

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

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Import for Export; Reporting and Recordkeeping Requirements for Unapproved or Violative Products Imported for Further Processing or Incorporation and Subsequent Export; Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission Into the United States; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rules; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of two proposed rules. One proposed rule, which appeared in the **Federal Register** on November 24, 1998 (63 FR 64930), would have established reporting and recordkeeping requirements for certain products that are imported into the United States for further processing or incorporation into products that are then exported. The second proposed rule, which appeared in the **Federal Register** on January 22, 2001 (66 FR 6502), would have established requirements for marking imported food that has been refused entry into the United States for safety reasons. FDA is withdrawing these proposed rules due to recent changes in Federal law.

DATES: The proposed rules are withdrawn [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

SUPPLEMENTARY INFORMATION: On November 24, 1998, FDA published a proposed rule in the **Federal Register** (63 FR 64930) that would have established reporting and recordkeeping requirements for certain products that are imported under section 801(d)(3) and (d)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381(d)(3) and (d)(4)). These sections of the act allowed the importation of certain unapproved or otherwise noncompliant products or articles provided that those products or articles are further processed or incorporated into other products and then exported from the United States.

On January 22, 2001, FDA and the Department of the Treasury jointly prescribed a proposed rule in the **Federal Register** (66 FR 6502) that would have allowed FDA to require food importers or consignees to mark imported foods if, for safety reasons, FDA had refused to allow such foods to enter the United States. The mark would have stated, "UNITED STATES REFUSED ENTRY," and the proposed rule would have established the mark's size and required the mark to be affixed on packing containers holding the refused food and on invoices, bills of lading, and any other documentation accompanying the food when it is exported from the United States.

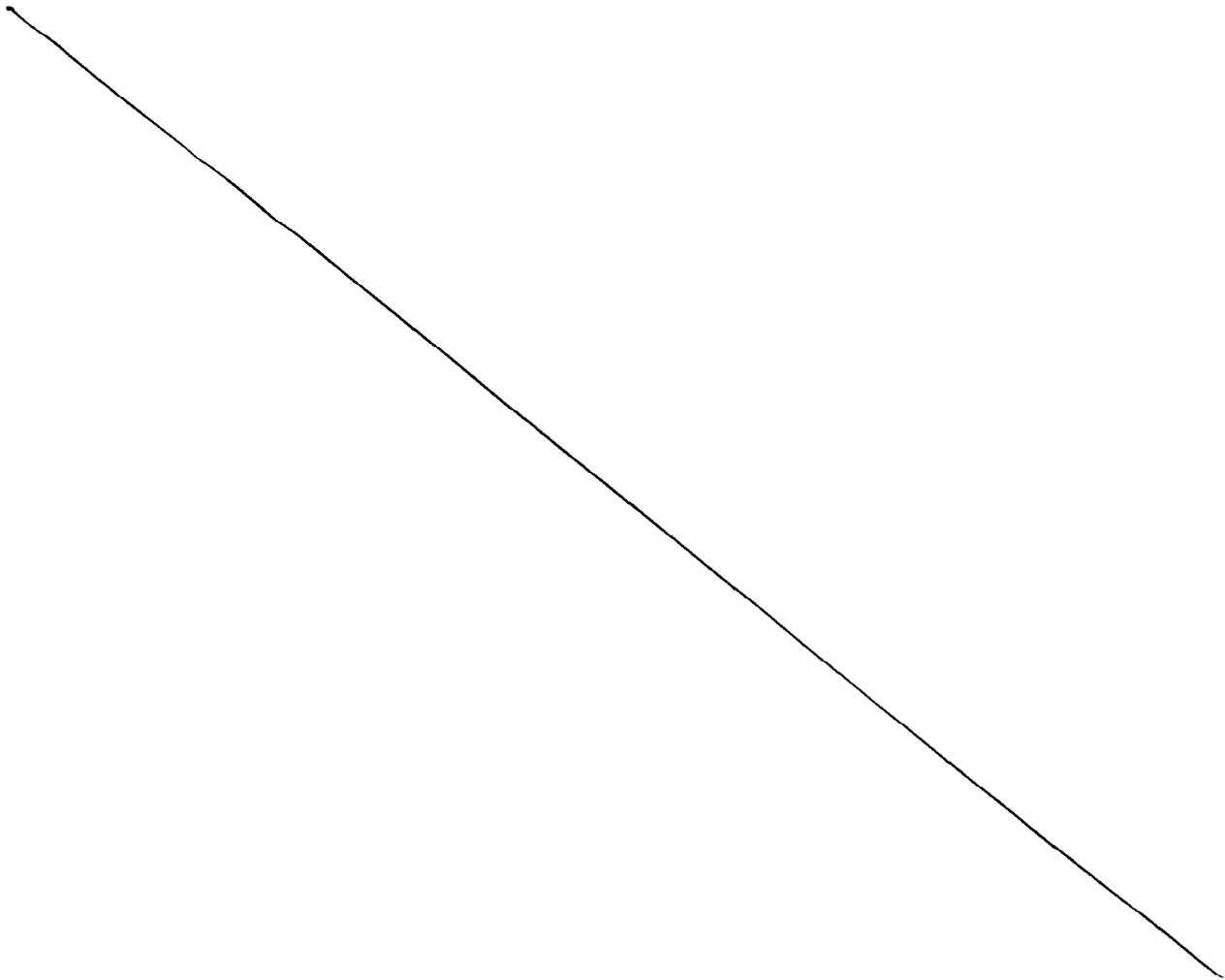
We received comments on both rules and also held public meetings to discuss the proposed rule on the marking of refused food imports. After reviewing the comments, we wrote and intended to issue final rules in 2002.

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-

188). The new law contains provisions that change the legal context of the two proposed FDA regulations described previously in this document. For example, the new law gives FDA express authority to require marking on any food product that had been refused admission into the United States whereas the proposed rule would have required marking on food refused admission for safety reasons only.

The new law also significantly revises section 801(d)(3) of the act; it prescribes new reporting requirements that differ from those in the FDA proposed rule.

Because of the changes brought about by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA is withdrawing both



proposed rules. FDA will consider whether new rulemakings or other actions are necessary to implement the new statutory requirements.

Dated: August 13, 2002

August 13, 2002.



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

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