

the number of respondents for listing of ingredients under section 904 of the act from 100,000 to 11,000 in response to comments that this estimate was too high. FDA also added the activity of applying for a Dun and Bradstreet D-U-

N-S number to the burden of this information collection for those who chose to use eSubmitter.

In the **Federal Register** of February 18, 2010 (75 FR 7269), FDA published a 60-day notice requesting public

comment on the proposed collection of information. One comment was received but was outside the scope of the PRA requirements.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

| Activity                                                                             | Number of Respondents | Annual Frequency per Response | Total Annual Respondents | Hours per Response | Total Hours |
|--------------------------------------------------------------------------------------|-----------------------|-------------------------------|--------------------------|--------------------|-------------|
| Registration and Product Listing for Owners and Operators of Domestic Establishments | 100,000               | 1                             | 100,000                  | 3.75               | 375,000     |
| Listing of Ingredients                                                               | 11,000                | 1                             | 11,000                   | 3.0                | 33,000      |
| Obtaining a Dun and Bradstreet D-U-N-S Number                                        | 1,550                 | 1                             | 1,550                    | 0.5                | 775         |
| Total                                                                                | 112,550               |                               | 112,550                  |                    | 408,775     |

Dated: May 4, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-10781 Filed 5-6-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0487]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleman, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, email: [Daniel.Gittleman@fda.hhs.gov](mailto:Daniel.Gittleman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 19, 2010 (75

FR 2868), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0582. The approval expires on February 28, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: May 4, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; REDS-II—Does Pre-Donation Behavioral Deferral Increase the Safety of the Blood Supply?

**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 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 24, 2010 in Volume 75, No. 36, pages 8367-8368 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: REDS-II Does Pre-Donation Behavioral Deferral Increase the Safety of the Blood Supply?

**Type of Information Collection Request:** New. **Need and Use of Information Collection:** While it is well-accepted that deferrals, as part of the "layers of safety" concept, increase the safety of the blood supply, studies with sufficiently large sample size to quantify HIV infection and other infectious marker rates in deferred donors are lacking. Evidence in support of increased safety is frequently inferred from studies conducted in other health care settings. For example, a small hospital-based case control study conducted in Brazil examined the association between infectious markers and body tattoos. Even though tattoos are not used as a criteria to determine blood donor eligibility in Brazil, having a tattoo was associated with HCV and also with having at least one positive infectious marker.(1) Significant associations were not independently observed for HIV, HBV, syphilis or Chagas. The authors reported an overall sensitivity of 11% and specificity of

97% for the presence of a tattoo as indicator of having HIV, HCV, HBV, or syphilis infection. The researchers then estimated the impact on blood donor selection and disease marker testing using the results from their hospital-based case control study. However, the assumptions such as disease marker prevalence of as much as 15% in donors who are deferred for tattoos and a prevalence of 4% of the potential donor base having a tattoo (2) do not represent current temporary deferrals in Brazil and do not address the most common behavior-related deferrals. A more detailed and targeted assessment of the value of relevant deferrals could be used to help inform blood donation policies in Brazil.

In Brazilian blood collection centers, donor deferral is initiated either by the blood center staff, based on information disclosed by prospective donors, or by the donor through self-deferral. Either type of deferral occurs because of the belief that a donor's behavior, exposures, or history represents an increased risk to the safety of the blood supply.

Although the general eligibility criteria are mandated by the Brazilian Ministry of Health, the specific criteria for screening potential donors and the procedures for implementing them may vary across the regional blood collection centers. This study will focus on sexual behavior deferrals and their impact on blood safety. The two main study aims are: (1) To assess infectious disease marker prevalence in donors who are deferred for higher risk sexual and non-injection drug use behavior; and (2) To determine if the different deferral classification procedures used by different blood centers in Brazil lead to a measurable difference in disease marker prevalence in deferred donors. To do this, deferred donors who agree to participate in this study will be asked to complete an audio computer assisted self interview (ACASI) questionnaire that measures two content areas (1) motivations for attempting to donate, (2) additional information on the deferral and other potentially undisclosed deferrable behaviors. A blood sample will be collected from the deferred donors and tested for the panel of infections currently screened for in

Brazil (HIV, Hepatitis C, Hepatitis B, Human T-lymphotropic virus, syphilis, and Trypanosoma cruzi) using the same high-throughput laboratory reagents and procedures that are used to screen donations. These deferred donor marker rates will be compared to the marker rates among accepted donors with the same demographic characteristics. Marker rates in deferred donors will also be compared between the blood centers.

*Frequency of Response:* Once.  
*Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 4,860; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.33 (including administration of the informed consent form and questionnaire completion instructions); and *Estimated Total Annual Burden Hours Requested:* 1,604. The annualized cost to respondents is estimated at: \$10,426 (based on \$6.50 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

| Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours requested |
|---------------------------------|----------------------------------------------|-----------------------------------|-----------------------------------------------|
| 4,860 .....                     | 1                                            | 0.33                              | 1,604                                         |

*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,  
*OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974, 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 10042, 6701 Rockledge Drive, Bethesda, MD 20892-7950, or call 301-435-0075, or E-mail your request 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: April 29, 2010.

**George Nemo,**  
*Project Officer, NHLBI, National Institutes of Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; Comment Request; A Generic Submission for Formative Research, Pretesting, and Stakeholder Measures at NCI

**SUMMARY:** Under the provisions 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 Cancer Institute (NCI), 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:* A Generic Submission for Formative Research, Pretesting, and Stakeholder Measures at NCI. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* In order to carry out NCI's legislative mandate, the Office of Advocacy Relations (OAR) disseminates cancer-related information to a variety of stakeholders, seeks their