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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[DEA No. 113F]

Registration of Manufacturers and Importers of Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This final is issued by the Drug Enforcement Administration to eliminate the requirement of an administrative hearing on objections, raised by third-party manufacturers, to the registration of certain bulk manufacturers of controlled substances. This action amends the current regulation and removes the third-party manufacturer hearing provision when requested by another applicant or registrant. Other applicants and registrants may still submit written comments and objections for consideration by DEA and may participate in hearings on bulk manufacturer applications requested by the applicant. This final rule amends the regulation concerning withdrawal of applications to be consistent with this action.

EFFECTIVE DATE: July 20, 1995.

FOR FURTHER INFORMATION CONTACT: Julie C. Gallagher, Associate Chief Counsel, Diversion/Regulatory Section, Office of Chief Counsel, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307–8010.

SUPPLEMENTARY INFORMATION: On October 7, 1993, DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (58 FR 52246) to amend its regulations to eliminate the third-party manufacturer hearing requirement for objections to the registration of certain bulk manufacturers and importers of controlled substances. The DEA proposed to amend two sections of its regulations, specifically 21 CFR 1301.43(a) and 1311.42(a), wherein DEA is required to hold an administrative hearing on an application for registration to manufacture or import a bulk Schedule I or II controlled substance when requested to do so by any current bulk manufacturer of the substance(s) or by any other applicant for a similar registration. The NPRM proposed to modify section 1301.43(a) and provide for a hearing only when DEA ''determines that a hearing is necessary to receive factual evidence and/or expert testimony with respect to issues raised by the application or objections thereto.''

On June 14, 1994, DEA published a Supplemental Notice of Proposed Rulemaking (SNPRM) in the **Federal Register** (59 FR 3055) proposing to eliminate altogether the third-party manufacturer hearing regulation, section 1301.43(a). DEA would continue to hold hearings when requested by the applicant pursuant to an order to show cause, section 1301.44. DEA would continue to solicit written comments or objections from current registrants and applicants concerning an application for registration. Current registrants and applicants would also be granted an opportunity to participate in any hearings conducted pursuant to section 1301.44.

The SNPRM provided notice that DEA would not change the hearing provision relating to registration of importers, section 1311.42(a), because of the statutory requirements under 21 U.S.C. 958(i). Section 958(i) states that DEA shall provide current bulk manufacturers of controlled substances an opportunity for a hearing prior to issuing an importer registration to another bulk manufacturer. With an existing statute in effect, DEA is not empowered to adopt regulations that contravene the express language of that statute.

Five comments were received in response to the NPRM. Three comments were received concerning the SNPRM, although one commentor had previously commented on the NPRM. To the extent that comments received in response to the NPRM are relevant, they have been considered. Of the seven independent commentors, two supported removing the mandatory third party hearing provision while five commentors opposed the proposed rulemaking.

One commentor that supported the proposed rule provided an example of its own experience as an applicant for a bulk manufacturer registration to demonstrate how ''currently registered manufacturers use the regulatory hearing requirement to deter others from applying or to delay entry of their competitors in the marketplace.'' The five opposing commentors advanced numerous arguments and proposed alternatives to the proposed rule, their primary concerns are summarized below.

Three commentors believed that elimination of the third-party manufacturer hearing regulation would be contrary to Congress' intent that DEA should limit the number of bulk manufacturers in the United States where supply and competition are adequate. One of these commentors noted that the United States had been a party to several international agreements recognizing the need to limit licensing of drug manufacturers. This commentor then argued that the Narcotic Manufacturing Act (NMA) of 1960, which specified limitations on the licensing of bulk manufacturers of controlled substances, provided historical precedent for similar limitations within the Controlled Substances Act (CSA). Similarly, two commentors argued that the proposed rule would run contrary to the intent of Congress to limit the number of bulk manufacturers of controlled substances to the most qualified applicants, and thus, limit the possible diversion of these controlled substances. One commentor interpreted the mandate of ''limiting'' registration under 21 U.S.C. 823(a) of the CSA as prohibiting DEA from approving additional registrations if there already exists uninterrupted supply and adequate competition.

The final rule is not contrary to either the direct or implied intent of Congress in passing the CSA. The final rule does not alter the DEA's responsibility to apply the factors set forth in 21 U.S.C. 823(a) to applications for bulk manufacturer registrations. While the commentors provide persuasive arguments regarding possible Congressional intent in the enactment of 21 U.S.C. 823(a), such arguments are irrelevant to the issue of whether the

regulations should provide for a third-party manufacturer hearing. The express language of the statute does not provide a hearing right to bulk manufacturer registrants or applicants regarding the registration of a bulk manufacturer, nor can such a right be inferred. *See Comprehensive Drug Abuse Prevention and Control Act of 1970, Committee on Interstate and Foreign Commerce*, H.R. Rep. No. 91–1444 (Part 1), 91st Cong., 2d Sess. (1970) (CSA). Moreover, even assuming that Congress intended to limit the number of bulk manufacturer registrants, the final rule does not purport to increase the number of such registrants. It is also worth noting that the regulations, 21 CFR 1301.43(b), provide that DEA is not required to limit the number of manufacturers even if the current registrants can provide an adequate supply, as long as DEA can maintain effective controls against diversion.

