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.

* * * * *

(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: