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Display Date 3-2-04
Publication Date 3-3-04
Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0333]

Guidance for Industry: Juice Hazard Analysis Critical Control Point 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 guidance document related to the processing of juice entitled "Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition." The guidance document supports and complements FDA's 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 guidance represents FDA's views on potential hazards in juice products and recommends how to control such hazards, and is designed to assist juice processors in the development of their HACCP plans.

DATES: You may submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written requests for single copies of the guidance to Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the

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Division of Dockets Management (HFA–305), 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 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, 301–436–2022, e-mail: *mkashtoc@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 12, 2002 (67 FR 57829), FDA announced the availability of a draft guidance document entitled "Draft Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition." Under FDA's 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(a)(4)), if a processor 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 guidance is to help processors of juice products evaluate the likelihood that a food safety hazard may occur in their product, and to guide them in the preparation of appropriate HACCP plans for those hazards that are reasonably likely to occur. Interested persons were given until November 12, 2002, to comment on the draft guidance.

FDA received 11 written comments on the draft guidance document. The agency reviewed and evaluated these comments and has modified the guidance where appropriate.

The guidance document is being issued as level 1 guidance, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the potential hazards that are associated with various juice products and processing operations, and how such hazards can be avoided using HACCP controls when the hazards 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 it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this guidance document at any time. Two paper copies of any mailed comments are to be submitted, 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.

III. Electronic Access

Interested persons also may access the guidance document at *http://www.cfsan.fda.gov/guidance.html.*

Dated: 2/19/04
February 19, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S

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Dawn P. Hawkins