Another commentor suggested that Congress intended that DEA ''implement such procedural safeguards when it enacted the CSA.'' This comment ignores the fact that neither 21 U.S.C. 823(a) nor 21 U.S.C. 824 provides for a third-party manufacturer hearing. Moreover, as one commentor noted, the procedural requirements of the APA are not affected by the removal of the third-party manufacturer hearing provision. Significantly, at the time of promulgation of the CSA, Congress afforded a third-party manufacturer hearing opportunity to current bulk manufacturers on the importer applications of other bulk manufacturers for Schedule I and II controlled substances. *See* 21 U.S.C. 958(i). Thus, a plain reading of the statute demonstrates that Congress did not intend to require a third-party manufacturer hearing for applications to bulk manufacture Schedule I and II controlled substances.

It is also not inconsistent to allow hearings on import registration applications but deny them for bulk manufacturers, as one commentor suggested. First, registrations to import Schedule I and II controlled substances are arguably granted under more limited conditions than manufacturer registrations. *See* 21 U.S.C. 952. Also, it is worth noting that the statute provides for the opportunity for a hearing where a current bulk manufacturer has applied for an importer registration. Thus, it can be inferred that Congress was concerned with the potential impact on domestic competition by existing bulk manufacturers who wanted to import controlled substances as well.

One commentor suggested that more companies will attempt to obtain a DEA registration because they could avoid the scrutiny of other bulk manufacturers and that DEA would have to increase personnel to conduct additional investigations and meet the greater demand for registrations. This commentor argued that it would be highly inadvisable to ''ease the entry'' of additional bulk manufacturers and promote creation of a class of ''opportunistic'' bulk manufacturers who would seek to produce products which are temporarily profitable, and felt no obligation to supply for the requirements of the U.S. market. These comments presume that removal of the third-party manufacturer hearing process would ''ease the entry'' of additional bulk manufacturers or that the applicant would be subject to less ''scrutiny.'' Such is not the case. DEA will continue to apply the same factors required by 21 U.S.C. 823(a) to evaluate applications for registrations of bulk manufacturers. Where DEA discovers information which warrants proceedings to deny a registration, either through its own investigation or as provided through comments of other manufacturers, it will issue an order to show cause seeking to deny the application for registration.

Two commentors found that DEA's conclusion regarding abuse of the regulatory hearing requirement is not supported by the record which reveals that in the last 20 years, DEA has held as few as five evidentiary hearings on importer or bulk manufacturer applications at the request of a current registrant. However, one of these commentors acknowledged that it believed that objections raised in a prior hearing involving one of its subsidiaries ''lacked substantive merit.'' More importantly, one commentor, who supported removing the third-party manufacturer hearing regulation, provided two examples in which it believed other manufacturers had used the hearing process for anti-competitive purposes and to delay entry into the marketplace. Notwithstanding the limited number of evidentiary hearings during the past twenty years, the final rule seeks to discourage potential future abuse of the hearing process.

Four commentors argued that the submission of written comments would be insufficient because either the comment period would be too short or because of the inability to produce witnesses and conduct cross-examination. One of these commentors suggested that this proposal would make it ''impossible for any currently registered bulk manufacturer to provide meaningful information to the Administrator'' on these applications. Two of these commentors stated that 30 or even 60 days would be insufficient to prepare meaningful comments on an application.

First, regarding all subsequent manufacturer applications, DEA will not consider a comment period less than 60 days. Second, DEA maintains that 60 days is sufficient time for interested parties to submit adequate comments and documentation to notify DEA concerning potential issues that warrant DEA issuing an order to show cause. There is no evidence that DEA would fail to consider such evidence prior to making a final determination. Moreover, these individuals could still participate in any hearing, requested after the issuance of an order to show cause, thereby providing an additional opportunity to present evidence.

DEA does not suggest that written comments are a replacement for direct testimony or cross-examination. However, DEA does argue that applicants should not be subjected to the rigors and delay accompanying an administrative hearing absent some prior good faith belief and evidence that such procedure is warranted. Further, this final rule will foreclose current registrants and applicants from using the third-party manufacturer hearing process as a forum for discovery of non-relevant information from its competitors, such as marketing and pricing data.

