

## IX. Request for Comments

FDA is issuing this rule as an interim final rule, with an opportunity for public comment on specific issues identified below. Although the agency is seeking comment on this interim final rule, it is effective December 12, 2003. This means that the rule's requirements will be in effect and have the force and effect of law from that date until any subsequent modification by the issuance of a final rule. Accordingly, as required by section 305 of the Bioterrorism Act, all covered facilities must be registered with FDA by December 12, 2003.

As noted, elsewhere in this issue of the **Federal Register**, FDA is publishing an interim final rule concerning prior notice of imported food shipments. Given the relatedness of the prior notice and food facilities registration rules, FDA is establishing a comment period for the registration rule that coincides with the comment period on the prior notice interim final rule. Thus, the comment period for the registration interim final rule will open today for a period of 75 days. Moreover, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule, the agency intends to reopen the comment period for an additional 30 days in March 2004.

As noted elsewhere in this issue of the **Federal Register**, FDA's economic analysis is based on a number of assumptions. To improve this analysis, FDA invites public comment on the following issues:

1. The cost to foreign facilities of hiring and retaining a U.S. agent. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The costs to a foreign facility of hiring a U.S. agent;

b. The number of foreign facilities that have hired a U.S. agent or negotiated additional duties from someone with whom they have an existing relationship in response to this interim final rule, instead of relying on an existing relationship with a person who qualifies as a U.S. agent;

c. The number of foreign facilities that have ceased exporting to the United States because they have decided not to hire/retain a U.S. agent for registration purposes.

d. The distribution of costs between submitting registrations and other services offered by the U.S. agent;

e. The assumptions underlying FDA's estimates of the costs of hiring and retaining a U.S. agent.

2. The effects on domestic small businesses, if any, if some foreign facilities cease exporting to the United States due to the U.S. agent requirement for registration. Specifically, FDA invites comment, and the submission of data or other information, on the following:

a. The number of domestic small businesses that have been adversely affected by trading partners that have ceased exporting to the United States due to the U.S. agent requirement for foreign facility registration; and

b. The costs incurred by these domestic small businesses due to the loss of these trading partners.

FDA will seriously consider all comments submitted. FDA is dedicated to updating this estimate with the best available information in order to inform decision makers who may be considering regulatory alternatives in developing a final rule.

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) written or electronic comments regarding this interim final rule by December 24, 2003. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit one electronic copy. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, this regulation is effective on December 12, 2003. The agency will address comments received and confirm or amend the interim final rule in a final rule. The agency, however, will not consider any comments that have been previously considered during this rulemaking.

## X. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(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.

## XI. Federalism

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the interim final rule does not contain policies that have substantial direct effects on the States, on the relationship between the

National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency concludes that the interim final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

## XII. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses in this document, but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Brown, Bradley, Memorandum to the file, July 21, 2003.
2. U.S. Census Bureau, 2000 County Business Patterns, available at <http://www.census.gov/epcd/cbp/view/cbpview.html>.
3. U.S. Census Bureau, 1999 Nonemployer Statistics, available at <http://www.census.gov/epcd/nonemployer/index.html>.
4. U.S. Food and Drug Administration, Field Accomplishments and Compliance Tracking System (FACTS), fiscal year 2002.
5. U.S. Department of Agriculture, National Agriculture Statistics Service, 1997 Census of Agriculture-United States Data, available at <http://www.nass.usda.gov/census/>.
6. U.S. Census Bureau, 1997 Economic Census of Transportation and Warehousing, available at <http://www.census.gov/svsd/www/97trans.html>.
7. Direct Selling Association, Direct Selling by the Numbers, accessed at <http://www.dsa.org/research/numbers.htm#DISTTYPE>, 7/10/2003.
8. Direct Sales World, Facts and Figures and Comment of the World of Direct Sales, accessed at <http://www.nmworld.com/pages/Countries/USA/index.html>, 7/10/2003.
9. U.S. Census Bureau, Guam: 1997 Census of the Outlying Areas, available at <http://www.census.gov/prod/ec97/oa97e-6.pdf>.
10. U.S. Census Bureau, Northern Mariana Islands: 1997 Census of the Outlying Areas, available at <http://www.census.gov/prod/ec97/oa97e-7.pdf>.
11. U.S. Census Bureau, Puerto Rico: 1997 Census of the Outlying Areas, available at <http://www.census.gov/prod/ec97/oa97e-4.pdf>.
12. U.S. Census Bureau, Virgin Islands: 1997 Census of the Outlying Areas, available at <http://www.census.gov/prod/ec97/oa97e-5.pdf>.
13. U.S. Food and Drug Administration, Operational and Administrative System for Import Support (OASIS), fiscal year 2002.