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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