

detain that firm's products in a given time period. The most we can say about costs on a per firm basis is that the average expected cost per firm across all potentially affected firms would presumably be quite low, but the cost for a particular firm in a particular year could be significant, depending on a number of variables including the type and amount of product involved. FDA requests comment on the impact of this proposed rule on small entities.

The fact that most of the potentially affected firms are small businesses suggests that the options that would be relevant to small businesses are the same as the options relevant for all firms discussed in the impact analysis above. Options two and three would both reduce the impact on small firms. However, these options would also reduce benefits, and we do not have sufficient information to estimate the change in net benefits.

Administrative detention involves preventing the movement of food upon credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. This standard is applicable without regard to the size of any business involved. Most of the businesses impacted by this proposed rule are small businesses. To provide an exemption for small businesses under this proposed rule would defeat the purposes of the statute. Accordingly, we are not providing exemptions from the requirements of this regulation to small businesses.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-benefit and other analyses before any rule making if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is \$112.3 million per year. We have estimated that the total cost of the proposed rule would be no more than \$38 million per year. Therefore, we have determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

D. SBREFA Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 SBREFA (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the

economy of \$100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, the Office of Management and Budget (OMB) has determined that this proposed rule, when final, will not be a major rule for the purpose of congressional review.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

We tentatively conclude that these proposed information collection provisions are exempt from OMB review under 44 U.S.C. 318(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations in 5 CFR 1320(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. We seek comment on our tentative conclusion that these information collections are exempt from OMB review.

VII. 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.

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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 tentatively concludes that the

proposed 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.

IX. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measure of general application necessary to address an urgent problem related to the protection of human, plant, or animal health. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." The provisions in this proposed rule that describe the procedures for how FDA will detain an article of food, how FDA will expedite certain enforcement actions with respect to perishable food, and the process for appealing a detention order will enhance FDA's ability to prevent distribution of food that presents a threat of serious adverse health consequences or death to humans or animals. The legislative history of the Bioterrorism Act, with respect to the regulation required by section 303 of that act, notes that the "Secretary