original VICH documents have been substituted with ''should.'' Similarly, words such as ''requirement'' or ''acceptable'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context.

This draft guidance represents the agency's current thinking on reproduction safety studies for veterinary drug residues in human food. This draft guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public.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. Comments about the draft guidance documents will be considered by FDA and the VICH Safety Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidances and publish them as future guidances.

### IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Submit written comments to ensure adequate consideration in preparation of the final guidance by February 20, 2001. 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. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 7, 2000.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 00–32197 Filed 12–18–00; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health/National Institute of Environmental Health Sciences

### Submission for OMB Review; Comment Request; Environmental Factors in the Development of Polycystic Ovary Syndrome

**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 September 1, 2000, page 53326 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, 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.

**Proposed Collection**

*Title:* Environmental Factors in the Development of Polycystic Ovary Syndrome. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* We will administer a brief telephone survey to 2032 twin women from the Mid-Atlantic Twin Registry (MATR) who previously reported having irregular periods and/or cystic ovaries on a MATR General Health History Survey. Question in the proposed survey focus on the two hallmark features of Polycystic Ovary Syndrome (PCOS), hyperandrogenism and anovulation, other relevant physical characteristics, and if the woman has a living female twin sister. Women will also be asked for permission to recontact them for potential participation in future PCOS studies. The data will be used in statistical modeling analyses to identify those women with a high probability of having PCOS and estimate the number of potential candidates for future PCOS studies. *Frequency of Response:* One time. *Affected Public:* Individuals; *Type of Respondents:* Adult women. The annual reporting burden is as follows: *Estimated Number of Respondents:* 2,100; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 0.167; and *Estimated Total Annual Burden Hours Requested:* 350.7. The annualized cost to respondents is estimated at: $3,507.00. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

**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 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 comment 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 Dr. Patricia C. Chulada, Clinical Research Scientist, Clinical Research Office, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541–7736 or E-mail your request, including your address to: *chulada@niehs.nih.gov.*

**DATES:** *Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received on or before January 18, 2001.

Dated: December 7, 2000.

**Francine Little,**

*Associate Director for Management, NIEHS.*

[FR Doc. 00–32221 Filed 12–18–00; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request; The Family Health Study (Validation of a Family History of Cancer Questionnaire for Risk Factor Surveillance)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal**

**Register** on June 7, 2000, page 36149–36159 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.

**Proposed Collection**

*Title:* The Family Health Study (Validation of a Family History of Cancer Questionnaire for Risk Factor Surveillance).

*Type of Information Collection Request:* NEW.

*Need and Use of Information Collection:* In this methodologic pilot study, the NCI will develop a family history of cancer questionnaire for use in cancer risk factor surveillance, and will evaluate how accurately individuals in the general population can report major cancers occurring in their immediate and extended family. This study is needed because there are currently no validated questionnaires with which to collect comprehensive data for assessing the burden of family history of cancer in the U.S. population, and no general population estimates of reporting error for the major cancers that affect families. The results on reporting accuracy will be used to determine whether the quality of data is sufficient to justify conducting a comprehensive national prevalence study of family history of cancer. The questionnaire will be administered in a telephone survey of adults, age 25 to 64 years who will be randomly selected from households in Connecticut. Respondents will be asked to report about family structure and cancer diagnoses occurring in their first and second degree relatives. Positive and negative reports of five major cancer sites (*i.e* breast, prostate, colorectal, lung, and ovarian cancers) will be validated for approximately three relatives per respondent through data linkage to state and federal health registries or by review of death certificates and medical records. Living relatives and next-of-kin of deceased relatives may be interviewed as part of the validation process. Information about the accuracy of reports and factors associated with reporting error will help to evaluate the feasibility of conducting surveys on family history of cancer.

*Frequency of Response:* One-time study.

*Affected Public:* Individuals or households.

*Type of Respondent:* Adults, age 25 to 64, who reside in the state of Connecticut and their selected adult relatives over age 25 or the relative's next-of-kin. The annual reporting burden is presented in the table below. The annualized cost to respondents is estimated at $18,671. There are no capital costs to report. There are no Operating or Maintenance Costs to report.

| Type of respondents | Estimated No. of respondents | Estimated No. of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested |
|---|---|---|---|---|
| Respondents, age 25 to 64 | 1800 | 1 | 0.6179 | 1112 |
| Adult relatives of respondents or their next-of-kin | 5190 | 0.67 | 0.2171 | 755 |
| Total | | | | 1867 |

**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. Louise Wideroff, Project Officer, Applied Research Program, National Cancer Institutes, 6130 Executive Blvd, EPN 4010, Bethesda, MD 20892, or call non-toll-free number (301) 435–6823 or E-mail your request, including your address to *wideroff@nih.gov.*

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received before January 18, 2001.

Dated: December 7, 2000.

**Reesa Nichols,**

*NCI Project Clearance Liaison.*

[FR Doc. 00–32234 Filed 12–18–00; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Eye 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 a meeting of the National Advisory Eye Council.

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.

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