. 24, 1971). With a few exceptions, the administrative hearing provisions of those 1971 regulations are virtually identical to the ones in place today.

The general administrative hearing provisions which apply to all hearings brought pursuant

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[2] Before taking any action to deny, revoke, or suspend a registration to manufacture, distribute, dispense, import, or export a controlled substance or a registration to manufacture, distribute, import or export a list I chemical, DEA must serve upon the applicant or registrant an order to show (OSC) cause why the registration should not be denied, revoked, or suspended. *See* 21 U.S.C. 824(c) and 958(d)(4). The OSC cause must "contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before [DEA] at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order." *Id.* Proceedings for the denial, revocation, or suspension of a registration are to be conducted in accordance with the Administrative Procedure Act. *See id*.

[3] *See* 5 U.S.C. 556 and 557.

to 21 U.S.C. 823, 824 and 958 are found at 21 CFR part 1316, subpart D. Specific administrative hearing provisions relating to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances are in 21 CFR 1301.32, 34 through 37, and 41 through 46, as well as 21 CFR 1316.41 through 68. Administrative hearing provisions relating to the registration of manufacturers, distributors, importers, and exporters of list I chemicals are in 21 CFR 1309.42, 43, 46, 51 through 55, and 21 CFR 1316.41 through 68.

The changes proposed in this action would apply only to hearings relating to the denial, revocation, or suspension of a DEA registration pursuant to 21 U.S.C. 823, 824, and 958. This proposed rulemaking does not contemplate changes for any other types of hearings that DEA may conduct, including hearings relating to quota issuance, revision, or denial, or those relating to the scheduling of controlled substances.

Need for Change and Overview of the Proposed Amendments

Current DEA hearing regulations in 21 CFR parts 1301 and 1309 relating to actions to deny, suspend, or revoke a DEA registration contain neither a rule requiring a responsive pleading to an OSC nor a default provision, in contrast to the hearing regulations of many other Federal agencies. Provisions requiring a responsive pleading to a complaint and authorizing the entry of a default are an accepted part of civil and administrative practice. *See, e.g.*, 16 CFR 3.12 (Federal Trade Commission rule regarding answer and default); 40 CFR 22.15, 22.17 (Environmental Protection Agency rules regarding answer and default); 12 CFR 1081.201 (Consumer Financial Protection Bureau rule regarding answer and default); Fed. R. Civ. P. 8(b) and 55. Because of the absence of such provisions, DEA must expend significant resources to adjudicate registration matters even where the applicant or registrant has effectively opted not to litigate. This scenario occurs in a significant number of DEA administrative actions, and the

addition of these provisions would conserve scarce agency resources[4] and greatly increase the efficiency of the adjudicatory process. Requiring the applicant/registrant to file an answer would improve efficiency even in cases where an applicant/registrant requests a hearing, by narrowing the scope of the hearing to those issues about which there is a legitimate disagreement between the parties.

DEA proposes to add provisions to §§ 1301.37 and 1309.46 requiring applicants/registrants served with an OSC that request a hearing to file an answer responding to each of the allegations contained in the OSC, and to amend § 1316.47 accordingly. DEA also proposes to amend §§ 1301.43(c) and (d), and 1309.53(b) and (c) by adding provisions allowing for entry of a default in various circumstances.

The addition of §§ 1301.37(d) and 1309.46(d) and the proposed changes to § 1316.47 would require an applicant/registrant who requests a hearing to file an answer within 30 days of the date of receipt of the OSC. The deadline to file a request for a hearing would be shortened to 15 days to expedite the hearing process, but the request form would be amended to only require the hearing request itself, and not a substantive response to the OSC. The substantive response material would still be included in the answer, but would retain the same 30-day deadline provided by the current regulations governing time allowed for filing a response to an OSC under §§ 1301.43(a), 1309.53(a), and 1316.47. These staggered deadlines help keep the administrative process on track by compelling the recipient of an OSC to signal their intention to engage the DEA administrative process within 15 days of being served. Without this sort of a staggered deadline, requests to extend the 30-day deadline to file an answer are likely to arrive

[4] It is important to note that the administrative hearings that are the subject of this proposed rulemaking involve fee-paying DEA applicants and registrants. DEA believes that this proposed rulemaking will speed the disposition of cases, and enhance the protection of the public interest.

on, or after the deadline, and if the request for extension is granted, the administrative litigation process will be delayed for an additional 30 to 60 days. The staggered deadlines are not expected to preclude the filing of all extension requests; however, staggering deadlines will help decrease the number of such filings and ensure they are filed earlier in the process. This proposed rule would signal to DEA whether an applicant/registrant intends to contest an OSC, without reducing the amount of time the applicant/registrant has to prepare a substantive response to the OSC. This earlier knowledge (at the 15-day mark) would allow DEA to prioritize its resources on those matters that will proceed to an administrative hearing, and to prepare for the hearings that are most likely to occur.

