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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0333]

**Draft Guidance for Industry: Juice HACCP Hazards and Controls Guidance,
First Edition; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled “Guidance for Industry: Juice HACCP Hazards and Controls Guidance” (first edition) (the draft guidance). The draft guidance supports and complements the FDA regulation that requires a processor of juice to evaluate its operations using Hazard Analysis Critical Control Point (HACCP) principles and, if necessary, to develop and implement HACCP systems for its operations. The draft guidance represents FDA’s views on potential hazards in juice products and how to control them, and it is designed to assist juice processors in the development of HACCP plans.

DATES: Submit written or electronic comments concerning the draft guidance and collection of information by [*insert date 60 days after date of publication in the Federal Register*], to ensure adequate consideration in the preparation of the final guidance document. Comments on the draft guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Michael E. Kashtock, Center for Food Safety and Applied Nutrition (see **FOR FURTHER INFORMATION CONTACT**). Send two self-addressed adhesive labels to

assist that office in processing your request. Submit written comments concerning the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301 436-2022, FAX 301-436-2651, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the first edition of the draft guidance entitled “Guidance for Industry: Juice HACCP Hazards and Controls Guidance.”

Under the HACCP regulations in part 120 (21 CFR part 120), juice processors are required to evaluate their operations using HACCP principles and, if necessary, to develop and implement HACCP systems for their operations. Under § 120.9, juice products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) if a processor or importer fails to have and implement a HACCP plan when one is necessary, or otherwise fails to meet any of the requirements of the regulations. The primary purpose of the draft guidance is: (1) To help processors and importers of juice products identify the likelihood that a food safety hazard may occur in their product, and (2) to guide them in the

preparation of appropriate HACCP plans for those hazards that are reasonably likely to occur.

II. Significance of the Guidance

The draft guidance is a level 1 guidance issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The draft guidance represents the agency's current thinking on the potential hazards that are associated with various juice products and processing operations, and how the occurrence of these hazards can be avoided with HACCP controls when they are reasonably likely to occur, as required under part 120. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

This draft 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 the draft guidance has been submitted to OMB for review and was approved under OMB control number 0910–0466.

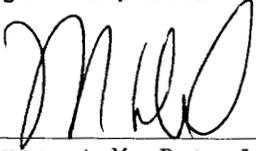
III. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at <http://www.cfsan.fda.gov/~dms/guidance.html>.

Dated: 8/29/02
August 29, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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