21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, e-mail: *Cathy.Groupe@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 25, 2006, the committee will meet between 8 a.m. to 5 p.m., to discuss new drug application (NDA) 21–359 CELLEGESIC (nitroglycerin [NTG] ointment), 0.4% intra-anal, Cellegy Pharmaceuticals, Inc., for the proposed indication of relief of pain associated with anal fissures. On April 26, 2006, the committee will meet between 8 a.m. to 12 noon, to discuss the agency's draft recommendations for relabeling of antihypertensive drugs for outcome claims, as a followup to the committee's meeting on June 15, 2005, where the committee discussed class labeling of antihypertensive drugs based on the proximity of their data to outcome trials. Following this, from approximately 1 p.m. to 5 p.m., the committee will discuss the ''Placebo in Hypertension Adverse Reaction Meta-Analysis'' Study, a meta-analysis of more than 80,000 patients in placebo-controlled trials of antihypertensive medications, which evaluated the risk of irreversible harm in conducting placebo-controlled trials in patients with hypertension. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/orhms/dockets/ac/acmenu.htm* under the heading ''Cardiovascular and Renal Drugs Advisory Committee.'' (Click on the year 2006 and scroll down to the above named committee).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 14, 2006. On April 25, 2006, oral presentations from the public will be scheduled between approximately 8:15 a.m. to 8:45 a.m. On April 26, 2006, oral presentations from the public will be scheduled between approximately 8:15 a.m. to 8:45 a.m. and 1 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 14, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact John Lauttman at least 7 days in advance of the meeting at 301–827–7001.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 15, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–2542 Filed 2–22–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. This meeting was announced in the **Federal Register** of January 27, 2006 (71 FR 4593). The amendment is being made to reflect a change in *Date and Time* and *Procedure* portions of the document. An additional day is being added to this meeting and the length of time allotted for the open public hearing portion is being extended. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Sohail Mosaddegh, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *sohail.mosaddegh@fda.hhs.gov*, or the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 27, 2006, FDA announced that a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee would be held on March 7, 2006, from 8 a.m. to 5 p.m., and the open public hearing portion scheduled between approximately 1 p.m. and 2 p.m. On page 4593, in the third column, the *Date and Time* portion of the document is amended to read as follows:

Date and Time: The meeting will be held on March 7 and 8, 2006, from 8 a.m. to 5 p.m.

On page 4594, in the first column, in the *Procedure* portion of the document, the third sentence is amended to read as follows:

Procedure: Oral presentations from the public will be scheduled between approximately 1 p.m. and 5 p.m. on March 7, 2006.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: February 15, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–2541 Filed 2–22–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Proposed Collection; Comment Request; The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer. *Type of Information Collection Request:* Revision of OMB No. 0925–0522 and expiration date 31 July 2006. *Need and Use of Information Collection:* The purpose of the Sister Study is to study genetic and environmental risk factors for the

development of breast cancer in a cohort of sisters of women who have had breast cancer. In the United States, there were approximately 210,000 new cases in 2003, accounting for 30% of all new cancer cases among women. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. Sisters of women with breast cancer are one group at increased risk for breast cancer; we would expect about 2 times as many breast cancers to accrue in a cohort of sisters as would accrue in a cohort identified through random sampling or other means. In addition, a cohort of sisters will be enriched with regard to the prevalence of relevant genes and/or exposures, further enhancing the ability to detect gene-environment interactions. Sisters of women with breast cancer will also be at increased risk for ovarian cancer and possibly for other hormonally-mediated diseases. We are enrolling a cohort of 50,000 women who have not had breast cancer. Initial recruitment of the first 2,000 women took place from August 2003–September 2004 before beginning nationwide recruitment in October 2004. The data collected in the initial phase allowed us to evaluate subject recruitment and data collection procedures, and helped us better target our recruitment efforts. We estimate that a cohort of 50,000 sisters aged 35–74 years would provide about 1,500 breast cancer cases over five years (approximately 300 new cases per year once the cohort is fully enrolled). *Frequency of Response:* At enrollment, one initial 15-minute screening (either on the telephone OR on the internet), 2 one-hour telephone interviews, 3 mailed self-administered questionnaires (90 minutes total), and some biological and household specimens collected. Women are advised that they will be contacted every year to update contact information and health status and asked to complete shorter (45–60 minutes, total) follow-up interviews or questionnaires every two years. Women diagnosed with breast cancer or other health outcomes of interest will be asked to provide additional information about their diagnosis (20 minutes per response) and their doctors will be contacted to provide documentation regarding diagnosis and treatments (15 minutes per response). *Affected Public:* Individuals or households; doctors' offices. *Type of Respondents:* Unaffected sisters of women diagnosed with breast cancer, aged 35–74, from all socioeconomic backgrounds and ethnicities. The annual reporting burden is as follows: *Estimated Number of Respondents:* 67,500 (~12,500 enrolled per year over ~4 years, plus ~14,000 persons ultimately determined ineligibles or refusals at initial screening, and 3,500 persons who partially complete enrollment before terminating). *Estimated Number of Responses per Respondent:* See table below. *Average Burden Hours per Response:* 6.0; and *Estimated Total Burden Hours Requested:* 176,553 (over 3 years). The average annual burden hours requested is 58,851. The annualized cost to respondents is estimated at $135 (assuming $20 hourly wage × 6 hours + $15 babysitting estimate). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Activity (3-yrs)	Estimated number of respondents	Estimated responses per respondent	Average burden hours per response	Estimated total burden hours requested
Eligibility Screening	22,750	1	0.25	5,688
Enrollment Interviews	22,750	1	2	45,500
Enrollment SAQs	22,750	1	1.5	34,125
Enrollment Specimen Collection *	22,750	1	1	22,750
1st Annual Update	50,000	1	0.17	8,500
1st Bienniel Follow-Up Questionnaire	50,000	1	1	50,000
2nd Annual Update	25,001	1	0.17	4,250
Ineligible **	14,000	1	0.25	3,500
Dropout **	3,500	1	2.25	7,875
Incident BC Case Follow-Up	1,800	1	0.33	594
Incident Other Case Follow-Up	300	1	0.33	99
Incident Case/Physician Contact	2,100	1	0.25	525
Total	.....	.....	.....	183,406

* Includes waiting time, and scheduling appointment for blood draw.
** Expect 17% ineligible at screening plus 7% dropout during enrollment activities.

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.

FOR FURTHER INFORMATION CONTACT: To request more information on the project or to obtain a copy of the data collection plans and instruments, contact: Dr. Dale P. Sandler, Chief, Epidemiology Branch, NIEHS, Rall Building A3–05, PO Box 12233, 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 60 days of the date of this publication.

Dated: February 13, 2006.

Richard Freed,

NIEHS, Associate Director for Management.

[FR Doc. 06–1690 Filed 2–22–06; 8:45 am]

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