

or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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 interim final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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 has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. References

The following references have been placed on display in the Division of Dockets Management (*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 addresses, but is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Ruling NY G89921 (June 12, 2001), U.S. Bureau of Customs and Border Protection, <http://rulings.customs.gov>.
2. Bureau of Economic Analysis, <http://www.bea.doc.gov>.
3. U.S. 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/ncbl0354.pdf>.
4. USDA Agricultural Marketing Service, March 2002, "Fresh Fruits and Vegetable Shipments," <http://www.ams.usda.gov>.
5. Kasmire, Dr. Robert F., Vegetable Marketing Specialist, <http://www.thepacker.com/rbcs/handbookarticles/properis.htm>, accessed on 9.16.02.
6. USDA Agricultural Marketing Service produce point price reports for various border crossings for the dates September 12, 2002, and September 16, 2002, <http://www.ams.usda.gov>.

7. Florida Department of Agriculture and Consumer Services (FDACS), <http://www.ffva.com/rps.htm>.

8. National Marine Fisheries Service, Fisheries Statistics and Economics Division, <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 <http://www.ffva.com/rps.htm>.

10. Center for Food Safety and Applied Nutrition, <http://www.cfsan.fda.gov/~dms/qa-sto8.html>.

11. Small Business Administration Office of Advocacy, "Small Business by the Numbers", May 2002, <http://www.sba.gov/advo/>.

12. Herwaldt B.L., M.L. Ackers, and Cyclospora Working Group, "An Outbreak in 1996 of Cyclosporiasis Associated With Imported Raspberries," *New England Journal of Medicine*, May 29, 1997, 1548-1556.

13. Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable, GAO Publication, April 1998, <http://www.gao.gov>.

14. "Port Lockout Could Harm U.S. Economy," http://www.firstcoastnews.net/news/2002-10-01/usw_portlockout.asp.

15. "Transportation official says strike at U.S. port would ripple across globe," <http://www.govexec.com/dailyfed/0202/022702gsn1.htm>.

16. "The Informal Sector in El Salvador," Embassy of the United States of America in El Salvador, <http://salsalvador.usembassy.gov/SelectEconomicInfo> (left column), then select the first option "Economic and Commercial Reports, Updates," at next screen under Socio-Economic Reports, select the last article "The Informal Sector in El Salvador, 1999," and Import Alert 1A1211, FDA Guidance, March 1998, http://www.fda.gov/ora/_import_ia1211.html.

17. Guidance for Industry, Importers and Filers, Food Security Preventive Measures Guidance, FDA Publication, March 2003.

18. Investigations Operations Manual, FDA Publication, page 179.

19. FDA Registration of Food Facilities interim final rule, published elsewhere in the issue of the **Federal Register**.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Subpart I, consisting of §§ 1.276 through 1.285, is added to part 1 to read as follows:

Subpart I—Prior Notice of Imported Food

General Provisions

Sec.

1.276 What definitions apply to this subpart?

1.277 What is the scope of this subpart?

Requirements to Submit Prior Notice of Imported Food

1.278 Who is authorized to submit prior notice?

1.279 When must prior notice be submitted to FDA?

1.280 How must you submit prior notice?

1.281 What information must be in a prior notice?

1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

Consequences

1.283 What happens to food that is imported or offered for import without adequate prior notice?

1.284 What are the other consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under 21 CFR part 1, subpart H?

General Provisions

§ 1.276 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart, unless defined below.

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article originates* means FDA Country of Production.

(3) *Country from which the article is shipped* means the country in which the article of food is loaded onto the conveyance that brings it to the United States or, in the case of food sent by international mail, the country in which the article will be mail.

(4) *FDA Country of Production* means:

(i) For an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown,