

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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DDM

[FDA-2008-D-0108 (formerly Docket No. 2006D-0079)]

Guidance for Industry: Guide to Minimize Food Safety Hazards for Fresh-cut Fruits and Vegetables; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (the fresh-cut guidance or guidance). Previously, FDA announced the availability of the fresh-cut guidance as a "draft final" document, pending approval by the Office of Management and Budget (OMB) of the information collection provisions in the guidance. FDA is publishing this notice to announce that the fresh-cut guidance is now final. The text of the guidance has not changed from the previously published draft final version. The fresh-cut guidance complements FDA's current good manufacturing practice (CGMP) requirements for foods by providing specific guidance on the processing of fresh-cut produce. The fresh-cut guidance and the CGMP regulations are intended to assist processors in minimizing microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables sold to consumers and retail establishments in a ready-to-eat form.

DATES: Submit written or electronic comments on the guidance at any time.

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ADDRESSES: Submit written comments on the guidance 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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written requests for single copies of the guidance to the Office of Food Safety (HFS-317), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1700 or FAX: 301-436-2651. Send one self-addressed adhesive label to assist the Center in processing your request.

FOR FURTHER INFORMATION CONTACT: Rhoma Johnson, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2066 or FAX: 301-436-2651.

SUPPLEMENTARY INFORMATION:

I. Background

Fresh-cut fruits and vegetables are minimally processed fruits and vegetables that have been altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. The methods by which produce is grown, harvested, and processed may contribute to its contamination with pathogens and, consequently, the role of the produce in transmitting foodborne illness. Factors such as the high degree of handling and mixing of the product, the release of cellular fluids during cutting or chopping, the high moisture content of the product, the absence of a step lethal to pathogens, and the potential for temperature abuse in the processing,

storage, transport, and retail display all enhance the potential for pathogens to survive and grow in fresh-cut produce.

On March 6, 2006, FDA published in the **Federal Register** a notice entitled “Draft Guidance for Industry: Guide to Minimize Food Safety Hazards of Fresh-Cut Fruits and Vegetables” (71 FR 11209) (the March 2006 notice). FDA gave interested persons 60 days to comment on the draft guidance. The comment period closed on May 5, 2006. The draft guidance was revised based on public comments. The draft guidance contained information collection provisions subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). Under the PRA, Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, in the March 2006 notice (71 FR 11209), FDA gave interested persons 60 days to comment on the information collection provisions in the draft guidance. After providing the 60-day notice requesting public comment, section 3507 of the PRA (44 U.S.C. 3507) requires Federal agencies to submit the proposed collection to OMB for review and clearance. In compliance with 44 U.S.C. 3507, FDA submitted the proposed collection of information to OMB for review and clearance.

On March 13, 2007, FDA published in the **Federal Register** a notice announcing the availability of a “Draft Final Guidance for Industry: Guide to

Minimize Food Safety Hazards for Fresh-Cut Fruits and Vegetables” (72 FR 11364). This document was issued as a “draft final” guidance pending OMB approval of the collection of information. FDA announced OMB’s approval of the collection of information in a notice published on October 19, 2007 (72 FR 59295). With OMB approval, FDA is publishing this notice announcing that the fresh-cut guidance is final and providing an OMB control number (See section II of this document).

The fresh-cut guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The fresh-cut guidance is intended to assist processors in minimizing microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables sold to consumers and retail establishments in a ready-to-eat form. This guidance represents FDA’s current thinking on the microbiological hazards presented by most fresh-cut fruits and vegetables and the recommended control measures for such hazards in the processing of such produce. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

