requirement to prepare an environmental assessment or an environmental impact statement where they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. Preemption

Section 26(a) of the CPSA provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued under that provision ''consumer product safety standards.'' Therefore, once a rule issued under section 104 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

K. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standards organization revises a standard that the Commission adopted as a mandatory standard, the revision becomes the CPSC standard within 180 days of notification to the Commission, unless the Commission timely notifies the standards organization that it has determined that the revision does not improve the safety of the product, or the Commission sets a later date in the **Federal Register**. 15 U.S.C. 2056a(b)(4)(B). The Commission is taking neither of those actions with respect to the standard for gates and enclosures. Therefore, ASTM F1004–22 will take effect as the new mandatory standard for gates and enclosures on January 21, 2023, 180 days after July 25, 2022, when the Commission received notice of the revision.

L. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a ''major rule.'' The CRA states that the Office of Information and Regulatory Affairs determines whether a rule qualifies as a ''major rule.''

Pursuant to the CRA, this rule does not qualify as a ''major rule,'' as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1239

Consumer protection, Imports, Incorporation by reference, Infants and children, Law enforcement, Safety.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

PART 1239—SAFETY STANDARD FOR GATES AND ENCLOSURES

■ 1. The authority citation for part 1239 continues to read as follows:

Authority: 15 U.S.C. 2056a.

■ 2. Revise § 1239.2 to read as follows:

§ 1239.2 Requirements for gates and enclosures.

Each gate and enclosure must comply with all applicable provisions of ASTM F1004–22, *Standard Consumer Safety Specification for Expansion Gates and Expandable Enclosures,* approved on June 1, 2022. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A read-only copy of the standard is available for viewing on the ASTM website at *https://www.astm.org/READINGLIBRARY/.* You may obtain a copy from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; telephone (610) 832–9585; *www.astm.org.* You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504–7479, email *cpsc-os@cpsc.gov,* or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–24561 Filed 11–10–22; 8:45 am]

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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 Registration

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its regulations by adding and revising provisions which enable DEA to hold registrants or applicants in default when they fail to timely request a hearing, or otherwise fail to participate in hearings. DEA is also amending its regulations to include an answer provision which will regulate how registrants respond to an Order to Show Cause (OTSC). These changes involve the revocation, suspension, or denial of a registration and do not affect other types of hearings.

DATES: This final rule is effective 30 days from November 14, 2022.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory History

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).[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

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

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).

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, which included administrative hearing provisions.[2] With a few exceptions, the administrative hearing provisions of those 1971 regulations are virtually identical to the ones in place today.

The changes in this action 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 rule does not implement changes for any other type of hearings that DEA may conduct, including hearings relating to quota issuance, revision, or denial, or those relating to the scheduling of controlled substances.

B. Existing Regulations

The general administrative hearing provisions which apply to all hearings brought pursuant 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, 1301.34–37, and 1301.41–46, as well as 21 CFR 1316.41–68. Administrative hearing provisions relating to the registration of manufacturers, distributors, importers, and exporters of list I chemicals are in 21 CFR 1309.42, 1309.43, 1309.46, 1309.51–55, and 21 CFR 1316.41–68.

In contrast to the hearing regulations of many other federal agencies, current DEA regulations contained in 21 CFR parts 1301, 1309, and 1316 relating to actions to deny, suspend, or revoke a DEA registration do not contain a responsive pleading to an OTSC (*i.e.,* an answer provision) or a default provision. The changes in this final rule 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 rulemaking does not amend any other type of hearings regulations that DEA may conduct, including hearings relating to quota issuance, scheduling of controlled substances, etc.

II. Purpose and Need for Rulemaking

DEA is revising its regulations by adding new provisions to increase the efficiency of, and facilitate the processing of, its administrative hearings. In the current practice, the lack of an answer provision or default provision resulted in agency inefficiencies where litigants waive their right to a hearing or otherwise fail to participate in the administrative hearing process. DEA is promulgating several new provisions for the purpose of mitigating the issues of litigants failing to participate generally in the administrative process.

A. Need for New Provisions

DEA needs to revise its regulations in order to expedite the administrative hearing process as the current provisions may cause administrative waste for DEA and potential delays for registrants. First, the lack of a default provision has led to excessive extension requests in circumstances where the registrant eventually decides to not request a hearing. Additionally, the lack of clear provisions regarding responsive pleadings has led to confusion and inefficiency, and it unnecessarily slowed down the administrative hearing process.

The absence of a default provision has led to inefficiencies in circumstances where DEA prepared extensively for hearings that never occurred, or occurred later than they should due to respondents not complying with orders in the case. Respondents presently are permitted 30 days to request a hearing upon receipt of an OTSC. If a request for an extension was granted by the presiding officer, this gives respondents up to an additional 30 to 60 days to respond. DEA could thus be preparing for litigation for up to 90 days under some circumstances, which is excessively long for the filing of a request for hearing. This problem is exacerbated in light of the absence of any default provision, as DEA could be preparing for litigation for 90 days in cases where no hearing is actually requested.

Furthermore, as noted, DEA regulations currently have no default provision which permits the government's (or respondent's) entry of default upon a litigant's failure to participate. Additionally, if respondents fail to otherwise participate in the hearing process, DEA must submit an entry for final order to the Administrator. This final order requires a voluminous record providing evidence in support of every factual allegation that was included in the OTSC. This results in a very large time and resource investment for DEA to review the record and draft the final order.

Last, DEA lacks a comprehensive set of rules for responsive pleadings, or the answer. The existing rules are unclear what the answer should contain, thus resulting in ambiguity for the general public (pro se litigants in particular). As a result, DEA occasionally receives responsive pleadings that were incomplete or insufficient, thus leading to an unnecessary delay of the administrative process. Furthermore, the regulations lack a provision dictating what happens procedurally should the respondent fail to file an answer. Thus, DEA needs amendments to its administrative hearing regulations in the form of adding default provisions and updating responsive pleading rules.

B. Purpose and Description of Changes

DEA is amending its administrative hearing regulations by adding certain provisions and revising other provisions to increase the efficiency of the administrative hearing process. As stated above, these changes are necessary to prevent the unnecessary expenditure of agency resources, to clarify obligations, and to expedite the hearing process for both parties. The changes in this action 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. Again, this rulemaking does not contemplate changes for any other types of hearings that DEA may conduct, such as hearings relating to the scheduling of controlled substances, quota issuance, etc.

15 Days To Request a Hearing

In the Notice of Proposed Rulemaking (NPRM), DEA had proposed to revise the existing regulations to decrease the deadline for submitting a request for a hearing from the current 30 days to 15 days. In light of the public comments and upon further consideration of the issues, DEA has decided to maintain the current deadline for requesting a hearing and the final rule retains the 30-day deadline after receipt of the OTSC for submitting a request for a hearing.

As a result of this decision, DEA is thus revising the provisions pertaining to this deadline as follows: 21 CFR

[2] *See Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970,* 36 FR 7776 (Apr. 24, 1971).

1301.37(d) by adding paragraph (1); [3] § 1309.46(d) by adding paragraph (1); and § 1316.47 by amending paragraphs (a) and (b). These changes reflect the requirement of respondents, should they desire to contest the OTSC, to file a request for a hearing in response to an OTSC within 30 days of receipt of the OTSC.[4] DEA believes these changes will achieve the desired ends of administrative efficiency while not materially changing the burden of respondents as the time in which to request a hearing is not changed. Allowing 30 days for requesting a hearing is consistent with the 30-day time period for respondents to file an answer.

Filing an Answer

DEA is amending the following provisions, which require that respondents who request a hearing will file an answer to the OTSC within 30 days of the receipt of the OTSC: § 1301.37(d) by adding paragraph (2); § 1309.46(d) by adding paragraph (2); and § 1316.47 by revising paragraph (b).

First, § 1301.37(d)(2) permits the presiding officer, the Administrative Law Judge, to consider an answer that was filed after the deadline upon a showing of good cause. DEA anticipates that, in contrast to simply requesting a hearing, preparing an answer will take more time and effort than simply requesting a hearing. Thus, DEA believes the 30-day requirement to file an answer, with a good cause provision in the event of delay, is sufficiently tailored to balance the needs of the public with the interest in administrative efficiency.

Next, DEA is amending § 1301.37(d) by adding paragraph (3), and § 1309.46(d) by adding paragraph (3). These provisions require respondents to admit, deny, or state they are unable to answer each factual allegation contained in the OTSC. It also provides that any allegation not denied shall be deemed admitted. This addition is necessary to clarify the requirements of an answer to the general public, in order to limit the scope of the proceeding to issues which are genuinely in dispute. Last, DEA is amending § 1301.37(d) by adding paragraph (4), and § 1309.46(d) by adding paragraph (4), which state that a party may amend its answer as a matter of right once before the prehearing ruling. These provisions also grant the presiding officer leave to permit amendments to the answer as justice so requires.

The changes to these provisions are needed to clarify, to the general public, when and under what circumstances an answer is required. As stated, prior to adopting this rule it has been unclear to respondents when and under what circumstances an answer must be filed, and what must be contained in the answer. These changes elucidate exactly when an answer is required and what must be contained, and grant authority to the presiding officer to make exceptions when merited.

