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.