

Dated: May 4, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-7159 Filed 5-10-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0038]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Irradiation in the Production, Processing, and Handling of Food

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 12, 2006.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Irradiation in the Production, Processing, and Handling of Food—(OMB Control Number 0910-0186)—Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum energy of radiation emitted by x-ray tube sources. Section 179.21(b)(2)(i) requires that the label or accompanying labeling bear adequate directions for installation and use. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.) The records required by § 179.25(e) are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and

are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

In the **Federal Register** of February 6, 2006 (71 FR 6075), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one letter in response which contained several comments and suggestions. These suggestions and FDA's responses follow.

The comment expresses concern that records maintained under the regulation must only be retained for a maximum of 3 years. The comment asserts that irradiation of food is a new process, the long-term effects of which are unknown. The comment recommends that the required records be retained for 7 years.

FDA disagrees. The records required by § 179.25(e) must be retained for a period of time that exceeds the shelf life of the irradiated food product by 1 year, up to a maximum of 3 years, whichever period is shorter. There is no need to retain the information longer than 1 year after the end of the shelf life of the irradiated food because by that time the food has either been consumed or discarded. Thus, it is unnecessary for FDA to require firms to retain the records for a longer period of time.

The comment also suggested that FDA permit comments to the docket to be filed by e-mail and suggested that food treated under part 179 of the regulations should be labeled with the word, "Irradiated."

FDA agrees that irradiated food should be labeled and notes that labeling requirements for irradiated foods are found at § 179.26(c). These comments are outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed further.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
179.25(e)	6	120	720	1	720

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 4, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Children's Study Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Children's Study Advisory Committee.

*Date:* May 31–June 1, 2006.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* For questions or to register, please call Circle Solutions (703) 902-1339 or visit <http://www.circlesolutions.com/ncs/ncsac>. Registration deadline is 5/23/06. Agenda will include an update of the Study status and protocol; gene-environment interaction, social-behavioral determinants, and environmental exposure assessment; recruitment and retention; and human subjects activities.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

*Contact Person:* Marion Balsam, MD, Executive Secretary, National Children's Study Advisory Committee, 6100 Executive Boulevard, Bethesda, MD 20892, 301-594-9147.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 2, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel, Member Conflict Meeting.

*Date:* May 1, 2006.

*Time:* 2:30 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Mark R. Green, PhD, Deputy Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401, (301) 435-1431, [mgreen1@nida.nih.gov](mailto:mgreen1@nida.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute on Drug Abuse Initial Review Group, Health Services Research Subcommittee.

*Date:* June 6-7, 2006.

*Time:* 8:30 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Madison Hotel, 15th & M Streets, NW., Washington, DC 20005.

*Contact Person:* Meenaxi Hiremath, PhD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6101 Executive Blvd., Suite 220, MSC 8401, Bethesda, MD 20892, 301-402-7964, [mh392g@nih.gov](mailto:mh392g@nih.gov).

*Name of Committee:* National Institute on Drug Abuse Initial Review Group, Medication Development Research Subcommittee.

*Date:* June 6, 2006.

*Time:* 8:30 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Housing Center, 1201 15th Street, NW., Washington, DC 20005.

*Contact Person:* Paul A. Coulis, PhD, Health Scientist Administrator, Office of

Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6101 Executive Boulevard, Suite 220, Bethesda, MD 20892-8401, 301-443-2105.

*Name of Committee:* National Institute on Drug Abuse Initial Review Group, Treatment Research Subcommittee.

*Date:* June 6-7, 2006.

*Time:* 9 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Madison, 1177 15th & M Streets, NW., Washington, DC 20005.

*Contact Person:* Kesinee Nimit, MD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401, (301)435-1432.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel, Member Conflict.

*Date:* June 6, 2006.

*Time:* 2 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Housing Center, 1201 15th Street, NW., Washington, DC 20005.

*Contact Person:* Gerald L. McLaughlin, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Blvd., Bethesda, MD 20892-8401, 301-402-6626, [gm145a@nih.gov](mailto:gm145a@nih.gov).

*Name of Committee:* National Institute on Drug Abuse Initial Review Group, Training and Career Development Subcommittee.

*Date:* July 18-20, 2006.

*Time:* 9 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Eliane Lazar-Wesley, PhD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Room 220, MSC 8401, Bethesda, MD 20892-8401, 301-451-4530, [el6r@nih.gov](mailto:el6r@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse national Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, national Institutes of Health, HHS)

Dated: May 2, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

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