ESTIMATE OF ANNUALIZED BURDEN HOURS

| Form name | Type of respondent | No. of respondents | No. of responses per respondent | Average burden per respondent (in hours) | Total response burden hours |
|---|---|---|---|---|---|
| Form A 83.9 ..... | Petitioner using Form A ..... | 30 | 1 | 3/60 | 2 |
| Form B 83.9 ..... | Petitioner using Form B ..... | 40 | 1 | 5 | 200 |
| Form B 83.9 ..... | Petitioner submission format other than Form B (as permitted by rule). | 5 | 1 | 6 | 30 |
| 83.18 ..... | Petitioner Appealing final HHS decision (no specific form is required). | 5 | 1 | 45/60 | 4 |
| | Claimant authorizing a party to submit petition on his/her behalf. | 20 | 1 | 3/60 | 1 |
| Total ..... | ..... | 100 | ..... | ..... | 237 |

Dated: February 18, 2010.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2010–3702 Filed 2–23–10; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection; Comment Request; REDS—II—Does Pre-Donation Behavioral Deferral Increase the Safety of the Blood Supply?

**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:* 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:* 1,620. The annualized cost to respondents is estimated at: $10,530 (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 | 1,620 |

*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 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 60 days of the date of this publication.

Dated: February 17, 2010.

**Dr. George Nemo,**

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

[FR Doc. 2010–3754 Filed 2–23–10; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0067]**

### Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on March 17, 2010, from 7:30 a.m. to 3 p.m.

*Location*: Atlanta Marriott Marquis, 265 Peachtree Center Ave., Atlanta, GA 30303. The hotel phone number is 404–521–0000.

*Addresses*: Submit electronic comments on this document to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. Comments received on or before March 8, 2010, will be provided to the committee before the meeting. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

*Contact Person*: Yvette Waples, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *yvette.waples@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda*: On March 17, 2010, the committee will discuss and provide comments on the following topics: (1) General scientific issues related to the application of pharmacogenomics in the early stages of drug development. Pharmacogenomics examines the genetic differences that influence a person's responses, both beneficial and harmful, to certain drugs; (2) a new patient-centric clinical pharmacology approach to drug safety; (3) the design and analysis of clinical pharmacology studies focusing on how the renal function changes in the way the body absorbs, distributes, metabolizes, and excretes a drug in patients with kidney impairment; and (4) scientific considerations and recent developments in transporter-mediated drug interactions. These interactions are between two or more drugs that either inhibit or enhance the roles of specialized proteins known as "transporters" and, in turn, the interactions can affect a drug's safety and/or efficacy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 8, 2010. Oral presentations from the public will be scheduled between approximately 9:25 a.m. and 10 a.m., and 1:15 p.m. and 1:45 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed