

December 12, 2003, deadline for registration.

(Comment 160) One commenter requests that FDA provide a facility's registration confirmation in the form of a certificate or card that facilities can display so inspectors can see if the facility is in compliance with the registration requirement.

(Response) FDA will send facilities a confirmation when FDA receives their complete registration. Facilities may use this confirmation to show their registration status.

IV. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

FDA has examined the economic implications of this interim final rule as required by Executive Order 12866. 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this interim final rule is a significant regulatory action as defined by Executive Order 12866.

This Final Regulatory Impact Analysis reflects changes made in the regulation from the proposed rule to the interim final rule, as well as changes in estimates in response to comments. It also includes responses to comments on the Preliminary Regulatory Impact Analysis (PRIA) (*see* 68 FR 5387 to 5413). Where there were no changes in the estimates provided in the PRIA, the estimates are summarized here.

Interested persons are directed to the text of the PRIA for a fuller explanation of the estimates about which there were no controversy or changes. As noted in section III of this document, FDA received approximately 350 submissions in response to the proposed rule, which raised almost 200 issues. We continue with the discussion of the comments and FDA's responses to those comments using the same presentation as in section III, focusing here on the comments FDA received on the PRIA. Accordingly, the word "Comment"

again will appear in parenthesis before the description of the comment, and the word "Response" will appear in parenthesis before FDA's response. As in section III, FDA has numbered each comment to make it easier to identify a particular comment. The number assigned to each comment below continues in sequence from section III and is purely for organizational purposes; it does not signify the comment's value or importance or the order in which it was submitted.

1. Description of Interim Final Rule

This interim final rule requires the registration of facilities that manufacture/process, pack, or hold food intended for consumption in the United States. In the event of an actual or threatened bioterrorist attack on the U.S. food supply or other food-related emergency, this information will help FDA and other authorities determine the source and cause of the event, and communicate with potentially affected facilities.

2. General Comments

(Comment 161) FDA received a number of comments that asserted that the costs or benefits of the proposed rule were incorrectly estimated.

(Response) If the comment asserted costs or benefits were incorrectly estimated without specifying which costs or benefits, there was not sufficient information for FDA to respond to that comment. However, comments that specified which costs or benefits were incorrectly estimated are addressed in later sections of this analysis.

(Comment 162) FDA received a comment that asked what a line entry is.

(Response) A line entry is a term used by FDA's automated system for imports, the OASIS reporting system (Ref. 2). A "line entry" refers to a line on an invoice that reflects a certain article specific to a manufacturer or packaging: *e.g.*, 100 cases containing 48 6-ounce cans of tuna.

3. Number of Facilities Affected

In the PRIA, FDA estimated the number of affected establishments by counting facilities, not firms. A firm may be composed of many facilities under the same ownership. The changes in behavior needed to comply with this regulation may take place at the firm or facility level. However, because facilities must be registered, and for ease of analysis, FDA focused on the facility as the unit of analysis. For a count of domestic facilities, FDA used the 2000 County Business Patterns (Ref. 3), 1999 Nonemployer Statistics (Ref. 4), the FDA

Field Accomplishments and Compliance Tracking System (Ref. 5), the Census of Agriculture (Ref. 6), 1997 Economic Census of Transportation and Warehousing (Ref. 7), and information from direct selling marketing trade associations (Refs. 8 and 9). The analysis relies primarily on the Nonemployer Statistics for its count of very small businesses (no paid employees) that may or may not be home-based. The Nonemployer Statistics' primary source is administrative data from Internal Revenue Service records. This may overcount the number of facilities required to register, as some of the facilities may be exempt on the basis of being an individual's private residence. Additional small facilities that are direct marketers are counted using data from direct marketing trade associations. FDA counted the number of facilities in the U.S. outlying islands of Puerto Rico, Guam, Virgin Islands, and Northern Mariana Islands using Economic Censuses available from the U.S. Census Bureau (Refs. 10, 11, 12, and 13). To count the number of foreign manufacturers/processors, FDA used FDA's OASIS database (Ref. 2). As noted, OASIS is an automated FDA system for processing and making admissibility determinations for shipments of foreign-origin FDA-regulated products seeking to enter domestic commerce. FDA also estimated that 16 percent of the foreign manufacturers/processors would stop exporting to the United States because of the cost of complying with this regulation. Also counted were foreign holders of products to be exported to the United States. FDA did not have data on the number of foreign holders and so assumed that they were equal to the number of consignees, brokers, and importers of food products in the United States. Foreign de minimis processors and packagers were not included in the OASIS count and so were estimated using U.S. data on the number of packer/repackers. Tables 3 through 7 of this document present the counts of domestic and foreign facilities.

(Comment 163) FDA received a number of comments stating that the number of affected facilities had been underestimated.

(Response) Many of these comments did not provide any specific information about the categories of facilities that were undercounted or not included or information about the correct number of facilities. Without this additional information, FDA has no basis for responding to these comments. However, FDA responds in the number of facilities section to comments that