does not apply, because section 10809 of the Farm Security and Rural Investment Act of 2002 provides that the petition is deemed denied if the Secretary (FDA) fails to act on the petition within 180 days of its receipt, unless the parties mutually agree upon an extension.

This guidance is a level 1 guidance issued consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The agency is soliciting public comment, but is implementing this guidance document immediately in accordance with § 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate. The Farm Security and Rural Investment Act of 2002 (Public Law 107–171) was enacted on May 13, 2002, and section 10809 is now in effect and must be implemented immediately. Thus, there is a pressing need for guidance to help effect such implementation. Accordingly, FDA is making this guidance effective immediately. This guidance represents the agency's current thinking on this subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used 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 citizen petitions under § 10.30 is approved under OMB control number 0910–0183.

III. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on this guidance at any time. Groups or organizations must submit two copies of any written comments. Individuals may submit one copy of their comments. Identify your written comments by placing the docket number at the top of your comment(s). If you base your comments on scientific evidence or data, please submit copies of the specific information along with your comments. Any comments submitted will be filed under the docket number identified in brackets in the heading of this document. The guidance and received comments may be seen 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 document at *http://www.cfsan.fda.gov/~dms/guidance.html*.

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25390 Filed 10–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P–0009]

Draft Guidance for Industry: Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices; 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 on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices.'' This draft guidance document is intended to provide processors of juice concentrates and certain shelf stable juice products with recommendations for the use of appropriate control measures to ensure that juice concentrates and certain shelf stable juices do not become contaminated or recontaminated with microbial pathogens during bulk transport.

DATES: Submit written or electronic comments concerning the draft guidance by December 6, 2002, to ensure adequate consideration in the preparation of the final guidance document. Comments on this guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Amy Green (*see* **FOR FURTHER INFORMATION CONTACT**). *See* **SUPPLEMENTARY INFORMATION** section for electronic access to this draft guidance.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Amy Green, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2025, FAX 301–436–2651.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed the draft guidance document to provide processors of juice concentrates and certain shelf stable juice products with recommendations for the use of appropriate control measures to help ensure that juice concentrates and certain shelf stable juice products do not become contaminated or recontaminated with microbial pathogens during bulk transport. The draft guidance recommends control measures for several transport modalities, including: (1) Multiuse or reusable containers (*e.g.*, tankers, reusable drums without liners, and reusable totes without liners) and (2) single-use sanitary containers or liners (*e.g.*, single-use sanitary totes, single-use sanitary drums, bag-in-box containers, totes with single-use sanitary liners, and drums with single-use sanitary liners). The draft document describes five major areas of concern with bulk transport systems, special considerations for tankers, and provides examples of a cleaning and sanitizing protocol for a tanker, control measures that might be used in loading and unloading a tanker, and critical control points a producer might use to include bulk transport in its hazard analysis critical control point (HACCP) plan.

This draft guidance is partly in response to a citizen petition submitted by certain representatives of the juice industry asking that FDA: (1) Amend 21 CFR 120.24(c) to exempt processors of juice concentrate and certain shelf stable juice products from the ''single facility requirement'' and (2) delay the effective date of the ''single facility requirement'' until the agency has disposed of the citizen petition. The petitioners contend that transportation hazards, which the ''single facility requirement'' was designed to address, could be adequately addressed as part of a processor's HACCP plan. This draft guidance provides recommendations that producers and users of juice concentrates and certain shelf stable juice products can use to prevent, reduce to acceptable levels, or eliminate the risk of contamination or recontamination of these products with microbial pathogens during bulk transport and thus satisfy the conditions under which FDA will consider the exercise of enforcement discretion.

The draft guidance entitled ''Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable

Juices'' is being issued as a level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance represents the agency's current thinking on this subject. 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 statutes and regulations.

II. 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 may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25342 Filed 10–4–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0384]

Draft Guidance for Industry: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing; 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: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing'' (the draft guidance). The draft guidance advises juice processors of FDA's view that the first edition of the ''Juice HACCP Training Curriculum'' of the Juice HACCP Alliance (the standardized curriculum) is adequate for use in training individuals to meet the requirements of the juice hazard analysis and critical control point (HACCP) regulation. The draft guidance also advises processors and educators on how the requirements of the juice HACCP regulation may be met using the standardized curriculum or alternative curricula for training individuals and on how they can view, download, or purchase the standardized curriculum.

DATES: Submit written or electronic comments concerning this draft guidance by December 6, 2002, to ensure adequate consideration in preparation of the final guidance document. Comments on this draft guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Michael E. Kashtock, (see **FOR FURTHER INFORMATION CONTACT**). Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments on 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.

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's juice HACCP regulation in part 120 (21 CFR part 120) includes in §120.13 a requirement that individuals who perform certain specified functions, e.g., developing the hazard analysis or the HACCP plan, ''shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions.'' This draft guidance advises juice processors of FDA's view that the first edition of the ''Juice HACCP Training Curriculum'' of the Juice HACCP Alliance (coordinated through the efforts of the National Center for Food Safety and Technology at the Illinois Institute of Technology) (the standardized curriculum) is adequate for use in training individuals to meet the requirements of the juice HACCP regulation. This guidance also advises processors and educators on how the requirements of the juice HACCP regulation may be met using the standardized curriculum or alternative curricula for training individuals and on how they can view, download, or purchase the standardized curriculum.

The draft guidance entitled ''Guidance for Industry: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing,'' is being issued as a level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance represents the agency's current thinking on curricula for training juice processing personnel in the application of HACCP principles to juice processing. 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.

II. 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 the brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at the CFSAN Web site at http://www.cfsan.fda.gov/~dms/guidance.html.

Dated: September 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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