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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N-0278]

RIN 0910-AC41

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation that would require U.S. purchasers or U.S. importers or their agents to submit to FDA prior notice of the importation of food. The proposed regulation implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires prior notification of imported food to begin by December 12, 2003. The Bioterrorism Act requires FDA to issue final regulations that specify the period of advance notice by this date or a statutory notice provision requiring not less than 8 hours prior notice and not more than 5 days prior notice will take effect until a final rule is issued.

DATES: Submit written or electronic comments by April 4, 2003. Submit written or electronic comments on the collection of information by March 5, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mary Ayling, Center for Food Safety and Applied Nutrition (HFS-32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2428.

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I. Background and Legal Authority

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Bioterrorism Act, which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 307, which amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 801(m) (21 U.S.C. 381(m)). This new provision changes when FDA will receive certain information about imported foods by requiring the Secretary of Health and Human Services (the Secretary), after consultation with the Secretary of the Treasury, to issue implementing regulations by December 12, 2003, mandating prior notification to FDA of food that is imported or offered for import into the United States. Functions of the U.S. Customs Service (U.S. Customs) will soon be a part of the Department of Homeland Security (DHS). Future consultations may be with DHS instead of, or in addition to, the Department of Treasury.

Section 801(a) of the act sets out procedures for imports under FDA's jurisdiction. When an FDA-regulated product is imported or offered for import, generally brokers submit entry information to the U.S. Customs on behalf of the importers of record. U.S. Customs then provides entry information and may deliver samples to FDA to enable admissibility decisions to be made. Under U.S. Customs authorities, entry of the merchandise must be made within 15 days after importation.

U.S. Customs regulations provide for different kinds of entries. Commonly, merchandise is the subject of an entry for consumption (i.e., unrestricted, general use) under a basic importation and entry bond at the first port of arrival, but U.S. Customs authorities also allow for the entry of merchandise for transportation under a custodial bond from the port of arrival to another port where the consumption entry will be made. If no entry of any kind is made within 15 days, the article cannot move and the carrier or other authorized party must notify U.S. Customs and a general order (i.e., bonded or secure) warehouse that the article remains unentered. Generally, at that point, the article is moved to the bonded warehouse (or