regulatory requirement. However, any final guidance document issued according to § 10.115(i) must contain the elements in § 10.115(i)(2). In this draft revised guidance, any language that is mandatory under U.S. laws and/or regulations is followed by a citation to the appropriate statutory or regulatory provision. In accordance with § 10.115(i)(3), any mandatory language in this draft revised guidance that does not describe a statutory or regulatory requirement will be revised in the final guidance document to comply with § 10.115(i)(2).

The draft revised VICH guidance represents the agency's current thinking on the management of AERs of approved new animal drugs. This draft revised guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

V. Comments

This draft revised guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft revised guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft revised guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Electronic comments may also be submitted electronically on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select Docket No. 2000D–1632, entitled ''Draft Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' VICH GL24 and follow the directions.

Copies of the draft revised guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)'' VICH GL24 may be obtained on the Internet from the Center for Veterinary Medicine home page at *http://www.fda.gov/cvm*.

Dated: April 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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: A Prospective Study of the Genetic and Environmental 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 February 23, 2006 on pages 9358–9359 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 control number.

5 CFR 1320.5: Reporting and Recordkeeping Requirements: Final Rule: Respondents to this collection of information are not required to respond unless the data collection instruments display a currently valid OMB control number.

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 July 31, 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 2000 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 1500 breast cancer cases over five years (approximately 300 new cases per year once the cohort is fully enrolled).

Frequency of Response: Burden calculations include eligibility screening for 22,750 more women, and completion of enrollment activities for 25,000 more women (difference due to expected 2,250 women, and completion of enrollment activities for 25,000 more women (difference due to expected 2,250 women whose time lag between initial screening and fully completing enrollment baseline activities is expected to cross OMB expiration/revision date) to reach 50,000. These women will complete one initial 15-minute screening (either on the telephone OR on the Internet), two 1-hour telephone interviews, 4 mailed self-administered questionnaires (90 minutes total), and will collect biological and household specimens. Also in the next 3 years, all 50,000 sisters will complete one annual update (10 minutes) and one biennial follow-up questionnaire (60 minutes); in addition 25,000 will complete a second annual update. Women diagnosed with breast cancer or other health outcomes of interest (~1800 allowing for 300 bc/year over our first 6 years, plus 1800 other outcomes) 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). In addition to direct Sister Study participants, up to 300 women will be recruited to provide an anonymous blood sample for Sister Study laboratory quality control activities. A total of up to 200 women (70 during the first year) will be recruited to provide a one-time blood and urine sample and complete a past 24-hour questionnaire. These samples will be used to test long-term storage effects and to provide quality control pools for future assays. Up to 100 women will be sampled on four occasions over the course of a year (20 in the first year), providing blood, urine, and dust samples. On each occasion an abbreviated version of the previously approved past 24-hour questionnaire will be completed. Thus up to 300 women will complete a 5-minute telephone screener to determine eligibility. The 200 women (maximum) who provide a one-time sample will complete a short form describing activities and medication use in the 24 hours prior to blood draw (10 minutes). The 100 women (maximum) will complete the 24-hour form with each of 4 blood draws.

Estimated Number of Respondents: The estimated total number of respondents is 67,800, which includes ~12,500 enrolled per year over ~4 years, plus ~14,000 persons ultimately determined ineligible or refusals at initial screening, 3,500 persons who partially complete enrollment before terminating, and up to 300 women for anonymous quality sample collection.

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 Responses per Respondent: The table below shows the estimated number of responses per respondent per activity over the next 3 years.

Average Burden Hours per Response: 6.0;

Estimated Total Burden Hours Requested: 194,131 (over 3 years). The average annual burden hours requested is 64,710.

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	25,000	1	2	50,000
Enrollment SAQs	25,000	1	1.5	37,500
Enrollment Specimen Collection*	25,000	1	1	25,000
1st Annual Update	50,000	1	0.17	8,500
1st Biennial 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	1800	1	0.33	594
Incident Other Case Follow-Up	300	1	0.33	99
Incident Case/Physician Contact	2100	1	0.25	525
QC Sample Collection A†	200	1	0.15	200
QC Sample Collection B†	100	4	0.15	400
Total	.....	.....	.....	194,131

*includes waiting time, and scheduling appointment for blood draw.
**expect 17% ineligible at screening plus 7% dropout during enrollment activities.
† includes travel time, 10 minutes for Past-24 hour Qx, and blood draw.

Request for Comments Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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 item(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: (Insert IC applicable information. Include automated, electronic, mechanical, or other technological collection techniques, if applicable.)

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: April 20, 2006.

Laurie K. Johnson, NIEHS,

Acting Associate Director for Management

[FR Doc. 06–4087 Filed 5–1–05; 8:45 am]

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