Staggered deadlines would place only a marginal burden on recipients of OSC. As noted, a recipient need only send an email to the address provided in the OSC stating "I request a hearing" within 15 days of being served with an OSC. DEA believes that these staggered deadlines are appropriate given the relative lack of effort and complexity of a hearing request affirming that the applicant/registrant intends to engage the administrative process in response to the OSC. Filing an answer would likely require more time and effort. Accordingly, DEA believes that requiring the filing of an answer in 30 days—which is more generous than deadlines set by the Federal Rules of Civil Procedure for analogous parties—is appropriate. *See* FED. R. CIV. P. 12(a)(A)(i) (21 day deadline for filing answer).

For each factual allegation in the OSC, the answer must specifically admit, deny, or state that the party does not have, and is unable to obtain, sufficient information to admit or deny the allegation. The proposed rule provides that a party may amend its answer one time prior to the presiding officer's issuance of the prehearing ruling, after which a party may amend its answer only with leave of the presiding officers. These rules would also require an applicant/registrant

to serve a copy of its request for a hearing and its answer on the Administration at the address listed in the OSC, in addition to filing these documents with the Office of the Administrative Law Judges (ALJ).

Under the proposed new language in §§ 1301.43(c)(1) and 1309.53(b)(1), a person who fails to timely request a hearing after properly being served with an OSC pursuant to § 1301.37 or 1309.46 would be deemed to have waived his/her/its right to a hearing and to be in default. The proposed new language of §§ 1301.43(c)(1) and 1309.53(b)(1) provides that a person who fails to timely request a hearing may seek to be excused from the default by filing a motion with the Office of ALJ establishing good cause to excuse the default no later than 45 days after the date on which the person received the OSC. Thereafter, any person who has failed to timely request a hearing and seeks to be excused from a default must file a motion with the Office of the Administrator, which shall have exclusive jurisdiction to rule on the motion.

Similarly, the proposed new language in §§ 1301.43(c)(2) and 1309.53(b)(2) provides that any person who has requested a hearing but fails to timely file an answer, or fails to demonstrate good cause (via a motion for relief) for failing to timely file an answer, will be deemed to have waived his/her/its right to a hearing and to be in default. The proposed new language also provides that, upon motion of the Administration in such circumstances, the presiding officer shall then enter an order terminating the proceeding. However, under § 1316.47(b), the presiding officer, upon request and a showing of good cause (*e.g.*, an unexpected medical emergency, death in the family, excusable neglect), may grant a reasonable extension of the time allowed for filing the answer. *See e.g.*, *Rene Casanova*, *M.D.*, 77 FR 58,150, 58, 150 n.2 (2012) (collecting cases applying "good cause" standard in context of request for extensions). As with any motion for relief from a deadline, a respondent could seek an extension of time prior to the deadline in

question, and the non-moving party would have the opportunity to respond.

The proposed language in §§ 1301.43(c)(3) and 1309.53(b)(3) provides that if the Administration fails to prosecute, or a person who has requested a hearing fails to plead or otherwise defend, that party shall be deemed in default, and the opposing party may move to terminate the proceeding. The proposed rule further provides that upon such motion, the presiding officer shall then enter an order terminating the proceeding absent a showing of good cause by the party deemed to be in default. Upon termination of the proceeding by the presiding officer, a party may seek relief only by filing a motion establishing good cause to excuse its default with the Office of the Administrator. This rule is being proposed because on occasion, applicants/registrants have filed a timely hearing request but, for whatever reason, subsequently failed to participate further in the proceeding, repeatedly failed to adhere to the orders of the presiding officer, or otherwise defend the allegations in the OSC. This means that even if a party who timely filed an answer could subsequently be held in default if it essentially stopped participating in the litigation process, or if its conduct was sufficiently contumacious of the tribunal such that default was an appropriate sanction. This rule, which mirrors the authority trial judges have under the Federal Rules of Civil Procedure to dismiss cases for significant failures to defend or the failure of a party to prosecute a case, *see* Fed. R. Civ. P. 41(b), 55, would authorize the presiding officer to issue an order terminating the proceeding in such cases.

The proposed new language for §§ 1301.43(e) and 1309.53(d) provides that a default shall be deemed to constitute a waiver of the applicant's/registrant's right to a hearing and an admission of the factual allegations of the OSC.

The proposed new language in §§ 1301.43(f)(1) and 1309.53(e)(1) sets forth the procedures to be followed where a party is deemed to be in default. With respect to an applicant/registrant

who is deemed to be in default based on the failure to file a timely hearing request, or where the applicant/registrant is deemed to be in default for failure to file an answer or otherwise defend and the presiding officer has issued an order terminating the proceeding, the proposed rule provides that the Administration may then file a request for final agency action along with a record to support its request with the Administrator who may enter a default pursuant to § 1316.67. This record should include, for instance, documents demonstrating adequate service of process and, where a party held to be in default asserted that the default should be excused, any pleadings filed by both the parties addressing this issue.

In contrast, under the current rules, in cases where the applicant/registrant waives his/her/its right to a hearing, DEA counsel must provide the Administrator with a much more voluminous record, including evidence to support each factual allegation which the Administration seeks to establish. This may include recordings and transcripts of undercover visits, medical records, invoices and dispensing records, and expert reports. Because DEA's current rules do not provide that an applicant's/registrant's waiver of his/her/its right to a hearing constitutes an admission of the factual allegations of the OSC, both the preparation of the record by DEA counsel for submission to the Administrator and the process of reviewing the record and drafting the Administrator's final order require a significant investment of agency resources. The changes proposed here would thus save these resources, which can then be devoted to other pending matters and reduce the time it takes for the Administrator's final order to issue in those cases where applicants/registrants choose not to challenge the proceeding or fail to properly participate in the proceeding.

The proposed rule provides that in the event the Administration is deemed to be in default pursuant to § 1301.43(f)(2) or 1309.53(e)(2), the presiding officer shall transmit the record to the

Administrator for his consideration no later than five (5) business days after the date of issuance of the order. The proposed rule also provides that upon termination of the proceeding by the presiding officer, the Administration may seek relief only by filing a motion establishing good cause to excuse its default with the Office of the Administrator.

The proposed new language in §§ 1301.43(f)(3) and 1309.53(e)(3) provides that a party held to be in default may move to set aside an entry of default final order issued by the Administrator by filing a motion no later than 30 days from the date of issuance by the Administrator of an entry of default. However, any such motion shall be granted only upon a showing of good cause to excuse the default.

Under the proposed amendments to §§ 1301.43(e)(1) and 1309.53(d)(1), the Administrator would be authorized to issue a final order on the basis of a default, but would have the discretion not to take such action. For example, the Administrator might conclude that the factual allegations of the OSC, even deeming them admitted, do not establish violations of the CSA or other conduct which is inconsistent with the public interest. The Administrator may also conclude that any violations or misconduct proved by the admissions nonetheless do not warrant the sanction proposed by the Administration. In such instance, the Administrator would retain the discretion to dismiss the OSC, or issue an appropriate order imposing whatever sanction is warranted by the admitted allegations.

DEA also proposes to remove the provisions in §§ 1301.43(c) and 1309.53(b) that allow for the submission of a written statement in lieu of a hearing. For adjudications relating to registrations and applications, these provisions have proven to be unworkable in practice because these proceedings typically involve the need to resolve disputed historical facts and to make credibility determinations. Either party would, however, retain the ability (as exists currently) to

seek summary disposition on any allegation for which no material facts were in dispute. The current provisions of §§ 1301.43(c) and 1309.53(b) are ambiguous and do not necessarily even allow for, or require the submission of, additional evidence supporting a position statement. Given that the Administration provides an opportunity for a full and fair hearing to any person issued an OSC in accordance with the Due Process Clause and the Administrative Procedure Act, the current provision allowing the submission of unsworn written statements does not enhance the reliability of the Administration's adjudications. Accordingly, DEA is proposing to remove this procedural option, which historically has been invoked by respondents only sparingly.

DEA is also proposing to remove the opportunity of third parties who are entitled to participate in a hearing under § 1301.43(c) to submit a written position statement in lieu of participating in the hearing. In DEA's experience, no party has ever requested this opportunity, and any such party retains the opportunity to participate in the hearing if the applicant/registrant avails itself of its right to a hearing.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This proposed rule was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory

review as established in Executive Order 12866. Executive Order 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. DEA has determined that this proposed rule is not a "significant regulatory action" under Executive Order 12866, section 3(f).

DEA estimates that there are both costs and cost savings associated with the proposed rule. The provisions of this proposed rule apply only to the small minority of applicants and registrants who are issued an OSC. Therefore, a very small minority of registrants would potentially be economically impacted if this rule were promulgated. From 2016 to 2018, there were on average 81 OSCs issued annually. These 81 OSCs fall into one of three categories: (1) an average of 29 cases in which the registrant/applicant surrendered and/or withdrew his/her/its application, thus mooting the case, (2) an average of 11 cases in which the registrant/applicant properly requested a hearing, and (3) the remaining 41 registrants per year who failed to timely file a request for a hearing and were deemed to have waived their right to a hearing and who would be in default under the proposed rule. The 11 registrants per year who properly requested

a hearing are estimated to incur costs while the registrants in the remaining two categories do not.

The proposed rule requires that an applicant/registrant must file an answer responding to every allegation in the OSC. The average of 29 cases in which the registrant/applicant surrenders or withdraws his/her/its application, thus mooting the case, would not result in the registrant/applicant filing an answer to the OSC. Therefore, these registrants/applicants would not incur any costs. The average of 11 cases per year where an applicant requests a hearing may incur a cost associated with answering the factual allegation(s) of the OSC. To estimate the cost of this proposed change, DEA estimates that, on average, it will take five hours for a registrant's attorney to review the OSC and prepare an answer to all allegations. The total estimated cost of this proposed change is $36,190 per year.[5]

