

accept for processing, reviewing, and archiving. Recent recommendations from the Institute of Medicine and the National Committee on Vital and Health Statistics and mandates in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) have created a new role for electronic labeling information. Electronically formatted content of labeling will be used to support health information management initiatives such as electronic prescribing and the electronic health record (EHR).

Because FDA's current procedures using PDF are not adequate to support these initiatives, the agency is proposing to change the way it processes, reviews, and archives the content of labeling. We are proposing to adopt a new technology for exchanging information between computer systems developed by Health Level Seven (HL7), a standards development organization accredited by the American National Standards Institute. The new technology, Clinical Document Architecture (CDA), allows information to be exchanged in extensible markup language (XML) and is the standard being investigated for the EHR. FDA, working with other interested parties in HL7, has adapted CDA for labeling in a proposed HL7 standard called Structured Product Labeling (SPL).

FDA is developing an automated system using SPL for processing and managing labeling and labeling changes. When the draft guidance is finalized, absent significant objections, FDA is likely to identify SPL in public docket number 92S-0251 as a format that we can use to process, review, and archive the content of labeling. During our transition to the automated system, the agency would be able to accept the content of labeling in either PDF or SPL file format. After the automated system is implemented, PDF would no longer be a format that we can use to process, review, and archive the content of labeling. At this time, it is our goal to complete the transition to SPL format for content of labeling submissions by the end of 2004.

This draft guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on providing in electronic format the content of labeling required in 21 CFR parts 314 and 601. 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.

### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Paperwork Reduction Act of 1995

The information requested for human drug and biological products in this guidance is already covered by the collection of information in "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format" (Office of Management and Budget control number 0910-0530, expiring November 30, 2006).

### V. 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 at <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: January 25, 2004.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 04-2536 Filed 2-3-04; 9:39 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **National Heart, Lung, and Blood Institute Proposed Collection; Comment Request Exam 2—The Jackson Heart Study, Annual Follow-Up Component**

*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 of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 9, 2003, pages 53177-53178, 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 Jackson Heart Study: Annual Follow-up with Third Party Respondents. *Type of Information Collection Request:* Revision of a currently approved collection (OMB 0925-0491). *Need and Use of Information Collection:* This project involves follow-up by telephone of participants in the JHS study, review of their medical records, and interviews with doctors and family to identify disease occurrence. Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in African American men and women. The continuation of the study will allow continued assessment of subclinical coronary disease, left ventricular dysfunction, progression of carotid atherosclerosis and left ventricular hypertrophy, and responses to stress, racism, and discrimination as well as new components such as renal disease, body fat distribution and body composition, and metabolic consequences of obesity. *Frequency of Response:* One-time. *Affected Public:* Individuals or families; businesses or other for-profit; not-for-profit institutions. *Affected Public:* Third party respondents (next-of-kin decedents and physicians). *Type of Respondents:* Middle aged and elderly adults; doctors and staff of hospitals and nursing homes. *Estimated Number of Respondents:* 600; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 0.50; and *Estimated Total Annual Burden Hours Requested:* 300. The annualized cost to respondents is estimated at: \$6,500. 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 response	Average time per response	Annual hour burden
Morbidity & Mortality AFU 3rd party next-of-kin .....	300	1	0.5	150
Morbidity & Mortality AFU 3rd party Physicians .....	300	1	0.5	150
Total .....	600	.....	.....	300

*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: Ms. Cheryl Nelson, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892-7934, or call non-toll-free number (301) 435-0707 or E-mail your request, including your address to: [NelsonCH@nhlbi.nih.gov](mailto:NelsonCH@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: January 30, 2004.

**Peter Savage,**

*Director, DECA, NH.*

[FR Doc. 04-2388 Filed 2-4-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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 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 applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Initial Review Group, Subcommittee H—Clinical Groups.

*Date:* March 22, 2004.

*Time:* 7:30 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard Crystal City, 2899 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* Deborah R. Jaffe, PhD, Scientific Review Administrator, Resources and Training Review Branch, National Cancer Institute, Division of Extramural Activities, 6116 Executive Blvd., Rm 8135, Bethesda, MD 20892, (301) 496-7721, [jaffed@mail.nih.gov](mailto:jaffed@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the 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.

(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: January 28, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-2376 Filed 2-4-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary & Alternative Medicine; 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 meeting.

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 associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Complementary and Alternative Medicine Special Emphasis Panel; Loan Repayment.

*Date:* March 4-5, 2004.

*Time:* 7 p.m. to 5 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Carol Pontzer, PhD, Scientific Review Administrator, National Center for Complementary, and Alternative Medicine, 6707 Democracy Blvd., Bethesda, MD 20892.

*Name of Committee:* National Center for Complementary and Alternative Medicine Special Emphasis Panel; Training and Education.

*Date:* March 4-5, 2004.

*Time:* 7 p.m. to 5 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Carol Pontzer, PhD, Scientific Review Administrator, National Center for Complementary, and Alternative Medicine, 6707 Democracy Blvd., Bethesda, MD 20892.