

new importers to spend \$620,000 on computers and \$74,400 on Internet access to be able to submit prior notice information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, FDA Desk Officer.

## VI. 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.

## VII. 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.

## VIII. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard 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 or sanitary or phytosanitary protection. 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." In order to meet these objectives, section 307 of the Act requires the FDA to propose and issue final regulations requiring prior notice of food imported or offered for import into the United States within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. Section 307 also provides that if FDA does not issue final regulations by this date, FDA still must receive prior notice of food imported or offered for import into the United States by December 12, 2002, of no less than 8 hours and no more than 5 days, subject to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the United States government's need to prepare to respond to bioterrorism and other food-related emergencies and FDA's need to have the final rule in place, tested, and fully operational by December 12, 2003. This means that the final rule must publish in early October 2003.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.

## IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

1. Compilation of food entry documents, with corresponding invoices and screens, taken from FDA's Operational and Administrative System for Import Support (OASIS).
2. Bureau of Economic Analysis, <http://www.bea.doc.gov>
3. United States Department of Labor, Bureau of Labor Statistics, National Compensation Survey: Occupation Wages in the United States, 2000, Summary 01-04. Available at <http://www.bls.gov/ncs/ocs/sp/nchl0354.pdf>.
4. USDA Agricultural Marketing Service (March 2002) Fresh Fruits and Vegetable Shipments. [www.ams.usda.gov](http://www.ams.usda.gov)
5. Kasmire, Dr. Robert F. Vegetable Marketing Specialist, [www.thepacker.com/rbcs/handbookarticles/properis.htm](http://www.thepacker.com/rbcs/handbookarticles/properis.htm) Accessed on September 16, 2002.
6. USDA Agricultural Marketing Service produce point price reports for various border crossings for the dates September 12, 2002 and September 16, 2002. [www.ams.usda.gov](http://www.ams.usda.gov)
7. Florida Department of Agriculture and Consumer Services (FDACS) [www.ffva.com/rps.htm](http://www.ffva.com/rps.htm)
8. National Marine Fisheries Service, Fisheries Statistics and Economics Division, [www.st.nmfs.gov](http://www.st.nmfs.gov) accessed September 2002.
9. Florida Department of Agriculture and Consumer Services, <http://doacs.state.fl.us/press/1999/090999.html> and [www.ffva.com/rps.htm](http://www.ffva.com/rps.htm)
10. Center for Food Safety and Applied Nutrition, <http://www.cfsan.fda.gov/~dms/qa-sto8.html>
11. Hennessy T.W., C.W. Hedberg, L. Slutsker, K.E. White, J.M. Besser-Wiek, M.E. Moen, J. Feldman, W.W. Coleman, L.M. Edmonson, K.L. MacDonald, M.T. Osterholm, and the Investigation Team, "A National Outbreak of Salmonella Enteritidis Infections From Ice Cream," *The New England Journal of Medicine*, May 16, 1996, pp. 1281-1286.
12. Cutler, D., E. Richardson, 1999, "Your Money and Your Life: The Value of Health and What Affects It," Working Paper 6895, National Bureau of Economic Research.
13. Zorn, D., K. Klontz, 1998, "Appendix: The Value of Consumer Loss to Foodborne Reactive Arthritis," **Federal Register**, 63 FR 24292-24299, May 1, 1998.
14. Scharff, R., and A. Jessup, "Valuing Chronic Disease for Heterogenous Populations: the Case of Arthritis," 2002, Mimeo.
15. Lee, L.A., S.M. Ostroff, H.B. McGee, D.R. Johns, F.P. Downes, D.N. Cameron, N.H. Bean, and P.M. Griffin, "An Outbreak of Shigellosis at an Outdoor Music Festival,"