and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3127.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance outlines FDA's current thinking on the use of Bayesian statistical methods in medical device clinical trials. Bayesian statistical methods are currently used in a variety of medical device applications to FDA. This draft guidance includes a general description of Bayesian methods, discussions on design and analysis of Bayesian medical device clinical trials, the benefits and difficulties with the Bayesian approach, and comparisons with standard (frequentist) statistical methods. Finally, the draft guidance presents some ideas on using Bayesian methods in postmarket studies.

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on use of Bayesian statistics in medical device clinical trials. 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

To receive ''Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1601) 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Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet.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 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 refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807 have been approved under 0910–0120; the collections of information in 21 CFR part 812 have been approved under 0910–0078; the collections of information in 21 CFR part 814 have been approved under 0910–0231; and the collections of information in 21 CFR part 822 have been approved under 0910–0449.

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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–7855 Filed 5–22–06; 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 Leukocyte Antibodies Prevalence (LAP) Study

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 to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 1, 2006, pages 5344–5355 and allowed 60 days for public comment. No comments were received in response to this notice. 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 current valid OMB control number.

Proposed Collection: Title: The Leukocyte Antibodies Prevalence (LAP) Study. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The two current hypotheses for pathogenesis of transfusion-related acute lung injury (TRALI) include the development of acute pulmonary insufficiency from immune and non-immune causes. The immune mediated mechanism postulates that passively transferred anti-leukocyte antibodies from blood donors are responsible for TRALI. The donor antibodies implicated in TRALI include antibodies directed towards HLA class I and class II antigens, and anti-neutrophil antibodies. The LAP Study is a cross-sectional multi-center study to measure the prevalence of HLA and neutrophil antibodies in blood donors with or without a history of blood transfusion or pregnancy, and the development of a repository of blood samples obtained from these donors. Specifically, 7,900 adult blood donors across six blood centers participating in the Retrovirus Epidemiology Donor Study II (REDS–II) will be enrolled in the study. Eligible donors will be asked to complete a short questionnaire on their transfusion history (ever, and date of last transfusion) and, for female donors, questions on pregnancy history (ever, number and outcome of pregnancies, last pregnancy). Each donor will also be asked to provide a sample of blood which will be tested for the presence of HLA class I and Class II antibodies. This data will help us evaluate variations in HLA antibody prevalence based on blood transfusion and pregnancy history and time since the last immunizing event. Further, neutrophil specific antibodies will be measured in those blood donors who have HLA antibodies. Also, donors with neutrophil antibodies will be tested to determine their neutrophil phenotype using routine serologic and DNA methods, since individuals homozygous for certain neutrophil antigens are more

prone to develop certain neutrophil antibodies. The results from testing HLA positive donors for neutrophil antibodies in this primary study could be used to develop an optimal testing strategy for large number of donors using the stored repository samples. These dat will provide the basis for calculating donor loss in the event that a TRALI prevention strategy is implemented that includes deferring donors with a history of transfusion or pregnancy or those with HLA or neutrophil antibodies. The second major goal of this study is to develop a repository of blood samples from well characterized blood donors whose detailed transfusion and pregnancy histories are known. Repository samples will be stored indefinitely. Although future research on repository samples is yet to be determined, they may be tested for studies designed to help transfusion safety and transfusion biology. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 7,900; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.17; and *Estimated Total Annual Burden Hours Requested:* 1343. The annualized cost to respondents is estimated at: $24,174 (based on $18 per hour). There are no Capital Costs to report. There are no 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
Adult Blood Donors	7,900	1	0.17	1343

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address 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 the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information 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 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. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Suite 361, 6700 Rockledge Drive, Bethesda, MD 20892, or call non-toll free number 301–435–0075, or e-mail your request, including your address to *nemog@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: May 12, 2006.

Charles M. Peterson,

Director, DBDR, National Institutes of Health.

[FR Doc. 06–4790 Filed 5–22–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; ActiGraph Accelerometer Validation Study

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 for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on January 23, 2006, page 3312 and allowed 60-days for public comment. One public 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: Actigraph Accelerometer Validation Study *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The NCI is collaborating with other NIH Institutes on a proposed longitudinal study of Hispanic subpopulations in the United States referred to as the Hispanic Community Health Study. The Hispanic population is now the largest minority population in the U.S. with a projected three-fold growth by 2050. Hispanic subgroups are influenced by a number of chronic disease risk factors associated with immigration from different cultural settings and environments. These factors include diet, physical activity, community support, working conditions, and access to health care. Hispanic groups have higher rates of obesity and diabetes than non-Hispanic groups, but have lower coronary disease and cancer (all sites) mortality. There are also observed differences in health outcomes between Hispanic subgroups. For example, Puerto Ricans have a four-fold higher asthma prevalence than Mexican-Americans. Hispanic populations are understudied with respect to many diseases and risk factors. Their projected population growth underscores the need for accurate evaluation of their disease burden and risk. A vast amount of research suggests that the level of physical activity influences many of the chronic diseases and conditions of interest, including obesity, diabetes, cardiovascular disease, and cancer. To better understand the relationship between physical activity and chronic disease, and to make specific activity prescriptions, it is necessary to be able to accurately assess levels and types of activity. In particular, better methods are needed to improve the validity and reliability of physical activity assessment instruments to better assess the frequency, duration, and intensity of physical activity. For that reason, NCI plans to evaluate the use of a new type of accelerometer, a small device worn on a belt at the waist that measures and