



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2007-N-0465]

Label Requirement for Food That Has Been Refused Admission Into the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the withdrawal of a proposed rule that published in the *Federal Register*. This proposed rule is not currently considered a viable candidate for final action. FDA is taking this action because this proposed rule does not reflect current technology and industry practice.

DATES: The proposed rule published September 18, 2008, at 73 FR 54106 is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Holli Kubicki, Office of Regulatory Affairs, Office of Strategic Planning and Operational Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-4557, holli.kubicki@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1990, FDA began a process of periodically conducting comprehensive reviews of its regulation process, including reviewing the backlog of

proposed rulemakings that had not been finalized. As FDA removed many proposed rules not finalized, the Agency implemented a process of reviewing existing proposed rules every 5 years.

As part of this process and the Administration's regulatory reform initiative, we continue to conduct reviews of existing proposed rules. The review determines if the proposals are outdated, unnecessary, or can be revised to reduce regulatory burden while allowing FDA to achieve our public health mission and fulfill statutory obligations.

As part of these efforts, FDA is withdrawing the proposed rule entitled "Label Requirement for Food That Has Been Refused Admission Into the United States" (September 18, 2008, 73 FR 54106).

The proposed rule does not reflect current technology and industry practice. For example, the proposed rule directed owners or consignees to affix labels to physical documents such as invoices, packing lists, bills of lading, and any other documents accompanying refused food. Many of these documents are now electronic. Therefore, since implementation of the proposed rule would not adequately address how to permanently mark electronic documentation accompanying refused food, it would not achieve the public health and efficiency benefits discussed in the notice of proposed rulemaking. As directed by section 304 of the FDA Food Safety Modernization Act (Pub. L. 111-353) that was enacted after FDA issued the proposed rule, FDA now requires, as part of its prior notice regulations, notice to FDA of the name of any country to which imported food has been refused entry. (See 21 CFR 1.281(a)(18).) This includes situations where the United States has refused entry, and it therefore provides FDA with information related to what the proposed marking rule would require.

FDA may reassess how to effectively implement the labeling of documentation accompanying refused food and consider whether to issue a revised proposed rule in the future.

The withdrawal of the proposal identified in this document does not preclude the Agency from reinstating rulemaking concerning the issues addressed. Should we decide to undertake such a rulemaking in the future, we will re-propose the action and provide a new opportunity for comment. Furthermore, this proposed rule withdrawal is only intended to address the specific actions identified in this document, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn proposed rule, you may review the Agency's website (<https://www.fda.gov>) for any current information on the matter.

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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