The remaining 41 cases, where there was neither a registration surrendered nor a hearing conducted, would be differently impacted by this proposed rule. The proposed rule provides that where a party defaults, the factual allegations of the OSC are deemed admitted. For these 41 cases, where there was registrant inaction, the registrant's cost of inaction is the same under current or proposed rules. There is no additional cost to registrants. This proposed rule would also provide that a default may only be set aside upon a party establishing good cause to excuse its default. DEA has no basis to estimate the number of affected parties who will seek to establish good cause to set aside a default and any costs associated with such activities. However, under *Kamir Garces Mejias*, 72 FR 54931 (2007), a party seeking to be excused from

[5] Hourly rate using Laffey Matrix for lawyers with 8-10 years of experience from 6/1/18 to 5/31/19 is $658 per hour. Total Cost = ($658 x 5 x 11). While it is possible the fees incurred for legal review and to answer the allegations would be offset by a reduction in fees later in the process. This is a new requirement and DEA conservatively estimates this requirement as a new cost.

an ALJ order terminating a proceeding for failing to comply with the ALJ's orders is required to show good cause to excuse its default. Thus, because this proposed requirement of the rule simply codifies case law, it imposes no additional cost to registrants.

Finally, this proposed rule would also result in cost savings for DEA by streamlining the Administrator's review process using the default determination. The proposed rule provides that when an applicant/registrant is deemed to be in default, the Administration may then file a request for final agency action along with a record to support its request with the Administrator who may enter a default. This record should include, for instance, documents demonstrating adequate service of process and, where a party held to be in default asserted that the default should be excused, any pleadings filed by both the parties addressing this issue. In contrast, under the current rules, in cases where the applicant/registrant waives his/her/its right to a hearing, DEA counsel must provide the Administrator with a much more voluminous record, including evidence to support each factual allegation which the Administration seeks to establish. Because DEA's current rules do not provide that an applicant's/registrant's waiver of his/her/its right to a hearing constitutes an admission of the factual allegations of the OSC, both the preparation of the record by DEA counsel for submission to the Administrator and the process of reviewing the record and drafting the Administrator's final order require a significant investment of agency resources. The changes proposed here would thus save these resources, which can then be devoted to other pending matters and reduce the time it takes for the Administrator's final order to issue in those cases where applicants/registrants choose not to challenge the proceeding or fail to properly participate in the proceeding.

To estimate the cost savings of this rule, DEA first estimates the amount of time and resources that would be saved for cases that would be resolved via entry of a default. The

complexity of a given case would impact both how much time it would take to prepare the request for final agency action (FAA) and for the Administrator's Office to draft the final order based on that FAA request, which cumulatively would represent the amount of resources saved in a given case. For a case based solely on allegations related to a lack of state authority, or an exclusion from federal health care programs, the gathering of the evidence, including declarations, and preparation of the FAA motion take, on average, approximately 10-15 hours. For cases with allegations (most commonly, improper prescribing or filling of prescriptions), the preparation of the FAA materials is considerably longer – approximately 30-40 hours per case. It is estimated that of the cases in which there was neither a hearing request nor a registration surrender, roughly 30-40% are No State License (NSL) cases and 60-70% of cases would be considered other non-NSL cases. For the purpose of this analysis, DEA estimates that of the 41 cases this rule would impact on average each year, 65% would be considered non-NSL cases and take 35 hours to prepare a FAA for, while 35% would be considered NSL cases and take 13 hours to prepare a FAA for. Applying the loaded wage[6] for GS-15 Step 5 employees,[7] DEA estimates the cost savings of this rule for the time it would take to prepare the FAA request is around $134,065 per year.[8]

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[6] The loaded wage includes the average benefits for employees in the government. Therefore, the loaded wage is the estimated cost of employment to the employer rather than the compensation to the employee.

[7] Hourly rate for GS-15 Step 5 employees in the Washington, D.C. region is $74.86. 2019 General Schedule Locality Pay Tables for the Washington-Baltimore-Arlington area, Office of Personnel Management, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/DCB_h.pdf. Average benefits for state government employees is 37.5% of total compensation. Employer Costs for Employee Compensation – December 2018, Bureau of Labor Statistics, https://www.bls.gov/news.release/archives/ecec_03192019.pdf. The 37.5% of total compensation equates to 60% (37.5% / 62.5%) load on wages and salaries. The loaded hourly rate is $119.78 ($74.86 x 1.6). The ECEC does not provide figures for Federal Government employees; therefore, figures for state employees are used as estimate.

[8] ($119.78 x 41 x 65% x 35) + ($119.78 x 41 x 35% x 13).

Additionally, there are cost savings from the time it would take the Administrator's Office to draft the final order based on that FAA request. The cost savings for the Administrator's review process would be the most significant for all substantive cases that would be subject to the rule. The Administrator's review process consists of the time to review the FAA request, evaluate the evidence submitted by DEA counsel, draft a decision, and the time the Administrator must spend reviewing the proposed decision. On average, there are four substantive cases per year that would be subject to the rule. Currently, the estimated time it takes for the substantive cases is 30 days or 240 hours. With the rule promulgated, the estimated time it will take for these substantive cases will be between one day and two weeks depending on the complexity of the case. For the purpose of this analysis, DEA estimates it will take seven days or 56 hours with the rule promulgated. Using the loaded hourly wage of a GS-15 Step 5 employee, the estimated cost savings for substantive cases is $88,155 per year.[9] There is also cost savings for non-substantive cases, but DEA believes this cost savings to be minimal for the Administrator's review process. Also, while there is a difference in the legal definition of "deemed to have waived" versus "deemed to be in default," there is no enhancement of potential sanctions. The Administrator will continue to issue the final order based on the same set of circumstances regarding the OSC and the default determination, versus the current "deemed to have waived" determination with the additional voluminous record provided. Therefore, the cost savings due to the Administrator's review process is estimated to be around $88,155 per year.

In summary, there are both costs and cost savings associated with this proposed rule. DEA has no basis to estimate the additional litigation costs for registrants who are "deemed to be in default" as a result of the proposed rule as compared to registrants who are "deemed to have

[9] (4 x 240 x $119.78) – (4 x 56 x $119.78) = $88,155.

waived" under the existing regulations, but believes this additional litigation cost to be minimal due to the small number of these cases occurring each year. The total cost to registrants due to the requirement that an applicant/registrant must file an answer to an OSC is $36,190 per year. This proposed rule has an estimated cost savings of $222,220 ($134,065 + $88,155) per year for DEA by streamlining the Administrator's review process using the default determination. The estimated net cost savings of this rule is $186,030 ($222,220 - $36,190) per year.

Therefore, DEA does not anticipate that this rulemaking will have an annual effect on the economy of $100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

This proposed rule has been characterized as "Other" for purposes of E.O. 13771 because costs of this proposed rule have not finally been determined.

Executive Order 12988, Civil Justice Reform

The proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–12) (RFA), has reviewed this rule and by approving it certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

In accordance with the RFA, DEA evaluated the impact of this rule on small entities. The proposed rule would add provisions allowing the entry of a default where a party served with an OSC fails to request a hearing, fails to file an answer to the OSC, or otherwise fails to defend against the OSC. *Cf.* Fed. R. Civ. P. 55(a). The proposed rule provides that where a party defaults, the factual allegations of the OSC are deemed admitted. Further, the proposed rule would remove the current provisions allowing a recipient of an OSC to file a written statement while waiving his/her/its right to an administrative hearing. As all DEA registrants would be subject to the amended administrative enforcement procedures described in the notice of proposed rulemaking, the proposed rule could potentially affect any person holding or planning to hold a DEA registration to handle controlled substances and those manufactures, distributors, importers, and exporters of list I chemicals. As of March 2019, there were approximately 1.8 million DEA registrations for controlled substances and list I chemicals. Registrants include individual practitioners (such as physicians, dentists, mid-level practitioners, etc.), business entities (such as offices of physicians, pharmacies, hospitals, pharmaceutical manufacturers, distributors, importers, exporters, etc.), and governmental or tribal agencies that handle controlled substances or list I chemicals.

In practice, a very small minority of DEA registrants are served with OSCs in connection with the denial or cancellation of registration, and thus a very small minority of DEA registrants would be impacted by the proposed rule. Over the three-year period 2016-2018, there was an average of 81 OSCs served per year. These 81 OSCs fall into one of three categories: (1) an average of 29 cases in which the registrant/applicant surrendered the registration and/or withdrew his/her/its application, thus mooting the case, (2) an average of 11 cases in which the registrant/applicant properly requested a hearing, and (3) the remaining 41 registrants per year who failed to timely file a request for a hearing and were deemed to have waived their right to a hearing (and would be in default under the proposed rule). The 11 registrants per year who properly requested a hearing are estimated to incur costs while the registrants in the remaining two categories do not.

The proposed rule requires that an applicant/registrant must file an answer responding to every allegation in the OSC. The average of 29 cases in which the registrant/applicant surrenders or withdraws his/her/its application, thus mooting the case, would not result in the registrant/applicant filing an answer to the allegations in the OSC. Therefore, these registrants/applicants would not incur any costs. The average of 11 cases per year where a registrant/applicant requests a hearing may incur a cost associated with answering the allegation(s) of the OSC. To estimate the cost of this proposed change, DEA estimates that, on average, it will take five hours for a registrant/applicant's attorney to review the OSC and prepare an answer to all allegations, or an average of $3,290 per registrant.[10]

[10] Hourly rate using Laffey Matrix for lawyers with 8-10 years of experience from 6/1/18 to 5/31/19 is $658 per hour. $658 x 5 = $3,290.

The remaining 41 cases, where there was neither a registration surrendered nor a hearing conducted, would be differently impacted by this proposed rule. The proposed rule provides that where a party defaults, the factual allegations of the OSC are deemed admitted. This proposed rule would also provide that a default may only be set aside upon a party establishing good cause to excuse its default. DEA has no basis to estimate the number of affected parties who will seek to establish good cause to set aside a default and any costs associated with such activities. However, under *Kamir Garces Mejias*, 72 FR 54931 (2007), a party seeking to be excused from an ALJ order terminating a proceeding for failing to comply with the ALJ's orders is required to show good cause to excuse its default. Thus, because this proposed requirement of the rule simply codifies case law, it imposes no additional cost to registrants.

In summary, it is estimated that there will be an average of 11 cases per year, in which the registrant/applicant properly requests a hearing and will incur an economic impact of $3,290 if this proposed rule is promulgated. Because the subject of the 11 cases can be an individual or entity (i.e., offices of physicians, pharmacies, hospitals, pharmaceutical manufacturers, distributors, importers, exporters, governmental or tribal agencies, etc.), DEA compared the estimated cost of $3,290 to the average revenue of the smallest entities for some representative North American Industry Classification System (NAICS) codes for DEA registrants using data from U.S. Census Bureau, Statistics of U.S. Businesses (SUSB).

For example, there are a total of 174,901 entities in NAICS code, 621111-Office of Physicians (Except Mental Health Specialists). Of the 174,901 total entities, DEA estimates that 97.6% are small entities. DEA compared the estimated cost of $3,290 to the revenue of the smallest of small entities, those with 0-4 employees. There are 95,494 entities in the 0-4 employee category with a combined total annual revenue of $42,823,012,000, or an average of

$448,000 per entity (rounded to nearest thousand).[11] The estimated cost of $3,290 is 0.73% the average annual revenue of $448,000. The same analysis was conducted for each representative NAICS code. The cost as percent of average revenue for the smallest of small entities ranges from 0.24% to 1.30%. The table below summarizes the analysis and results.

NAICS Code	NAICS Code-Description	Total Number of Entities	Estimated Number of Small Entities	Smallest Employment Size Category Analysis				
				Employment Size (Number of Employees)	Number of Firms	Estimated Receipts ($000)	Average Revenue per Firm ($000)	Cost as % of Revenue
325412	Pharmaceutical Preparation Manufacturing	930	863	0-4	297	N/A	N/A	N/A
424210	Drugs and Druggists' Sundries Merchant Wholesalers	6,618	6,348	0-4	3,628	4,962,687	1,368	0.24%
446110	Pharmacies and Drug Stores	18,852	18,481	0-4	6,351	6,803,003	1,071	0.31%
541940	Veterinary Services	27,708	27,032	0-4	8,878	2,594,724	292	1.13%
621111	Offices of Physicians (except Mental Health Specialists)	174,901	170,634	0-4	95,494	42,823,012	448	0.73%
621112	Offices of Physicians, Mental Health Specialists	10,876	10,611	0-4	8,977	2,279,458	254	1.30%
621210	Offices of Dentists	125,151	122,097	0-4	50,711	16,801,830	331	0.99%
621320	Offices of Optometrists	19,731	19,250	0-4	10,913	2,946,400	270	1.22%
621391	Offices of Podiatrists	8,122	7,924	0-4	5,284	1,529,293	289	1.14%

[11] Data for NAICS codes are based on the 2012 SUSB Annual Datasets by Establishment Industry, June 2015. SUSB annual or static data include number of firms, number of establishments, employment, and annual payroll for most U.S. business establishments. The data are tabulated by geographic area, industry, and employment size of the enterprise. The industry classification is based on 2012 North American Industry Classification System (NAICS) codes.

In conclusion, this proposed rule will have an estimated cost of $3,290 on an average of 11 small entities per year. The $3,290 is estimated to represent 0.24%-1.30% of annual revenue for the smallest of small entities, entities with 0-4 employees. Therefore, DEA estimates the proposed rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The estimated annual impact of this rule is minimal. DEA has determined, in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 et seq., that this action would not result in any federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

Paperwork Reduction Act of 1995

This proposed rule would not create or modify a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports.

21 CFR Part 1316

Administrative practice and procedure, Authority delegations (Government agencies), Drug traffic control, Research, Seizures and forfeitures.

For the reasons stated in the preamble, DEA proposes to amend 21 CFR parts 1301, 1309, and 1316 as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

2. In § 1301.37, revise paragraph (d) to read as follows:

§ 1301.37 Order to show cause.

* * * * *

(d)(1) *When to File: Hearing Request*. A party that wishes to request a hearing in response to an order to show cause must file with the Office of the Administrative Law Judges and serve on the Administration a hearing request no later than fifteen (15) days after the date of receipt of the order to show cause. Service of the request on the Administration shall be accomplished by sending it to the address provided in the order to show cause.

(2) *When to File: Answer*. A party requesting a hearing shall also file with the Office of the Administrative Law Judges and serve on the Administration an answer to the order to show cause no later than thirty (30) days following the date of receipt of the order to show cause. A party shall serve its answer on the Administration at the address provided in the order to show

cause. The presiding officer may, upon a showing of good cause by the party, consider an answer that has been filed out of time.

(3) *Contents of Answer; Effect of Failure to Deny*. For each factual allegation in the order to show cause, the answer shall specifically admit, deny, or state that the party does not have and is unable to obtain sufficient information to admit or deny the allegation. When a party intends in good faith to deny only a part of an allegation, the party shall specify so much of it as is true and shall deny only the remainder. A statement of a lack of information shall have the effect of a denial. Any allegation not denied shall be deemed admitted.

(4) *Amendments*. Prior to the issuance of the prehearing ruling, a party may as a matter of right amend its answer one time. Subsequent to the issuance of the prehearing ruling, a party may amend its answer only with leave of the presiding officer. Leave shall be freely granted when justice so requires.

* * * * *

3. In § 1301.43:

a. Revise the section heading and paragraph (a);

b. Add a heading to paragraph (b);

c. Revise paragraphs (c) through (e); and

d. Add paragraph (f).

The revisions and additions read as follows:

§ 1301.43 Request for hearing or appearance; waiver; default.

(a) *Written request for a hearing.* Any person entitled to a hearing pursuant to § 1301.32 or §§ 1301.34 through 1301.36 and desiring a hearing shall, within 15 days after the date of receipt of the order to show cause (or the date of publication of notice of the application for registration

in the FEDERAL REGISTER in the case of § 1301.34), file with the Administrator a written request for hearing in the form prescribed in § 1316.47 of this chapter.

(b) *Written notice of intent.*

* * * * *

(c) *Default; criteria*. (1) Any person entitled to a hearing pursuant to § 1301.32 or §§ 1301.34 through 36 who fails to file a timely request for a hearing, shall be deemed to have waived his/her/its right to a hearing and to be in default. Any person who has failed to timely request a hearing under paragraph (a) of this section may seek to be excused from the default by filing a motion with the Office of Administrative Law Judges establishing good cause to excuse the default no later than 45 days after the date of receipt of the order to show cause. Thereafter, any person who has failed to timely request a hearing under paragraph (a) of this section and seeks to be excused from the default shall file such motion with the Office of the Administrator, which shall have exclusive jurisdiction to rule on the motion.

(2) Any person who has requested a hearing pursuant to this section but who fails to timely file an answer and who fails to demonstrate good cause for failing to timely file an answer, shall be deemed to have waived his/her/its right to a hearing and to be in default. Upon motion of the Administration, the presiding officer shall then enter an order terminating the proceeding.

(3) In the event the Administration fails to prosecute or a person who has requested a hearing fails to plead (including by failing to file an answer) or otherwise defend, said party shall be deemed to be in default and the opposing party may move to terminate the proceeding. Upon such motion, the presiding officer shall then enter an order terminating the proceeding, absent a showing of good cause by the party deemed to be in default. Upon termination of the proceeding by the presiding officer, a party may seek relief only by filing a motion establishing good cause

to excuse its default with the Office of the Administrator.

(d) *Failure to file; appear.* If any person entitled to participate in a hearing pursuant to § 1301.34 or 1301.35(b) fails to file a notice of appearance, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived his/her/its opportunity to participate in the hearing, unless such person shows good cause for such failure.

(e) *Default.* A default shall be deemed to constitute a waiver of the applicant's/registrant's right to a hearing and an admission of the factual allegations of the order to show cause.

(f) *Procedure*. (1) In the event that an applicant/registrant is deemed to be in default pursuant to paragraph (c)(1) of this section, or the presiding officer has issued an order terminating the proceeding pursuant to paragraphs (c)(2) or (3) of this section, the Administration may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default pursuant to § 1316.67.

(2) In the event the Administration is deemed to be in default and the presiding officer has issued an order terminating the proceeding pursuant to paragraph (c)(3) of this section, the presiding officer shall transmit the record to the Administrator for his consideration no later than five (5) business days after the date of issuance of the order. Upon termination of the proceeding by the presiding officer, the Administration may seek relief only by filing a motion establishing good cause to excuse its default with the Office of the Administrator.

(3) A party held to be in default may move to set aside a default issued by the Administrator by filing a motion no later than 30 days from the date of issuance by the Administrator of a default. Any such motion shall be granted only upon a showing of good cause to excuse the default.

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

4. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 953, 957, 958.

5. In § 1309.46, revise paragraph (d) to read as follows:

§ 1309.46 Order to show cause.

* * * * *

(d)(1) *When to File: Hearing Request*. A party that wishes to request a hearing in response to an order to show cause must file with the Office of the Administrative Law Judges and serve on the Administration such request no later than fifteen (15) days following the date of receipt of the order to show cause. Service of the request on the Administration shall be accomplished by sending it to the address provided in the order to show cause.

(2) *When to File: Answer*. A party requesting a hearing shall also file with the Office of the Administrative Law Judges and serve on the Administration an answer to the order to show cause no later than thirty (30) days following the date of receipt of the order to show cause. A party shall also serve its answer on the Administration at the address provided in the order to show cause. The presiding officer may, upon a showing of good cause by the party, consider an answer that has been filed out of time.

(3) *Contents of Answer; Effect of Failure to Deny*. For each allegation in the order to show cause, the answer shall specifically admit, deny, or state that the party does not have, and is unable to obtain, sufficient information to admit or deny the allegation. When a party intends in good faith to deny only a part of an allegation, the party shall specify so much of it as is true and

shall deny only the remainder. A statement of a lack of information shall have the effect of a denial. Any allegation not denied shall be deemed admitted.

(4) *Amendments*. Prior to the issuance of the prehearing ruling, a party may as a matter of right amend its answer one time. Subsequent to the issuance of the prehearing ruling, a party may amend its answer only with leave of the presiding officer. Leave shall be freely granted when justice so requires.

* * * * *

6. In § 1309.53, revise the section heading and paragraphs (b) and (d), and add paragraph (e) to read as follows:

§ 1309.53 Request for hearing or appearance; waiver; default.

* * * * *

(b) *Default; criteria*. (1) Any person entitled to a hearing pursuant to § 1309.42 or 1309.43 who fails to file a timely request for a hearing, shall be deemed to have waived his/her/its right to a hearing and to be in default. Any person who has failed to timely request a hearing under paragraph (a) of this section may seek to be excused from the default by filing a motion with the Office of Administrative Law Judges establishing good cause to excuse the default no later than 45 days after the date of receipt of the order to show cause. Thereafter, any person who has failed to timely request a hearing under paragraph (a) of this section and seeks to be excused from the default, shall file such motion with the Office of the Administrator, which shall have exclusive jurisdiction to rule on the motion.

(2) Any person who has requested a hearing pursuant to this section but who fails to timely file an answer and who fails to demonstrate good cause for failing to timely file an answer, shall be deemed to have waived his/her/its right to a hearing and to be in default. Upon motion of the

Administration, the presiding officer shall then enter an order terminating the proceeding.

(3) In the event the Administration fails to prosecute or a person who has requested a hearing fails to plead (including by failing to file an answer) or otherwise defend, said party shall be deemed to be in default and the opposing party may move to terminate the proceeding. Upon such motion, the presiding officer shall then enter an order terminating the proceeding, absent a showing of good cause by the party deemed to be in default. Upon termination of the proceeding by the presiding officer, a party may seek relief only by filing a motion establishing good cause to excuse its default with the Office of the Administrator.

* * * * *

(d) *Default.* A default shall be deemed to constitute a waiver of the applicant's/registrant's right to a hearing and an admission of the factual allegations of the order to show cause.

(e) *Procedure*. (1) In the event that an applicant/registrant is deemed to be in default pursuant to paragraph (b)(1) of this section, or the presiding officer has issued an order termination the proceeding pursuant to paragraphs (b)(2) or (3) of this section, the Administration may then file a request for final agency action with the Administrator, along with a record to support its request. In such circumstances, the Administrator may enter a default pursuant to § 1316.67 of this chapter.

(2) In the event that the Administration is deemed to be in default and the presiding officer has issued an order terminating the proceeding pursuant to paragraph (b)(3) of this section, the presiding officer shall transmit the record to the Administrator for his consideration no later than five (5) business days after the date of issuance of the order. Upon termination of the proceeding by the presiding officer, the Administration may seek relief only by filing a motion establishing good cause to excuse its default with the Office of the Administrator.

(3) A party held to be in default may move to set aside a default issued by the Administrator by filing a motion no later than 30 days from the date of issuance by the Administrator of a default. Any such motion shall be granted only upon a showing of good cause to excuse the default.

PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

7. The authority citation for part 1316, subpart D, continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 875, 958(d), 965.

8. Amend § 1316.47 by revising the section heading and paragraphs (a) and (b) to read as follows:

§ 1316.47 Request for hearing; answer.

(a) *Hearing request format.* Any person entitled to a hearing and desiring a hearing shall, within the period permitted for filing, file a request for a hearing that complies with the following format (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address):

(Date)_____

Drug Enforcement Administration, Attn: Hearing Clerk/OALJ

(Mailing Address)_____

____

Subject: Request for Hearing

Dear Sir:

The undersigned _____ (Name of the Person) hereby requests a hearing in the matter of: _____ (Identification of the proceeding).

(State with particularity the interest of the person in the proceeding.)

All notices to be sent pursuant to the proceeding should be addressed to:

(Name)_____

(Street Address)_____

(City and State)_____

Respectfully yours,

(Signature of Person)_____

(b) *Filing of an answer*. A party shall file an answer as required under § 1301.37(d) or 1309.46(d) of this chapter, as applicable. The presiding officer, upon request and a showing of good cause, may grant a reasonable extension of the time allowed for filing the answer.

9. Revise the first sentence of § 1316.49 to read as follows:

§ 1316.49 Waiver of hearing.

In proceedings other than those conducted under part 1301 or part 1309 of this chapter, any person entitled to a hearing may, within the period permitted for filing a request for hearing or notice of appearance, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. * * *

Timothy J. Shea,
Acting Administrator.

[FR Doc. 2020-19309 Filed: 9/29/2020 8:45 am; Publication Date: 9/30/2020]