

the system. At the second voice prompt, press 1 to order a document. Enter the document number (1512) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. 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 cleared submissions and 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 Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

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This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995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). The collection of information addressed in

the guidance document has been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit two paper copies of any mailed comments, 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 4, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–14768 Filed 6–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The Framingham Study

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 Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish period summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The Framingham Study. *Type of Information Request:* Revision (OMB No. 0925–0216). *Need and Use of Information Collection:* The Framingham Study will conduct examinations and morbidity and mortality follow-up in original, offspring, and third generation participants for the purpose of studying the determinants of cardiovascular disease. *Frequency of response:* The participants will be conducted annually. *Affected public:* individuals or households; businesses or other for profit; small businesses or organizations. *Types of Respondents:* Adult men and women; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 5,649; *Estimated Number of Responses per respondent:* 2.16; and *Estimated Total Annual Burden Hours Requested:* 6,886.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Participants	3,513	2.86	0.606	6,085
Physician, hospital, nursing home staff	1,068	1.0	0.67	716
Participant's next of kin	1,068	1.0	.08	85
Total	5,649	2.16	6,886

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 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 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 proposed project or to obtain a copy of data collection plans and instruments, contact Dr. Paul Sorlie, Division of Epidemiology and Clinical Applications, NHLBI, NIH, II Rockledge Centre, 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: sorliep@nhlbi.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: June 21, 2004.

Peter Savage,

Director, DECA, NHLBI, National Institutes of Health.

[FR Doc. 04–14775 Filed 6–29–04; 8:45 am]

BILLING CODE 4140–01–M