questions are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion? (2) what must a claim of categorical exclusion include by regulation? (3) what is an EA? (4) when is an EA required by regulation and what format should be used? (5) what are extraordinary circumstances? and (6) what suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in the guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations. FDA is requesting the extension of OMB approval for the information collection provisions in the guidance. The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

In the **Federal Register** of July 21, 2010 (75 FR 42446), FDA published a 60-day notice requesting public comment on the proposed collection of information. In response, the agency received one comment that was not responsive to the comment request on the information collection provisions.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.32(i)	34	1	34	1	34
25.32(o)	1	1	1	1	1
25.32(q)	2	1	2	1	2
Total					37

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for § 25.32(i) and (q) that the agency has received in the past 3 years. Please note that, in the past 3 years, there have been no submissions that requested an action that would have been subject to the categorical exclusion in § 25.32(o). To avoid counting this burden as zero, FDA has estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission.

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 1 hour per submission. For the information requested for the exclusions in § 25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: September 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24272 Filed 9–27–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Testing Successful Health Communications Surrounding Aging-Related Issues From the National Institute on Aging (NIA)

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 Institute on Aging, 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: Testing successful health communications surrounding aging-related issues from the National Institute on Aging (NIA). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will support NIA's mission "to communicate information about aging and advances in research on aging to the scientific community, health care providers, and the public." The primary objectives of this study are to:

- Assess audiences' trusted/preferred sources for information, knowledge, attitudes, behaviors, and other characteristics for the planning/development of health messages and communications strategies;
- Pre-test health messages and outreach strategies while they are in developmental form to assess audience response, including their likes and dislikes.

NIA's Office of Communications and Public liaison will collect this information through formative qualitative research with its key audiences—older people, caregivers, and health professionals. Methods will include focus groups, individual interviews, self-administered questionnaires, and website surveys. The information will be used to (1) Develop and revise health information resources and outreach strategies to maximize their effectiveness; (2) determine new topic areas to explore for future NIA publications; and (3) identify new ways to support the health information needs of older adults and people who serve older adults. NIA is requesting a generic clearance for a range of research data collection procedures to ensure that they successfully develop and disseminate effective health communications on aging-related issues. *Frequency of Response:* On occasion. *Affected Public:* Older people, caregivers, and health professionals (physicians and non-physicians). *Type of Respondents:* Older

people, caregivers, and health professionals (physicians and non-physicians). The annual reporting burden is as follows: *Estimated Number of Respondents:* 630. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours Per Response:* 0.37. *Estimated Total Annual Burden Hours Requested:* 234. The annualized cost to respondents is estimated at: $5,680. 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
Older adults	260	1	.37	97
Non-physician health professionals and caregivers	310	1	.35	107
Physicians	60	1	.5	30
Total				234

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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Megan Homer, Writer/Editor, Office of Communications and Public Liaison, NIH, Building 31C Room 5C27, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number 301–496–1752 or E-mail your request, including your address to: *homerm@mail.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: September 22, 2010.

Lynn Hellinger,

Director of Management, National Institutes of Health.

[FR Doc. 2010–24277 Filed 9–27–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors: Improving the Safety of the U.S. Blood Supply Through Hemovigilance

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 periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the U.S. blood supply through hemovigilance. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Information on current risk factors in blood donors as assessed using analytical study designs is largely unavailable in the U.S. Studies of risk factor profiles among HIV-infected donors were funded by the CDC for approximately 10 years after implementation of serologic screening in the mid-1980s, whereas studies of HTLV- and HCV-seropositive (and indeterminate) donors, funded by NIH, were conducted in the early 1990s, but unfortunately, none of these studies is ongoing. Infection trend analyses have been conducted by the American Red Cross (ARC). The findings show continued HIV risk with the prevalence of HIV in first time donors hovering around 10 per 100,000 donations in each of the last 10 years and the incidence in repeat donors increasing from 1.49 per 100,000 person-years in 1999–2000 to 2.16 per 100,000 persons-years in 2007–2008. While the prevalence of HCV in first time donors decreased over this time interval from 345 to 163 per 100,000 donations, the incidence in repeat donors did not decrease and evidence of incident infection in first time donors increased. Moreover specific age, gender and race/ethnicity groups were over-represented. Significantly increased incidence of both HIV and HCV were observed in 2007/2008 compared to 2005/2006. Similar analyses for HBV have shown an incidence in all donors of 3.4 per 100,000 person-years which is lower than earlier estimates, but remains higher than for HIV and HCV.

This project represents a collaborative pilot research study that will include a comprehensive interview study of viral infection positive blood donors at the American Red Cross (ARC), Blood Systems Inc. (BSI) and New York Blood Center (NYBC) in order to identify the current predominant risk factors for virus positive donations and will also establish a donor biovigilance capacity that currently does not exist in the U.S. At this time it is not easy to integrate risk factor data and disease marker surveillance information within or across different blood collection organizations because common interview procedures and laboratory confirmation procedures are not being used and so we cannot easily tabulate and analyze behavioral risks or viral infections in U.S. blood donors. This creates the potential for gaps in our understanding of absolute incidence and prevalence as well as risks that could lead to transfusion-transmitted disease. Combined data are critical for appropriate national surveillance efforts. For example, this information could be used to target educational interventions to reduce donations from persons with high risk behaviors. This is particularly important in the case of