SUPPLEMENTARY INFORMATION: The workshop is being held in response to the interest that small medical device manufacturers in the Dallas District area have expressed in the topics that will be addressed at the workshop. FMDIC and FDA will present this workshop to help achieve objectives set forth in section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This workshop is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), because it is an outreach activity by a government agency directed at small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the QSR (21 CFR part 820). Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Analysis of FDA 483s, (2) analysis of FDA warning letters, (3) how corrective and preventive actions (CAPA) relates to QSR and the Quality System Inspection Technique, (4) designing and implementing a CAPA system, and (5) the role of complaint files in a CAPA system.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, starting approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: May 22, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–13282 Filed 5–22–02; 3:52 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; Comment Request; Retrovirus Epidemiology Donor Study (REDS): A Study of Motivations and Deterrents to Blood Donation in the United States

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 May 29, 2001, pages 29, 152–29, 153 and allowed 60-days for public comment. The Institute mailed a summary of the protocol and copies of the survey instrument in response to a request. Additionally, the Institute received two comments. A professional association applauded the agency's efforts and urged the Institute to consider future population based studies that would account for views of those who never donate blood. The second comment was from an individual representing biomedical services of a national blood banking institution. This individual stressed the need to build upon previous research conducted by this blood banking organization. The Institute responded to both comments via letter. To the first the Institute replied that they were discussing future studies to assess reasons that some people never donate blood. To the second they responded that while it would be beneficial to build upon this previous data, published literature on this blood collection organization's research was not available. No further responses to the Institute 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: Retrovirus Epidemiology Donor Study (REDS): A Study of Motivations and Deterrents to Blood Donation in the United States. Type of Information Collection Request: NEW. Need and Use of Information Collection: There are serious blood shortages in the U.S. and the situation is predicted to worsen unless corrective measures are initiated. Through a randomized mail survey of individuals who have donated blood at one of the blood centers participating in the NHLBI Retrovirus Epidemiology Donor Study (REDS), this study will examine the personal, or intrinsic reasons for choosing to donate blood, as well as external influences for choosing to donate blood. Donors will be given the option to respond via a mailed survey or a secured website. Comparisons will be made between lapsed and repeat donors with the premise that repeat donors may have a stronger altruistic impetus for donating than donors who donate less frequently or discontinue donating. Donors will be asked about factors influencing them to donate, the donation experience, and questions addressing accessibility to donate. Additionally, the study will examine possible barriers to donation, such as inconvenience, discomfort, and confidentiality. With the majority of the blood supply coming from committed, repeat donors, information regarding why an individual decides to donate, and more importantly, what motivates them to come back, will provide valuable insight on possible strategies to encourage increased donation frequency among the current blood donor population. Assessment of possible barriers to donation will provide areas for focusing improvement in the blood donation process. Data from this survey will provide a valuable perspective for devising strategies to increase blood donation the U.S., thus helping insure that there is an adequate supply to meet the needs of the American public. Frequency of Response: Once. Affected Public: Individuals. Type of Respondents: Adult Blood Donors. The annual reporting burden is as follows: Estimated Number of Respondents: 40, 000; Estimated Number of Responses per Respondent: 1; Average Burden Hours Per Response: 0.25; and Estimated Total Annual Burden Hours Requested: 10,000. The annualized cost to respondents is estimated at: $157,000. There are no Capital Costs, Operating Cost, and/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	40,000	1	0.25	10,000

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 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 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.

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 J. Nemo, Group Leader, Transfusion Medicine, Scientific Research Group, Division of Blood Diseases and Resources, NHLBI, NIH, Two Rockledge Center, Suite 10042, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, 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 10, 2002.

Donald Christoferson,

Executive Officer, NHLBI.

[FR Doc. 02–13195 Filed 5–24–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial

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 February 7, 2002, page 5834 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: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. *Type of Information Collection Request:* Revision, OMB control number 0925–0407, expiration date October 31, 2002. *Need and Use of Information Collection:* This trial is designed to determine if screening for prostate, lung, colorectal and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 251,000 deaths annually in the U.S. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. The total sample size after more than 8 years of recruitment is 154,956. The primary endpoint of the trial is cancer-specific mortality for each of the four cancer sites (prostate, lung, colorectal, and ovary). In addition, cancer incidence, stage shift, and case survival are to be monitored to help understand and explain results. Biologic prognostic characteristics of the cancers will be measured and correlated with mortality to determine the mortality predictive value of these intermediate endpoints. Basic demographic data, risk factor data for the four cancer sites and screening history data, as collected from all subjects at baseline, will be used to assure comparability between the screening and control groups and make appropriate adjustments in analysis. Further, demographic and risk factor information will be used to analyze the differential effectiveness of screening in high versus low risk individuals. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households. *Type of Respondents:* Adult men and women. The annual reporting burden is as follows: *Estimated Number of Respondents:* 150,598; *Estimated Number of Responses per Respondent:* 1.38; *Average Burden Hours Per Response:* 0.19; and *Estimated Total Annual Burden Hours Requested:* 39,597. The annualized cost to respondents is estimated at: $395,970. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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 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.

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