

validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, 107.280 (OMB Control Number 0910-0188)—Extension**

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments,

consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations (part 107 (21 CFR part 107), subpart E) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office

within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	2	1	2	4,500	9,000
107.240	2	1	2	1,482	2,964
107.250	2	1	2	120	240
107.260	1	1	1	650	650
Total					12,854

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

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting burden estimate is based on agency records, which show that there are five manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years.

Dated: January 25, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-1815 Filed 1-31-05; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Notice of Meeting**

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 meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, 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.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), 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 Cancer Advisory Board Subcommittee on Planning and Budget.

*Open:* February 15, 2005, 7 p.m. to 9 p.m.

*Agenda:* To discuss activities related to the Subcommittee on Planning and Budget.

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

*Contact Person:* Ms. Cherie Nichols, Executive Secretary, National Cancer Institutes, National Institutes of Health, 6116 Executive Boulevard, 2nd Floor, Room 205, Bethesda, MD 20892-2590, (301) 496-6515.

*Name of Committee:* National Cancer Advisory Board.

*Open:* February 16, 2005, 8:30 a.m. to 6 p.m.

*Agenda:* Program reports and presentations; Business of the Board.

*Place:* National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institute of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

*Name of Committee:* National Cancer Advisory Board.

*Open:* February 17, 2005, 8:30 a.m. to 10:30 a.m.

*Agenda:* Program reports and presentations; Business of the Board.

*Contact Person:* Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

*Name of Committee:* National Cancer Advisory Board.

*Closed:* February 17, 2005, 10:30 a.m. to 12 p.m.

*Agenda:* Review of grant applications.

*Contact Person:* Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

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.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.gov/advisory/ncab.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 25, 2005.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05-1837 Filed 1-31-05; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

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 meeting.

The meeting 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 Cancer Institute Initial Review Group, Subcommittee G—Education.

*Date:* March 15–16, 2005.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Select, 480 King Street, Alexandria, VA 22314.

*Contact Person:* Ilda M. McKenna, Scientific Review Administrator, Research Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8111, Bethesda, MD 20892, 301-496-7481, [mckennai@mail.nih.gov](mailto:mckennai@mail.nih.gov).

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. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 25, 2005.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center on Minority Health and Health Disparities

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 meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with accordance 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.

The meeting 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 Advisory Council on Minority Health and Health Disparities.

*Date:* February 23, 2005.

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

*Agenda:* The Agenda will include Opening Remarks, Administrative Matters, Director's Report, NCMHD, Advisory Council Subcommittee Reports, NIH IC Health Disparities Update, Program Highlights: Select NCMHD Grantees, and other business of the Council.

*Place:* Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Closed:* 4 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.