

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.

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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.

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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,