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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: Interim final rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final regulation that requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The interim final rule 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 on December 12, 2003, even in the absence of a final regulation. The interim final rule requires that the prior notice be submitted to FDA electronically via either the Bureau of Customs and Border Protection (CBP) Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or the FDA Prior Notice System Interface (FDA PN System Interface). The information must be submitted and confirmed electronically as facially complete by FDA for review no more than 5 days and no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land/rail), and 2 hours (for food arriving by land/road) before the food arrives at the port of arrival. Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held.

DATES: This interim final rule is effective December 12, 2003. Submit written or electronic comments by December 24, 2003.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Deborah Ralston, Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6230.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
 - A. Current Process—Admissibility Determinations Under Section 801(a) of the FD&C Act
 - B. Process After December 12, 2003—Prior Notice Determination Followed by Admissibility Determination
- II. Overview of the Interim Final Rule and Significant Changes Made to the Proposed Rule
 - A. “What Definitions Apply to This Subpart?” (Section 1.276 Proposed as § 1.277)
 - B. “What is the Scope of This Subpart?” (Section 1.277 Proposed as § 1.276)
 - C. “Who Is Authorized to Submit Prior Notice?” (Section 1.278 Proposed as § 1.285)
 - D. “When Must Prior Notice Be Submitted to FDA?” (Section 1.279 Proposed as § 1.286)
 - E. “How Must You Submit Prior Notice?” (Section 1.280 Proposed as § 1.287)
 - F. “What Information Must Be in a Prior Notice?” (Section 1.281 Proposed as § 1.288)
 - G. “What Must You Do If Information Changes After You Have Received Confirmation of a Prior Notice From FDA?” (Section 1.282 Proposed §§ 1.289 to 1.294)
 - H. “What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice?” (Section 1.283 Proposed as § 1.278)
 - I. “What Are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart?” (Section 1.284 Proposed as § 1.278)
 - J. “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?” (Section 1.285)
- III. Comments on the Proposed Rule
 - A. General Comments and Outreach
 - B. Foreign Trade Issues
 - C. “What Definitions Apply to This Subpart?” (Section 1.276 Proposed as § 1.277)
 - D. “What is the Scope of This Subpart?” (Section 1.277 Proposed as § 1.276)
 - E. “Who Is Authorized to Submit Prior Notice?” (Section 1.278 Proposed as § 1.285)
 - F. “When Must Prior Notice Be Submitted to FDA?” (Section 1.279 Proposed as § 1.286)
 - G. “How Must You Submit Prior Notice?” (Section 1.280 Proposed as § 1.287)
 - H. “What Information Must Be in a Prior Notice?” (Section 1.281 Proposed as § 1.288)
 - I. “What Must You Do If Information Changes After You Have Received

Confirmation of a Prior Notice From FDA?” (Section 1.282 Proposed as §§ 1.289 to 1.294)

- J. “What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice?” (Section 1.283) and “What Are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart?” (§ 1.284 Proposed as § 1.278)
- K. “What Happens to Food That Is Imported or Offered for Import From Unregistered Facilities That Are Required to Register Under Section 415 of the FD&C Act, 21 U.S.C. 350d and 21 CFR Part 1, Subpart H?” (Section 1.285)
- IV. Issuance of an Interim Final Rule and Effective Date; Comments
- V. Analysis of Economic Impacts
 - A. Final Regulatory Impact Analysis
 - 1. Need for Regulation
 - 2. Interim Final Rule Coverage
 - 3. Regulatory Options Considered
 - 4. Summary of Options
 - 5. Benefits
 - B. Small Entity Analysis (or Final Regulatory Flexibility Analysis)
 - 1. Number of Establishments Affected
 - 2. Costs per Entity
 - 3. Additional Flexibility Considered
 - C. Unfunded Mandates
 - D. Small Business Regulatory Enforcement Fairness Act (SBREFA) Major Rule
- VI. Paperwork Reduction Act of 1995
- VII. Analysis of Environmental Impact
- VIII. Federalism
- IX. References

I. Background

In the **Federal Register** of February 3, 2003 (68 FR 5428), the Department of Health and Human Services (FDA) and the Department of Treasury (U.S. Customs Service) issued a joint notice of proposed rulemaking requiring submission to FDA of prior notice of human and animal food that is imported or offered for import into the United States. The events of September 11, 2001, had highlighted the need to ensure that FDA had additional tools to help prevent a food-related bioterrorism event or other public health emergency. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188), 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 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 an implementing regulation by December 12, 2003, to require prior notification to FDA of food that is imported or offered for import into the United States. Under