development of combination vaccines for licensure in the United States. Topics addressed in this document include: (1) Manufacturing issues for combination vaccines; (2) preclinical studies; (3) clinical studies to support the licensure of combination vaccines; and (4) vaccines administered simultaneously with combination vaccine. This document does not cover therapeutic combination vaccines. In addition, not all issues outlined in the document will pertain to all types of combination vaccines, e.g., some issues related to live vaccines may not apply to inactivated vaccines.

As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. This document is intended to provide information and does not set forth requirements. FDA anticipates that manufacturers and other interested parties may develop alternative methods and procedures, and discuss them with FDA. FDA recognizes that advances will continue in the area of combination vaccines, and FDA intends to update and revise this document in order to improve its usefulness. This guidance document represents the agency's current thinking on combination vaccines. 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, regulations, or both.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on this guidance document. 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 this document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether further revision of this document is warranted.

Dated: April 1, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–9169 Filed 4–9–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung and Blood Institute; Proposed Collection; Comment Request; The Atherosclerosis Risk in Communities 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 the proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: The Atherosclerosis Risk in Communities (ARIC) Study. *Type of Information Collection Request:* Revision of a currently approved collection (OMB No. 0925–0281). *Need and Use of Information Collection:* This project involves a physical examination and a survey of a new sample of 45–64 year olds living in the same communities as the original ARIC Study participants. Information from this sample and from the original cohort collected 10 years earlier will be used to assess temporal trends in selected atherosclerosis risk factor domains. *Frequency of Response:* The recruited individuals will participate in a home interview and an in-clinic examination. *Affected Public:* Individuals or households. *Type of Respondents:* Adults 45–64 years old. The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Individuals participating in home interview only	2,400	1	0.0501	120
Individuals participating in both home interview and clinic examination	1,200	1	1.8851	2,262
Total				2,382

The cost to the respondents consists of their time; time is estimated using a rate of $10.00 per hour. The annualized cost to respondents is estimated at: $23,820. There are no Capital Costs. The Operating and Maintenance Costs are $682,000.

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 functions of the agency, including whether the information shall 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project, to obtain a copy of the data collection plans and instruments, or to submit comments, contact Ms. Suzanne Anthony, Project Clearance Liaison, National Heart, Lung, and Blood Institute, NIH, Building 31, Room 5A10, MSC 2490, 31 Center Dr., Bethesda, MD 20892–2490 or call non-toll free number (301) 496–9737, or E-mail your request or comments, including your address, to: AnthonyS@nih.gov.

COMMENTS DUE DATE: Comments regarding this information collect are best assured of having their full effect if received by June 9, 1997.

Dated: April 4, 1997.

Sheila E. Merritt,

Executive Officer, NHLBI.

[FR Doc. 97–9296 Filed 4–9–97; 8:45 am]

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