

process than rulemaking for granting exemptions to the GST.

(Comment 4) Proposed § 610.11(g)(2) would allow manufacturers to request an exemption from the GST; it would not allow other entities to request such exemptions.

One comment argued that a letter from a trade association should suffice to obtain such an exemption.

We disagree with this comment. The request for exemption represents an alternative to the regulations to establish a firm, enforceable commitment by the manufacturer to FDA as to specific obligations. Submissions by an association would not be suitable because it is the manufacturer that must follow the regulations. Trade associations cannot compel specific actions by their member manufacturers. In addition, trade associations do not have the authority to change an applicant's submission.

However, anyone may submit a request to FDA, with supporting information, to revise the regulations to provide for exceptions from GST requirements.

(Comment 5) One comment noted that the proposal did not create a procedural mechanism to allow for partial exemptions. The comment explained that partial exemptions could be appropriate for specific subclasses of products.

We decline to amend the rule as suggested by the comment. The comment did not provide enough information that would allow us to determine the merits of or need for partial exemptions. However, under § 610.11(g)(2), we may accept a request for an exemption in the form of a biologics license supplement for a limited group of products after a case-by-case evaluation. Section 610.11(g)(2) gives manufacturers a mechanism for obtaining exemptions for specific biological products on an individual basis, rather than for whole "classes" of products, such as are excepted in § 610.11(g)(1). We believe such exemptions should be addressed on a case-by-case basis through a biologics license application or supplement.

(Comment 6) Two comments would revise the proposal to exempt allergenic products if each lot of stock concentrates of allergenic extracts and each lot of diluent contained in the final product satisfies the GST requirements. The comments requested that we modify 21 CFR 680.3(b)(1) to exempt allergenic extracts from the requirement to perform the repeat GST on final products when a GST is performed on a stock concentrate. The comments explained that the suggested

amendment would eliminate an unnecessary burden on the allergenic product industry that would result from separate rulemaking procedures.

The issue of exempting allergenic products is outside the scope of this rulemaking. Consequently, we decline to amend the rule as suggested by the comment.

#### IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles set forth in the Executive order. OMB has determined that the final rule is a significant regulatory action as defined by the Executive order and is subject to review under the Executive order.

In accordance with the principles of Executive Order 12866, the final rule will provide increased flexibility for applications with approved biological products and may substantially reduce the burdens on some applicants seeking approval of certain biological products.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small business entities. Because the final rule has no compliance costs and does not result in any new requirements, the agency certifies that the final rule will not have a significant negative economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. This rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of \$100 million or more by State, local, and tribal governments in the aggregate, or by the private sector in any one year.

#### V. Environmental Impact

This agency has determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,

neither an environmental assessment nor an environmental impact statement is required.

#### VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title:* Request for Exemptions from the General Safety Testing Requirements for Biological Products.

*Description:* FDA is revising the requirements for GST set forth in § 610.11. The test may detect harmful contaminants that may enter or be introduced through undetected failures in the manufacture of biological products. The revision would add an administrative procedure for obtaining exemptions from the GST requirements for biological products not already excepted under § 610.11(g)(1). FDA is codifying the new administrative procedure because alternatives to the GST may be feasible or appropriate for some biological products. FDA anticipates that manufacturers requesting exemptions would have demonstrated a record of the GST compliance, well-documented in-process safety controls, and use sophisticated analytical techniques to adequately characterize the product and validate its safety. Manufacturers would submit their requests and documentation to the Director, CBER, who may grant the exemption if it is determined that the manufacturer's submission justifies such an action.

*Description of Respondents:* Manufacturers of biological products.

This final rule requires only those manufacturers requesting an exemption from the GST under § 610.11(g)(2) to submit additional information as part of a biologics license application or supplement to an approved biologics license application. Based on our experience, we estimate that we will receive approximately 10 requests for administrative exemption from the GST under § 610.11(g)(2) annually. We also estimate that an applicant will take 40 hours to complete and submit the appropriate information for the exemption request. Since the applicant