Default Provisions

DEA is amending its regulations to permit the entry of default where a party fails to timely request a hearing, or fails to participate in the administrative hearing process. DEA is amending its regulations by revising § 1301.43(c)(1) and § 1309.53(b)(1),[5] to permit DEA's entry of default where the respondent fails to timely request a hearing in response to an OTSC. Respondents who fail to request a hearing are nevertheless able to waive the default by filing a motion with the Office of Administrative Law Judges within 45 days after the date of receipt of the OTSC. The presiding officer may rule on the motion timely filed within 45 days, and may waive the default after the 45-day period lapsed. The presiding officer is authorized to grant the motion. DEA believes this rule is necessary to prevent administrative waste while also providing sufficient discretion for the presiding officer to nevertheless permit a hearing in circumstances which merit excuse.

Under this rule, once a registrant is in default for failure to timely file a request for a hearing or file an answer, this means that the respondent is deemed to agree to all of the factual allegations in the OTSC.[6] Without this provision, DEA would be required to prepare an administrative record providing evidence sufficient to support every factual allegation in the OTSC, regardless of whether the respondent wishes to contest those allegations or whether, had he so contested, he would have challenged every factual allegation.

Next, DEA is amending its regulations by adding several instances where a party can be held in default for generally failing to participate in the administrative hearing process. First, DEA is adding § 1301.43(c)(2), as well as § 1309.53(b)(2), which state that respondents who request a hearing, but fail to timely file an answer (and fail to demonstrate good cause) are considered to have waived their opportunity for a hearing and are in default. Once a party is held in default for failing to timely file an answer and fails to establish good cause, the presiding officer is required to enter an order terminating the proceedings once DEA files a motion. Moreover, DEA is adding § 1301.43(c)(3), as well as § 1309.53(b)(3), which states a party shall also be in default for failing to plead or otherwise defend. Upon motion, the presiding officer must enter an order terminating the proceeding unless the party can demonstrate good cause to stay the order. After termination of the proceeding, a party may also file a motion to excuse default with the Office of the Administrator.

DEA is amending its regulations by revising § 1301.43(e) and 1309.53(d) to state that in all instances of default, the party's default shall be deemed to constitute a waiver of their right to a hearing, and an admission of the factual allegations of the order to show cause. Moreover, DEA is amending its regulations by adding § 1301.43(f)(1)–(3) and § 1309.53(e)(1)–(3), which specify the required procedure to follow once a respondent is in default. Once a respondent is in default, and the presiding officer has issued an order terminating the proceedings, DEA may file a request for a final agency action with the Administrator. Respondents have the right to appeal either the termination of proceeding or the final order by following the procedures contained therein.

The aforementioned provisions allow the entry of default in circumstances in which the respondent essentially waives their right and opportunity to participate in the hearing process by failing to request a hearing, failing to respond, or otherwise failing to participate. These provisions are necessary, as DEA is needlessly expending significant resources in common circumstances where the respondent fails to litigate. Under the default provisions in this final rule, this admission of the factual allegations of the OTSC in the event of default facilitates the enforcement process by eliminating the need for DEA to provide

[3] This rule is revising 21 CFR 1301.37(d) (relating to controlled substance registrations) by replacing paragraph (d) with paragraphs (d)(1) through (d)(4). New paragraph (d)(1) relates to requests for hearings, and new paragraphs (d)(2) through (d)(4) relate to the filing and amendment of the answer. 21 CFR 1309.46(d) (relating to listed chemical registrations) is similarly being revised according to the same structure.

[4] Receipt by the registrant, for the purposes of this paragraph, will be determined by when the registrant receives the OTSC via certified mail at the location listed on the registration.

[5] As mentioned above in the discussion of the answer and request for hearing provisions, part 1301 relates to controlled substance registrations, and part 1309 relates to listed chemical registrations.

[6] *See* 21 CFR 1301.43(e), 1309.53(d).

evidentiary support for every factual allegation. DEA believes these provisions will preserve scarce agency resources by eliminating excess time and resources spent on cases where respondents fail to contest the allegations of the OTSC on the merits. Additionally, DEA believes that the procedures in place grant sufficient ability for respondents to appeal the actions of the presiding officer and the Administrator. Thus, DEA believes these provisions will substantially expedite the administrative hearing process while preserving respondents' due process rights.

Other

DEA is also amending its regulations by revising § 1316.49 to exclude respondents engaged in proceedings held under parts 1301 or 1309 from the ability to file a waiver of a hearing and a statement in lieu of a hearing. DEA believes that matters litigated under parts 1301 and 1309 are uniquely enhanced by the hearing setting, namely credibility determinations and resolutions of factual disputes. Thus, DEA is limiting this exception to only matters adjudicated under § 1301 or § 1309, and other proceedings continue to be eligible for the waiver.

These regulatory changes and this rulemaking generally apply only to OTSCs and associated hearings issued on or subsequent to the effective date listed above.

