guidance describes the nonclinical data that should be generated to support the safety of an inactive ingredient in the amounts administered if adequate, relevant prior human use cannot be documented.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on nonclinical studies for development of pharmaceutical excipients. 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 written comments on the guidance to the Dockets Management Branch (address above). 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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 http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: September 23, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–24985 Filed 10–1–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Submission for OMB review; comment request; The Sister Study: Environmental and Genetic Risk Factors for Breast Cancer

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 20, 2001, page 33103–4 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

Proposed Collection

Title: The Sister Study: Environmental and Genetic Risk Factors for Breast Cancer. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* We will study environmental and genetic risk factors for the development of breast cancer in a cohort of sisters of women who have had breast cancer. In the United States, approximately 192,000 new cases were diagnosed in 2001, accounting for 30% of all new cancer cases among women. The etiology of breast cancer in complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. Sisters of women with breast cancer have nearly twice the risk of developing breast cancer themselves. By focusing on a susceptible population, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible.The increased risk of cancer, and the expected higher prevalence of both relevant genes and exposures (both shared with their sister who had breast cancer) will facilitate the study of gene-environment interactions. Once assembled, the cohort will be useful for studying other diseases in women. We will enroll a cohort of 50,000 women who have not had breast cancer over a 4-year period, with 37,500 enrolled during the first 3 years of the study. These breast cancer-free sisters will be followed annually for the development of breast cancer and other diseases. We expect 300 cases of breast cancer per year (on average) to develop in a cohort of 50,000 women. In addition, we will enroll and follow 1,500 of the index sisters (1125 during the first 3 years) whose breast cancer diagnosis was within four months prior to enrollment. These ''index'' cases will allow comparison of case-control pairs of sisters and prospective study of the impact of environmental exposures and genes on prognosis.

Frequency of Response: On occasion. For those who qualify and enroll: one initial 15-minute screening contact [telephone or internet, one 2-hour telephone interview, one mailed self-administered questionnaire (1.5 hours), biological and environmental specimen collection (1 hours), and annual follow-up questionnaires (0.5 hours). for those who don't enroll: one 15-minute screening contact (internet or phone). For women with breast cancer or who develop breast cancer during follow-up: validation of diagnosis through doctor's office. *Affected Pubic:* Individuals or households, doctor's office. *Types of Respondents:* Unaffected sisters of women diagnosed with breast cancer, aged 35–74, from all socioeconomic backgrounds and ethnicities and women with recently diagnosed breast cancer. The annual reporting burden in as follows: *Estimated Number of Respondents:* 151,800–50,000 study respondents per year, of whom 12,875 will qualify and enroll—including 12,500 unaffected women plus 500 index cases of incident breast cancer. (**Note:** Total cohort enrollment of 50,000 cancer-free sisters and 1,500 index cases of incident breast cancer will take 4 years to achieve, requiring an estimated 2000, 000 respondents in all.) In addition, there will be a total of 1,575 doctor office respondents to validate diagnoses. The first year cost per women who enrolls in the study is estimated to be $95 (based on 4.75 hours of $20 hourly wage). Cost equivalent per follow-up year for enrolled women is $10. Total cost to women who don't enroll is $5. Cost to doctor's offices is $10 (assuming $40 per hour). *Estimated Number of Responses per Respondent See* table below. *Average Burden Hours Per Response: See* table below. *Estimated Total Burden Hours Requested:* 231,240 over 3 years (see table). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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Type of Respondents	Estimated number of respondents – years 1-3	Estimated number of responses per respondent	Average burden hours per response	Estimated total burden hours requested
Women screened but ineligible or not willing to enroll (a)	111,375	1	0.25	27,843.75
Cancer-free sisters enrolled year 1 (b)	12,500	5	1.15	71,875.00
Cancer-free sisters enrolled year 2 (c)	12,500	4	1.3125	65,625.00
Cancer-free sisters enrolled year 3 (d)	12,500	3	1.58	59,375.00
Index breast cancer case enrolled year 1 (b)	375	5	1.15	2,156.25
Index breast cancer case enrolled year 2 (c)	375	4	1.3125	1,968.75
Index breast cancer case enrolled year 3 (d)	375	3	1.58	1,777.50
Women developing breast cancer during follow-up	225	1	1.00	225.00
Doctor's offices (validate index cases)	1,125	1	0.25	281.25
Doctor's offices (validate new cases and other diagnoses)	450	1	0.25	112.50
Total	151,800	------	------	231,240.00

(a) 150,000 contacts less 38,625 expected qualify and to enroll

(b) screener (0.25-hr), CATI (2-hr), self-administered (1.5-hr), specimen collection (1-hr), follow-up (2 @ 0.5-hr) = 5.75 hours total

(c) screener (0.25-hr), CATI (2-hr), self-administered (1.5-hr), specimen collection (1-hr), follow-up (@ 0.5-hr) = 5.25 hours total

(d) screener (0.25-hr), CATI (2-hr), self-administered (1.5-hr), specimen collection (1-hr),= 4.75 hours total

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Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the items(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Dale Sandler, Acting Chief, Epidemiology Branch, NIEHS, Building 101, A–304, P.O. Box 122233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541–4668 or E-mail your request, including your address to: *sandler@niehs.nih.gov.*

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: September 3, 2002.

Francine Little,

NIEHS, Associate Director for Management.

[FR Doc. 02–24965 Filed 10–1–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Director's Consumer Liaison Group.

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 Cancer Institute Director's Consumer Liaison Group.

Date: October 22, 2002.

Time: 2 p.m. to 4 p.m.

Agenda: To debrief on September 12, 2002 meeting with Dr. von Eschenbach and to get updates from the working group.

Place: 6116 Executive Blvd., Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Elaine Lee, Executive Secretary, Office of Liaison Activities, National Institutes of Health, National Cancer Institute, 6116 Executive Boulevard, Suite 300 C, Bethesda, MD 20892, 301/594–3194.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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/dclg/dclg.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: September 24, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–24970 Filed 10–1–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; 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 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 of Dental and Craniofacial Research Special Emphasis Panel, 03–18, Review of R44 Grants.

Date: October 8, 2002.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: 45 Center Drive, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Philip Washko, PhD, DMD, Scientific Review Administrator, 45 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892. (301) 594–2372.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 03–15, Review of R44 Grants.

Date: October 17, 2002.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: 45 Center Drive, Natcher Building, Room 3AN12, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Philip Washko, PhD, DMD, Scientific Review Administrator, 45 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892. (301) 594–2372.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 03–03, Review of RFA DE–03–001.

Date: November 10–11, 2002.

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

Agenda: To review and evaluate grant applications.

Place: Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Yujing Liu, MD, PhD, Scientific Review Administrator, National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Building, Rm. 4AN44F, Bethesda, MD 20892. (301) 594–2372.