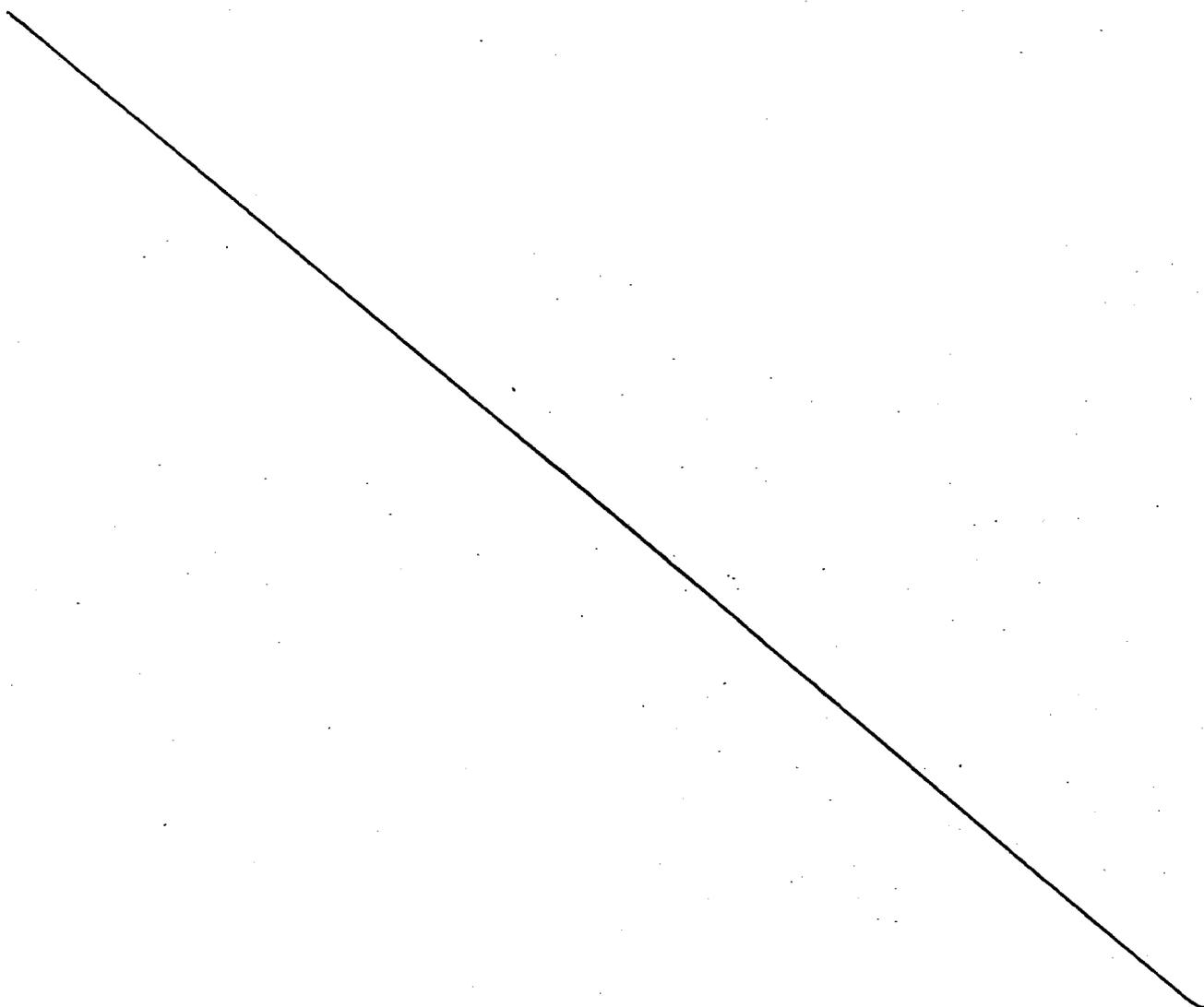
This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0609.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this guidance document at any time. Submit a single copy of electronic comments or two paper copies

of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

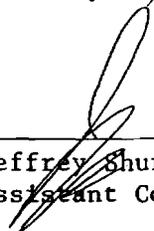
Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.



IV. Electronic Access

Persons with access to the Internet may obtain the guidance document at the following Web site: <http://www.cfsan.fda.gov/guidance.html>.

Dated: 2/15/08
February 15, 2008.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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