Two commentors suggested that DEA consider adopting procedures to prevent abuse of the third-party manufacturer hearing provision such as utilizing motions for summary judgement or requiring written submissions prior to the hearing. The final rule, in effect, resolves both issues because (1) DEA will only issue an order to show cause where it has a good faith basis that the applicant's registration should not be granted and (2) other bulk manufacturers will be required to submit substantive written comments within a reasonable time, after an application has been submitted.

Three commentors stated that the current hearing process enables third-parties to present relevant and useful information to DEA that might not otherwise be available because of limited agency resources or otherwise. DEA acknowledges the critical role that third-parties provide in identifying issues related to the registration of bulk manufacturers. DEA does not intend to discourage such participation. However, the final rule provides DEA with the authority necessary to protect the interests of applicants and current registrants alike.

Finally, four commentors requested a hearing on the issue of the third-party manufacturer hearing provision pursuant to 21 U.S.C. 875. Unlike other rulemaking conducted pursuant to the CSA, the present rulemaking presents no requirement that the rule be made on the record after opportunity for a hearing. For example, 21 U.S.C. 811(a) requires the opportunity for a hearing whenever there is a proposed rescheduling of controlled substances. In addition, 21 U.S.C. 875 identifies general powers available to DEA when exercising its authority under the CSA. Thus, 21 U.S.C. 875 complements existing hearing provisions under the CSA rather than conferring independent hearing authority. In any event, DEA believes that the notice and comment conducted pursuant to this rulemaking enabled interested parties to provide meaningful comment on the final rule.

The final rule removes the mandatory third-party manufacturer hearing requirement while retaining the hearing provision pursuant to an order to show cause. The proposed change as provided herein does not violate statutory intent but instead comports with sound principles of substantive and procedural due process. Eliminating the hearing requirement except when requested by the applicant after issuance of an order to show cause, supports the statutory and regulatory mandate that an applicant for registration as a bulk manufacturer shall have the burden of proof at ''any hearing'' that the requirements of registration are met. *See* 21 CFR 1301.55. The Administrative Procedures Act (APA) which controls these matters further provides that ''[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof.'' *See* 5 U.S.C. 556(d).

The final rule eliminates the problem of multiple hearings which not only promotes judicial economy but also avoids the anomalous result of DEA conducting administrative hearings which are not dispositive of the ultimate issue of whether an applicant should be registered. For example, because DEA must issue an order to show cause whenever it takes action to deny an application, 21 U.S.C. 824(c), under the current regulation a second hearing would likely be required when DEA decided to deny an application after a hearing held pursuant to a ''third-party'' request. Further, this second hearing would involve many of the same issues raised in the prior proceeding. The primary objective of the final rule is to limit abuse of the regulatory hearing process.

For the above-stated reasons and in the absence of express statutory language governing the right to an evidentiary hearing by bulk manufacturers concerning the application for registration of bulk manufacturers of controlled substances, as well as the absence of language in the legislative history of the CSA that would imply Congressional intent in this regard, 21 CFR 1301.43 shall be amended.

The Deputy Assistant Administrator hereby certifies that the final rule will have no significant impact upon those entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The registrants and applicants who use, or are affected by, the hearing covered by these regulations are typically not small entities.

The final rule is not a significant regulatory action pursuant to Executive Order (E.O.) 12866 and therefore, has not been reviewed by the Office of Management and Budget. This action has been analyzed in accordance with the principles and criteria in E.O. 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control and security measures.

For the reasons set forth above and pursuant to the authority vested in the Attorney General by 21 U.S.C. 821 and 871(b), as delegated to the Administrator of the Drug Enforcement Administration, and redelegated to the Deputy Assistant Administrator, Office of Diversion Control by 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control hereby amends part 1301 of Title 21, Code of Federal Regulations to read as follows:

PART 1301—[AMENDED]

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

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

2. Section 1301.37, paragraph (a) is revised to read as follows:

§ 1301.37 Amendments to and withdrawal of applications.

(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to § 1301.48. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

* * * * *

3. Section 1301.43, paragraph (a) is revised to read as follows:

§ 1301.43 Application for bulk manufacture of Schedule I and II substances.

(a) In the case of an application for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, the Administrator shall, upon the filing of such application, publish in the **Federal Register** a notice naming the applicant and stating that such applicant has applied to be registered as a bulk manufacturer of a basic class of narcotic or nonnarcotic controlled substance, which class shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that basic class and to any other applicant therefor. Any such person may, within 60 days from the date of publication of the notice in the **Federal Register**, file with the Administrator written comments on or objections to the issuance of the proposed registration.

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4. Section 1301.44 is amended by redesignating paragraph (b) as paragraph (c) and adding a new paragraph (b) to read as follows:

§ 1301.44 Certificate of registration; denial of registration.

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(b) If a hearing is requested by an applicant for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, notice that a hearing has been requested shall be published in the **Federal Register** and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any person entitled to file comments or objections to the issuance of the proposed registration pursuant to § 1301.43(a) may participate in the hearing by filing a notice of appearance in accordance with § 1301.54. Such persons shall have 30 days to file a notice of appearance after the date of publication of the notice of a request for a hearing in the **Federal Register**.

5. Section 1301.54, paragraph (a), (b), (c) and (d) are revised to read as follows:

§ 1301.54 Request for hearing or appearance; waiver.

(a) Any person entitled to a hearing pursuant to §§ 1301.42, 1301.44, or 1301.45 and desiring a hearing shall, within 30 days after the date of receipt of the order to shown cause, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) Any person entitled to participate in a hearing pursuant to § 1301.44(b) and desiring to do so shall, within 30 days of the date of publication of notice of the request for a hearing in the **Federal Register,** file with the Administrator a written notice of intent to participate in such hearing in the form prescribed in § 1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to §§ 1301.42, 1301.44, or 1301.45 may, within the period permitted for filing a request for a hearing or a notice of appearance, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding such person's position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to §§ 1301.42, 1301.44, or 1301.45 fails to file a request for a hearing or 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 the opportunity for a hearing or to participate in the hearing, unless such person shows good cause for such failure.

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6. Section 1301.55, paragraph (a) is revised to read as follows:

§ 1301.55 Burden of proof.

(a) At any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to section 303(a) of the Act (21 U.S.C. 823(a)) are satisfied. Any other person participating in the hearing pursuant to § 1301.44(b) shall have the burden of proving any propositions of fact or law asserted by such person in the hearing.

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Dated: June 14, 1995.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 95–15058 Filed 6–19–95; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Part 84

[Docket No. R–95–1736; FR–3639–F–02]

RIN 2501–AB97

Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals and Other Non-Profit Organizations—OMB Circular A–110 (Revised)

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: Office of Management and Budget (OMB) Circular A–110 provides standards for obtaining consistency and uniformity among Federal agencies in the administration of grants and agreements with institutions of higher education, hospitals, and other non-profit organizations. On September 13, 1994, the Department published a final rule which adopted the revised circular as it pertains to HUD. However, the September 13, 1994 rule contained, in subpart E, special provisions relating to the use of lump sum grants. Therefore, subpart E was treated as an interim rule, and the public was invited to submit comments on subpart E. This final rule addresses the public comments received on subpart E and makes final the provisions of subpart E.

EFFECTIVE DATE: July 20, 1995.

FOR FURTHER INFORMATION CONTACT: Aliceann B. Muller, Policy and Evaluation Division, Office of Procurement and Contracts, Department of Housing and Urban Development, 451 Seventh Street, SW, Room 5262, Washington, DC 20410. Telephone: (202) 708–0294; TDD: (202) 708–1112. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: Office of Management and Budget (OMB) Circular A–110 provides standards for obtaining consistency and uniformity among Federal agencies in the administration of grants and agreements with institutions of higher education, hospitals, and other non-profit organizations.

OMB Circular A–110 was issued under the authority of 31 U.S.C. 503 (the Chief Financial Officers Act), 31 U.S.C. 1111, 41 U.S.C. 405 (the Office of Federal Procurement Policy Act), Reorganization Plan No. 2 of 1970, and E.O. 11541 (''Prescribing the Duties of the Office of Management and Budget and the Domestic Policy Council in the Executive Office of the President'').

OMB issued Circular A–110 in 1976 and made a minor revision in February 1987. To update the circular, OMB established an interagency task force to review the circular. The task force solicited suggestions for changes to the circular from university groups, non-profit organizations and other interested parties and compared, for consistency, the provisions of similar provisions applied to State and local governments. On August 27, 1992, OMB published a notice in the **Federal Register**, at 57 FR 39018, requesting comments on proposed revisions to OMB Circular A–110. Interested parties were invited to submit comments. OMB received over 200 comments from Federal agencies, non-profit organizations, professional organizations and others. All comments were considered in developing the final revision. On November 29, 1993, at 58 FR 62992, OMB issued a revised circular which reflects the results of these efforts.

On September 13, 1994, the Department published a final rule which adopted the revised circular as it pertains to HUD. However, the September 13, 1994 rule contained, in subpart E, special provisions relating to the use of lump sum grants. Therefore, subpart E was treated as an interim rule, and the public was invited to submit comments on subpart E. This final rule addresses the public comments received on subpart E and makes final the provisions of subpart E.

Public Comments

The final rule published on September 13, 1994, at 59 FR 47010, invited public comments on Subpart E regarding lump sum grants. One (1) commenter, a national association, responded with a series of technical questions. Below is a listing of the questions presented and the Department's response to each question. The Department's responses set forth additional clarifications needed to aid in the commenter's understanding of the rule. No changes to the rule are necessary, and none are made by this final rule.

Question: Do these lump sum awards go through the same audit process as regular awards?