Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–396A	54	4	8	1,728
OCSE–34A	54	4	8	1,728

Estimated Total Annual Burden Hours: 3,456.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: October 1, 2002.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 02–25425 Filed 10–4–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Los Angeles District Office; Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing a meeting which is intended to give the drugs, devices, and biologics industries and consumers an opportunity to exchange information with the FDA Los Angeles District staff. The main focus of the meeting is to provide an opportunity for the Los Angeles District leadership to interact with industry and the public, and to discuss regulatory affairs, plans, and future programs. The open house is sponsored by the Orange County Regulatory Affairs Discussion Group (OCRA).

Date and Time: The open house will be held on Tuesday, October 22, 2002, from 6 p.m. to 9 p.m.

Location: The open house will be held at FDA Los Angeles District, 19900 MacArthur Boulevard, suite 300, Irvine, CA 92612.

Contact: Ramlah Oma, Food and Drug Administration, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949–798–7611, FAX: 949–798–7656, or Jack Dhuwalia, OCRA, PMB 624, 5405 Alton Pkwy, suite 5A, Irvine, CA 92604, 888–532–4357, FAX: 949–854–2672, Internet: www.ocra-dg.org.

Registration and open house Information: For registration information, including registration form and electronic payment, see the OCRA Internet site at www.ocra-dg.org (click on '' OCRA meetings'').

Registrations fees are $40.00 for members of OCRA, Southern California Pharmaceutical Discussion Group (SCPDG), and Parenteral Drug Association (PDA), and $45.00 for nonmembers. The cost includes hot and cold hors d'oeuvres, dessert and nonalcoholic beverages, but excludes parking fees.

If you need special accommodations due to a disability, please contact Ramlah Oma (see *Contact*) at least 7 days in advance.

Dated: October 1, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25392 Filed 10–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0385]

Guidance on the Petition Process to Request Approval of Labeling for Foods That Have Been Treated By Irradiation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance; Implementation of Section 10809 of the Farm Security and Rural Investment Act of 2002, Pub. L. No. 107–171, § 10809 (2002) Regarding the Petition Process to Request Approval of Labeling for Foods That Have Been Treated By Irradiation,'' which explains the recommended process for petitioning the agency for approval of labeling, which is not false or misleading in any material respect, of a food that has been treated by irradiation.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments 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.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document implementing the part of section 10809 of the Farm Security and Rural Investment Act of 2002 (Public Law 107–171, § 10809 (2002)), that states that ''[p]ending promulgation of the final rule * * *, any person may petition the Secretary [FDA] for approval of labeling, which is not false or misleading in any material respect, of a food which has been treated by irradiation using radioactive isotope, electronic beam, or x-ray.'' Section 10809 of the Farm Security and Rural Investment Act of 2002 also requires that, pending promulgation of the final rule, ''[t]he Secretary [FDA] shall approve or deny such a petition within 180 days of receipt of the petition, or the petition shall be deemed denied, except to the extent additional agency review is mutually agreed upon by the Secretary [FDA] and the petitioner.''

FDA is issuing this guidance to interested parties who wish to petition the agency for approval of the labeling of a food treated by irradiation. As explained in the guidance, FDA recommends that interested parties who wish to petition the agency use the procedures set forth in § 10.30 (21 CFR 10.30), except that § 10.30(e)(2)(iii), regarding 180-day tentative responses,

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