III. Public Comments on the NPRM

DEA received four comments during the 60-day comment period. All four commenters referenced § 1301.37(d)(1), stating that the 15-day time limit to request a hearing was too short. Two commenters referenced § 1301.37(2), arguing the 30-day time limit to file an answer was too short. One commenter referenced § 1309.46, arguing registrants should have up to three times to amend an answer as a matter of right. Last, one commenter argued that respondents engaged in proceedings under parts 1301 or 1309 should be permitted to submit a written statement in lieu of requesting a hearing.

DEA has closely reviewed and considered every comment and has decided for the following reasons to promulgate the regulations as drafted, with one change regarding the time limit for requesting a hearing.

15-Day Period for Requesting a Hearing, § 1301.37(d)(1)

The proposed rule would have required registrants to request a hearing within 15 days of receipt of an OTSC, instead of the 30 days allowed under the current regulations. This proposal received the most criticism during the comment period, as all commenters believe the 15-day requirement would generally be too prohibitive for registrants. Based on the comments from the public, DEA has decided not to adopt this provision from the proposed rule. The final rule permits registrants 30 days to request a hearing, rather than 15 days.

First, commenters generally stated the 15-day period is too short as it would not leave sufficient time to complete typical prehearing tasks. Specifically, commenters noted this was insufficient time to contact an attorney, contact and gather information from parties who may be involved, as well as investigate. Alternatively, the commenters proposed allowing 30–60 days to request a hearing because, according to their view, this would be sufficient time to prepare for a hearing. Moreover, one commenter argued that this short time period would lead to multiple requests for an extension, thereby contradicting the purpose of the new rule by further delaying the administrative process.

DEA Response: DEA has examined all comments related to this provision, and has decided to retain the existing 30-day period in this final rule to request a hearing, instead of shortening that period to 15 days. First, DEA believes this time period is reasonable, namely that this 30-day period provides sufficient time for the respondent to request a hearing. DEA understands and appreciates that the decision to request a hearing is often done after consulting with counsel to deliberate on the merits of the case; therefore, it makes sense to set the same 30-day deadline for requesting a hearing and for submission of an answer to the OTSC.

When drafting this rule, and after consideration of all the comments, DEA considered the option of providing registrants/applicants up to 60 days to request a hearing. Although this would provide the registrant/applicant maximum opportunity to evaluate all contingencies related to the hearing, DEA does not consider this necessary. This 30-day period should allow sufficient time for registrants/applicants to contact parties, conduct factual investigations, and otherwise prepare for the hearing should they choose to do so.

Requesting a hearing within this time period would eliminate a substantial amount of administrative waste, as most registrants who are served with an OTSC do not request a hearing. The provisions of this rule requiring the request for a hearing and the answer on the merits to both be filed within 30 days of the receipt of the OTSC will provide DEA a means of quickly and efficiently processing cases, as the majority will then be processed at an expedited pace. One commenter noted, and DEA agrees, that some cases will result in a request for an extension. DEA anticipates that this provision will, on balance, save more time by facilitating cases than will be lost by considering extension requests.

Last, DEA finds this provision reasonable and preserves the registrants' due process rights as it creates a means for registrants to file a motion to set aside default when good cause is shown within 45 days of the receipt of the OTSC. Thus, even in those circumstances where registrants are in default, they would be able to still request a hearing when good cause is shown.

30 Days To File Answer, § 1301.37(2)

DEA has closely reviewed all the comments relating to the requirement to file an answer in 30 days under § 1301.37(2) and has decided to promulgate the section as written. One commenter argued the requirement for a registrant to file an answer within 30 days of receipt of the OTSC is arbitrary, and does not permit sufficient time to contact parties involved or conduct factual investigations. Moreover, another commenter argued that 30 days is insufficient time to adequately respond to the OTSC, favoring 60 days instead.

DEA acknowledges that filing an answer will likely require more time and effort than simply requesting a hearing. DEA believes, however, the requirement to file an answer within 30 days is reasonable and sufficient time to adequately prepare a response to the OTSC.

First, requiring a response within such a time frame is commonplace among other administrative regulations as well as other state and federal level courts.[7] Although there are important differences between administrative hearings and federal court cases, it is telling that the Federal Rules of Civil Procedure require a responsive pleading within 21 days of being served, which is 9 days *less* than what DEA rules require.[8] Thus, even though the answer will likely require more time and effort than simply requesting a hearing, the time allotted is generous when compared to federal civil practice.

Moreover, as stated in the NPRM, this requirement will significantly improve efficiency by narrowing the scope of the

[7] *See* 85 FR 61662, 61664.

[8] Fed. R. Civ. P. 12(a)(A)(i).

factual issues to only that which is in genuine dispute. This efficiency will result in expediting cases significantly, benefitting both DEA and registrants.

Last, registrants are permitted to amend their answer should they choose, which cures many of the concerns raised by comments. DEA grants leave to amend the answer once as a matter of right under § 1309.46(d)(4), and permits the presiding offer to grant leave to amend. Thus, on balance, this provision allows DEA to process cases quickly and efficiently while enabling the registrants to adequately prepare for hearings.

Other Comments

DEA has closely reviewed all other comments and has decided to promulgate these regulations as written. First, one commenter stated the 30-day limit to file a motion to set aside default was too short, and should be 90 days. Another commenter stated that registrants should be able to amend their answer as a matter of right up to three times. Additionally, one commenter stated that requiring a hearing, rather than accepting a statement in lieu of requesting a hearing, creates administrative waste. Last, one commenter requested DEA to stay the proposed 15-day period to request a hearing until the COVID–19 pandemic is over.

First, as stated above, DEA believes the 45-day period to file motion to set aside default is reasonable and preserves the due process rights of registrants. In circumstances where registrants fail to request a hearing, they will then have 30 days from the entry of default to provide the presiding officer with an explanation as to why the request could not be filed. This safe harbor provision will enable registrants to set aside default where good cause is shown, and provide yet another opportunity for the registrant to present their case. Permitting 90 days to set aside default is unnecessary as this task only requires the filing of one motion. Moreover, this extended period would likely result in prolonging cases, contradicting the purpose and goal of default rules.

Next, DEA believes that granting leave to amend as a matter of right once, and subsequently granting the presiding officer the ability to amend when justice so requires, provides registrants sufficient opportunity to be heard. Granting leave to amend as a matter of right multiple times will likely result in a significant delay of processing cases. Registrants would then have no incentive to gather evidence, contact parties, prepare written statements, or otherwise respond to DEA in a comprehensive manner the first time. Moreover, DEA creates a safe harbor by granting authority to the presiding officer to grant leave to amend in circumstances which are justified, such as when evidence was recently discovered and could not have been discovered prior to filing the original answer. Thus, DEA believes this provision is reasonable and preserves the registrant's due process rights.

DEA closely reviewed the comment regarding statements in lieu of hearings and has decided to promulgate the regulations as written. This commenter argues that the elimination of a statement in lieu of requesting a hearing would be wasteful for both DEA and the registrant in circumstances where the registrant has clearly exculpatory information. This, in theory, would remove the requirement for a hearing and would allow the expedited processing of that case. As stated previously, these hearings deal specifically with the revocation, suspension, or denial of a registration which is substantially benefitted by the presiding officer being able to resolve factual disputes and make credibility determinations. DEA believes that simply permitting a statement in lieu of this hearing would be a detriment to both DEA and respondents, and requiring a hearing would be optimal for both parties.

Last, DEA has closely reviewed the statements regarding the COVID–19 pandemic. As noted above, the final rule does not adopt the 15-day time limit proposed in the NPRM, and this final rule retains the existing 30-day deadline for filing a request for hearing. Although DEA is sympathetic to the difficulties that are associated with this global change, DEA believes that the 30-day deadline will allow sufficient flexibility under the circumstances, because the filing of a request for a hearing is a routine action. Since this final rule is not making any change in the current 30-day deadline, there is no reason to consider ''staying'' the effective date of this regulation.

Conclusion

In sum, DEA has reviewed all comments extensively and has taken them in full consideration when drafting these regulations. Accordingly, DEA is promulgating these regulations as written, with the exception of the 15-day period to request a hearing, as they create reasonable obligations which promote administrative efficiency while maintaining the due process rights of registrants.

Regulatory Analyses

Introduction

DEA received, and closely reviewed, all four comments that were submitted regarding this rulemaking. None of the comments raised issues that would require amendment of the analysis contained in the NPRM, with the exception of maintaining the 30-day deadline to request a hearing. Thus, the regulatory analyses here closely mirror the data and conclusions contained in the NPRM, and are repeated here for convenience.

Executive Orders 12866, and 13563 (Regulatory Planning and Review and Improving Regulation and Regulatory Review)

This rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 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, and other advantages; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 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 E.O. The Office of Management and Budget (OMB) has determined that this rule is not a ''significant regulatory action'' under E.O. 12866, section 3(f), and it has not been reviewed by OMB.

DEA estimates that there are both costs and cost savings associated with this rule. The provisions of this rule apply only to the small minority of applicants and registrants who are issued an OTSC. Therefore, a very small

minority of registrants will be economically impacted. From 2016 to 2018, there were on average 81 OTSCs issued annually. These 81 OTSCs fall into one of three categories: (1) an average of 29 cases in which the registrant/applicant surrendered and/or withdrew their 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/applicants 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 this rule. The 11 registrants/applicants per year who properly requested a hearing are estimated to incur costs while the registrants/applicants in the remaining two categories do not.

This rulemaking requires that a registrant/applicant must file an answer responding to every factual allegation in the OTSC. The average of 29 cases in which the registrant/applicant surrenders or withdraws their application, thus mooting the case, will not result in the registrant/applicant filing an answer to the OTSC. Therefore, these registrants/applicants will 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 factual allegation(s) of the OTSC. To estimate the cost of this change, DEA estimates that, on average, it will take five hours for a registrant's/applicant's attorney to review the OTSC and prepare an answer to all allegations. Thus, the total estimated cost of this change is $36,190 per year.[9]

The remaining 41 cases, where there was neither a registration surrendered nor a hearing conducted, would be differently impacted by this rule. This rule provides that where a party defaults, the factual allegations of the OTSC are deemed admitted. For these 41 cases, where there was registrant/applicant inaction, the registrant's/applicant's cost of inaction is the same under current rules. There is no additional cost to registrants/applicants. This rule provides 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 may 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 Administrative Law Judge (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 requirement of the rule simply codifies case law, it imposes no additional cost to registrants.

Finally, this rulemaking will result in cost savings for DEA by streamlining the Administrator's review process using the default determination. The rule provides that when a registrant/applicant is deemed to be in default, DEA 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. A registrant/applicant who has defaulted under this rule is deemed to admit all of the factual allegations in the OTSC.

In contrast, under the current rules, in cases where the registrant/applicant waives their right to a hearing, DEA counsel must provide the Administrator with a much more voluminous record, including evidence to support each factual allegation which DEA seeks to establish. Because DEA's current rules do not provide that a registrant's/applicant's waiver of their right to a hearing constitutes an admission of the factual allegations of the OTSC, 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 implemented here would thus save these resources, which can then be devoted to other pending matters in which the registrant/applicant does contest the allegations in the OTSC, and reduce the time it takes for the Administrator's final order to issue in those cases where registrants/applicants 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 and for the Administrator's Office to draft the final order based on that final agency action 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 final agency action motion take, on average, approximately 10–15 hours. For cases with substantive allegations (most commonly, improper prescribing or filling of prescriptions), the preparation of the final agency action 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 percent are No State License (NSL) cases, and 60–70 percent 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 percent would be considered non-NSL cases and take 35 hours per case to prepare a final agency action, while 35 percent would be considered NSL cases and take 13 hours per case to prepare a final agency action. Applying the loaded wage[10] for GS–15 Step 5 employees,[11] DEA estimates the cost savings of this rule for the time it would take to prepare the final agency action request is around $134,065 per year.[12]

Additionally, there are cost savings from the time it would take the Administrator's Office to draft the final order based on that final agency action 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

[9] 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 × 5 × 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.

[10] 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.

[11] Hourly rate for GS–15 Step 5 employees in the Washington, DC 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 × 1.6). The ECEC does not provide figures for Federal Government employees; therefore, figures for state employees are used as estimate.

[12] ($119.78 × 41 × 65% × 35) + ($119.78 × 41 × 35% × 13).

the final agency action 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 per case. 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 per case. Using the loaded hourly wage of a GS–15 Step 5 employee, the estimated cost savings for substantive cases is $88,155 per year.[13] 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 savings. The Administrator will continue to issue the final order based on the same set of circumstances regarding the OTSC 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 sum, there are both costs and cost savings associated with this rule. DEA has no basis to estimate the additional litigation costs for registrants who are ''deemed to be in default'' as a result of their failure to comply with the requirements of the rule as compared to registrants who are ''deemed to have waived'' under the prior 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 a registrant/applicant must file an answer to an OTSC is $36,190 per year. This 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.

Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132 (Federalism)

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132, the DEA has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) requirements do not apply to ''the collection of information . . . during the conduct of . . . an administrative action or investigation involving an agency against specific individuals or entities.'' [14] These rules involve the collection of information pursuant to administrative actions, orders to show cause specifically, against specific registrants. Thus, this rulemaking is exempted from the requirements under PRA.

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 this rule will not 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. This rule adds provisions allowing the entry of a default where a party served with an OTSC fails to request a hearing, fails to file an answer to the OTSC, or otherwise fails to defend against the OTSC. *Cf.* Fed. R. Civ. P. 55(a). The rule provides that where a party defaults, the factual allegations of the OTSC are deemed admitted. Further, the rule removes the current provisions allowing a recipient of an OTSC to file a written statement while waiving their right to an administrative hearing.

As all DEA registrants are subject to the amended administrative enforcement procedures, the 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 OTSCs in connection with the denial or cancellation of registration, and thus a very small minority of DEA registrants would be impacted by the rule. Over the three-year period 2016–2018, there was an average of 81 OTSCs served per year. These 81 OTSCs fall into one of three categories: (1) an average of 29 cases in which the registrant/applicant surrendered the registration and/or withdrew their 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/applicants 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 this 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.

This rulemaking requires that a registrant/applicant must file an answer responding to every allegation in the OTSC. The average of 29 cases in which the registrant/applicant surrenders or withdraws their application, thus mooting the case, would not result in the registrant/applicant filing an answer to the allegations in the OTSC. 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 OTSC. To estimate the cost of this change, DEA estimates

[13] $(4 \times 240 \times \$119.78) - (4 \times 56 \times \$119.78) = \$88,155$.

[14] 44 U.S.C. 3501 *et. seq.*

that, on average, it will take five hours for a registrant/applicant's attorney to review the OTSC and prepare an answer to all allegations, or an average of $3,290 per registrant.[15]

The remaining 41 cases, where there was neither a registration surrendered nor a hearing conducted, would be differently impacted by this rule. This rulemaking provides that where a party defaults, the factual allegations of the OTSC are deemed admitted. This rulemaking also provides 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,* 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. 72 FR 54931 (2007). Thus, because this 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. 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).[16] 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

In conclusion, this rulemaking 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 this rulemaking will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

DEA has determined 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 1 year.'' [17] Therefore, neither a Small Government Agency Plan nor any other action is required under the UMRA.

Congressional Review Act

This rulemaking is not a ''major rule'' under the Congressional Review Act, 5 U.S.C. 801 *et seq.*[18] DEA has submitted a copy of this final rule to both Houses of Congress and to the Comptroller General.

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 amends 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.

[15] 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 × 5 = $3,290.

[16] 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.

[17] 2 U.S.C. 1532(a).

[18] 5 U.S.C. 804(2)(A)–(C), 804(3); *see* 5 U.S.C. 551(4).

■ 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 DEA such request no later than 30 days following the date of receipt of the order to show cause. Service of the request on DEA shall be accomplished by sending it to the address, or email 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 DEA an answer to the order to show cause no later than 30 days following the date of receipt of the order to show cause. A party shall also serve its answer on DEA at the address, or the email 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 factual 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. Amend § 1301.43, by revising the section heading and paragraphs (c), (d), and (e), and by adding paragraph (f) to read as follows:

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

* * * * *

(c)(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 their right to a hearing and to be in default, unless the registrant/applicant establishes good cause for failing to file a timely hearing request. 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 authority 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 their right to a hearing and to be in default. Upon motion of DEA, the presiding officer shall then enter an order terminating the proceeding.

(3) In the event DEA 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) If any person entitled to participate in a hearing pursuant to this section fails to file a notice of appearance either as part of a hearing request or separately, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived their opportunity to participate in the hearing, unless such person shows good cause for such failure.

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

(f)(1) In the event that a registrant/applicant is deemed to be in default pursuant to paragraph (c)(1) of this section, and has not established good cause to be excused from the default, or the presiding officer has issued an order terminating the proceeding pursuant to paragraphs (c)(2) or (c)(3) of this section, DEA 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 final order pursuant to § 1316.67 of this chapter.

(2) In the event that DEA 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 business days after the date of issuance of the order. Upon termination of the proceeding by the presiding officer, DEA may seek relief only by filing a motion with the Office of the Administrator establishing good cause to excuse its default.

(3) A party held to be in default may move to set aside a 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 a default final order. 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 DEA such request no later than 30 days following the date of receipt of the order to show cause. Service of the request on DEA shall be accomplished by sending it to the address, or email 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 DEA an answer to the order to show cause no later than 30 days following the date of receipt of the order to show cause. A party shall also serve its answer on DEA at the address, or email 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 factual 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. Amend § 1309.53, by revising the section heading and paragraphs (b), (c), and (d), and adding paragraph (e) to read as follows:

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

* * * * *

(b)(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 their right to a hearing and to be in default, unless the registrant/applicant establishes good cause for failing to file a timely hearing request. Any person who has failed to timely request a hearing under paragraph (a) 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) and seeks to be excused from the default, shall file such motion with the Office of the Administrator, which shall have exclusive authority 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 their right to a hearing and to be in default. Upon motion of DEA, the presiding officer shall then enter an order terminating the proceeding.

(3) In the event DEA 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.

(c) If any person entitled to participate in a hearing pursuant to this section fails to file a notice of appearance either as part of a hearing request or separately, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived their opportunity to participate in the hearing, unless such person shows good cause for such failure.

(d) A default, unless excused, 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)(1) In the event that a registrant/applicant is deemed to be in default pursuant to paragraph (b)(1) of this section and has not established good cause to be excused from the default, or the presiding officer has issued an order termination the proceeding pursuant to paragraphs (b)(2) or (b)(3) of this section, DEA 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 final order pursuant to § 1316.67 of this chapter.

(2) In the event that DEA 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 business days after the date of issuance of the order. Upon termination of the proceeding by the presiding officer, DEA may seek relief only by filing a motion with the Office of the Administrator establishing good cause to excuse its default.

(3) A party held to be in default may move to set aside a 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 a default final order. 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. Revise § 1316.47 to read as follows:

§ 1316.47 Request for hearing; answer.

(a) 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) 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. * * *

Signing Authority

This document of the Drug Enforcement Administration was signed on November 3, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative

purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

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DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 537

RIN 3141–AA58

Management Contracts

AGENCY: National Indian Gaming Commission.

ACTION: Final rule.

SUMMARY: The National Indian Gaming Commission (NIGC or Commission) issued a proposed rule revising its management contract regulations. The Indian Gaming Regulatory Act (IGRA) provides that an Indian tribe may enter into a management contract for the operation of Class II or Class III gaming activity if such contract has been submitted to and approved by the NIGC Chairman. Collateral agreements to a management contract are also subject to the Chairman's approval. This final rule makes background investigations required of all persons who have 10 percent or more direct or indirect financial interest in a management contract, of all entities with 10 percent or more financial interest in a management contract, of any other person or entity with a direct or indirect financial interest in a management contract otherwise designated by the Commission, and authorizes the Chairman, either by request or unilaterally, to exercise discretion to reduce the scope of the information to be furnished and background investigation to be conducted for certain entities.

DATES: This rule is effective December 14, 2022.

FOR FURTHER INFORMATION CONTACT: Michael Hoenig, 1849 C Street NW, Mail Stop #1621, Washington, DC 20240. Telephone: 202–632–7003.

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act establishes the NIGC and sets out a comprehensive framework for the regulation of gaming on Indian lands. On January 22, 1993, the NIGC published a final rule in the **Federal Register** called *Background Investigations for Person or Entities with a Financial Interest in a Management Contract* (58 FR 5831). The rule added a new part to the Commission's regulations implementing the mandates of the Indian Gaming Regulatory Act of 1988 by establishing the requirements and procedures for the approval of management contracts concerning Indian gaming operations and the conduct of related background investigations. The Commission has substantively amended them numerous times, most recently in 2012 (August 9, 2012; 77 FR 47514). On December 2, 2021, the NIGC published a notice of proposed rulemaking in the **Federal Register** called *Background Investigations for Persons or Entities With a Financial Interest in or Having a Management Responsibility for a Management Contract* (86 FR 68446).

II. Development of the Rule

On June 9, 2021, the Commission issued a Dear Tribal Leader Letter announcing the beginning of tribal consultations on 25 CFR 537.1(a)(3), among other regulations. On July 12, 2021, the Commission issued a second Dear Tribal Leader Letter announcing the dates of virtual consultations and seeking written comments on the proposed changes to part 537. On July 27, 2021, and July 28, 2021, the Commission held virtual consultations and accepted comments from Tribes on those changes.

Upon reviewing the comments received during the consultation period from July 12—August 12, 2021, the Commission published a Notice of Proposed Rulemaking (NPRM) on December 2, 2021 (86 FR 68446). The NPRM invited interested parties to participate in the rulemaking process by submitting comments and any supporting data to the NIGC by January 3, 2022. The consultation and the written comments have proven invaluable to the Commission in making amendments to the Management Contract regulations.

III. Review of Public Comments

Comment: One commenter suggested that the term ''Chairman'' be changed to ''Chair'' throughout the regulation.

Response: The Commission agrees with the recommendation and has made that change.

Comment: One commenter suggested that the term ''indirect financial interest'' was too vague and possibly too broad and should be deleted or defined.

Response: Under IGRA, the NIGC has broad authority to ensure compliance with IGRA. Individuals or entities can have an ''indirect financial interest'' in innumerable ways. Any effort to define this term to specific types of relationships would improperly and unnecessarily limit the Commission's authority to regulate financial interests in Indian gaming.

Comment: Several commenters suggest that the NIGC include information as to how and when the Commission will notify a TGRA of a unilateral decision by the Chair to reduce the scope of required information or, alternatively, what would need to be included in a request submitted by TGRAs for the same.

Response: The Commission appreciates the comments and clarifies that background investigations and suitability determinations discussed in this part pertain to management companies wishing to enter into an agreement with a tribe, not the tribe itself. As such, a request for a reduced scope background investigation would typically be made by, and granted to, a management company, individual or entity with management responsibility for the contract, or individual or entity with a direct or indirect financial interest. If a tribe or wholly owned tribal entity is proposing to manage another Tribe's gaming operation, they may request a reduced background investigation or the Chair may elect to perform one unilaterally. In either case, the NIGC will notify the requester of a decision. As to how to make a request, the Commission responds that it will set forth any process in a bulletin. If a potential management company has questions as to how to request a reduced scope background investigation prior to the issuance of that bulletin, the Commission invites them to contact the NIGC for further information.

Comment: Another commenter supports the change to clarify the reduced scope background investigation, but suggests the NIGC add examples of ''approaches the Chair may take to reduce the scope of information to be furnished. The commenter included suggested language to include