Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 240–276–3151. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Steven Turtil, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3747;

Chiu Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700; or

Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 301–827–0373.

**SUPPLEMENTARY INFORMATION:**

## I. Background

This draft guidance document updates and clarifies the procedures for reviewing premarket notification submissions (510(k)s) for devices labeled as sterile, particularly with respect to sterilization technologies FDA considers novel. The draft guidance provides details about the pyrogenicity information we recommend be included in 510(k)s for devices labeled as sterile. When final, this draft will supersede the guidance entitled ''Updated 510(k) Sterility Review Guidance K90–1'' that FDA issued on August 30, 2002 (available at *http://www.fda.gov/cdrh/ode/guidance/361.pdf*).

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on premarket notification submissions for devices labeled as sterile. 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 statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1615 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the CBER Internet site at *http://www.fda.gov/cber/guidelines.htm* or the Division of Dockets Management Internet site at *http://www.regulations.gov*.

## IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 3, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–29413 Filed 12–11–08; 8:45 am]

**BILLING CODE 4160–01–S**

---

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; Comment Request; The Hispanic Community Health Study (HCHS)/ Study of Latinos (SOL)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 3, 2008, page 57634, and allowed 60 days for public comment. One comment was 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:* Hispanic Community Health Study (HCHS)/Study of Latinos (SOL). *Type of Information Collection Request:* New Collection. *Need and Use of Information Collection:* The Hispanic Community Health Study (HCHS)/ Study of Latinos (SOL) will identify risk factors for cardiovascular and lung disease in Hispanic populations and determine the role of acculturation in the prevalence and development of these diseases. Hispanics, now the largest minority population in the US, are influenced by factors associated with immigration from different cultural settings and environments, including changes in diet, activity, community support, working conditions, and health care access. This project is a multicenter, six-and-a-half year epidemiologic study and will recruit 16,000 Hispanic men and women aged 18–74 in four community-based cohorts in Chicago, Miami, San Diego, and the Bronx. The study will examine measures of obesity, physical activity, nutritional habits, diabetes, lung and sleep function, cognitive function, hearing, and dental conditions. Closely integrated with the research component will be a community and professional education component, with the goals of bringing the research results back to the community, improving recognition and control of risk factors, and attracting and training Hispanic researchers in epidemiology and population-based research. *Frequency of Response:* The participants will be contacted annually. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Individuals or households; physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 30,401; *Estimated Number of Responses per Respondent:* 2.234; *Average Burden Hours Per Response: 0.7178*; and *Estimated Total Annual Burden Hours Requested:* 48,755. The annualized cost to respondents is estimated at $756,412, assuming respondents time at the rate of $15 per hour and physician time at the rate of $55 per hour. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

ESTIMATE OF ANNUAL HOUR BURDEN

| Type of response | Number of respondents | Frequency of responses | Average hours per response | Annual hour burden |
|---|---|---|---|---|
| Participant Recruitment Contact | 29,036 | 1 | 0.123 | 3,571 |
| Participant Examinations and Questionnaires | 5,333[1] | 1 | 6.49 | 34,611 |
| Participant Telephone Interviews | 5,333[1] | 1 | 1.83 | 9,759 |
| Physician, Medical Examiner, next of kin or other contact follow-up[2] | 1,284 | 1 | .50 | 642 |
| Focus Groups | 81 | 1 | 1.5 | 121 |
| Total unique respondents | 30,401 | | | 48,755 |

[1] Subset of participant recruitment contact.
[2] Annual burden is placed on doctors and respondent relatives/informants through requests for information which will help in the compilation of the number and nature of new fatal and nonfatal events.

*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, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, 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: Ms. Lorraine Silsbee, Deputy Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892–7936, or call non-toll-free number 301–435–0709 or E-mail your request, including your address to: *silsbeeL@nhlbi.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: December 2, 2008.

**Michael S. Lauer,**

*Director, Division of Prevention and Population Sciences, NHLBI, National Institutes of Health.*

Dated: December 3, 2008.

**Suzanne Freeman,**

*Chief, FOIA, NHLBI, National Institutes of Health.*

[FR Doc. E8–29427 Filed 12–11–08; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center for Scientific Review; Notice of Closed Meetings

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:* Center for Scientific Review Special Emphasis Panel; F05 K 21 Fellowships.

*Date:* December 10–11, 2008.

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