

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Non-Participants (or Proxies)	Telephone Interview	600	1	27/60	270

Mary Oliver-Anderson,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. E8-9176 Filed 4-25-08; 8:45 am]

BILLING CODE 4150-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood Safety and Availability (ACBSA) will hold a meeting. The meeting will be open to the public on both Thursday, May 29 and Friday, May 30, 2008.

DATES: The meeting will take place Thursday, May 29 and Friday, May 30, 2008 from 9 a.m. to 5 p.m.

ADDRESSES: The Hilton Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20852 Phone: (301) 468-1100.

FOR FURTHER INFORMATION CONTACT: Jerry A. Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootton Parkway, Suite 250, Rockville, MD 20852, (240) 453-8803, Fax (240) 453-8456, e-mail ACBSA@hhs.gov.

SUPPLEMENTARY INFORMATION: Updates will be provided to the Committee on previous recommendations as follows:

At the January 2003 meeting of the ACBSA, the Committee recognized that the leading causes of transfusion related fatalities were: bacterial contamination of platelets; hemolysis, primarily due to errors in release and administration of incorrect blood; and transfusion related acute lung injury (TRALI). Progress has been made on all three of these causes of transfusion related fatalities. Updates will be provided on the rate of bacterial contamination and reports of sepsis associated with 5 day and 7 day dating of apheresis platelets and on the use of improved methods to reduce errors in the identification of patients and

transfusion products. In addition, the Committee will review progress made to reduce the risk of TRALI. In 2007, the AABB recommended to its institutional members to devise strategies to reduce the risk of TRALI in transfused patients. Total voluntary implementation was to be complete by November 2008. To this end, many blood centers and hospitals have implemented strategies to decrease the adverse risk of TRALI by using male only apheresis platelets and plasma donors. Various strategies will be presented and discussed as well as messaging to potential donors.

The Committee will also hear an update from the Food and Drug Administration's sponsored public workshop entitled: "Hemoglobin Based Oxygen Carriers: Current Status and Future Directions," which will be held on April 29 and 30, 2008. The Committee will also hear an update from Health Resources and Services Administration (HRSA) regarding its April 4, 2008 meeting on potential rulemaking with respect to vascularized composite allografts and whether vascularized composite allografts should be included within the definition of organs covered by the regulations governing the operation of the Organ Procurement and Transplantation Network and covered by section 301 of the National Organ Transplant Act of 1984.

The Committee will then be asked to discuss and make recommendations on reports of adverse outcomes associated with transfusion of older red cells. There have been additional studies and peer reviewed publications reporting adverse outcomes associated with the administration of red cells older than 14 days of storage. Currently human red cells for transfusion are good for up to 42 days of storage depending on the anticoagulant and additive solutions used in storage. Presentations and discussions will review current blood distribution and transfusion practices as well as available outcome data related to clinical studies with older red cells.

Public comment will be solicited on both May 29 and 30, 2008. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Anyone planning to comment is encouraged to contact the Executive Secretary at his/her earliest

convenience. Those who wish to have printed material distributed to Advisory Committee members should submit thirty (30) copies to the Executive Secretary prior to close of business May 27, 2008. Likewise, those who wish to utilize electronic data projection to the Committee must submit their materials to the Executive Secretary prior to close of business May 27, 2008.

Dated: April 22, 2008.

Jerry A. Holmberg,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. E8-9230 Filed 4-25-08; 8:45 am]

BILLING CODE 4150-41-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the President's Council on Physical Fitness and Sports

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the President's Council on Physical Fitness and Sports will hold a meeting. This meeting is open to the public. A description of the Council's functions is included also with this notice.

DATES: May 14, 2008, from 9 a.m. to 4 p.m.

ADDRESSES: Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Melissa Johnson, Executive Director, President's Council on Physical Fitness and Sports, Hubert H. Humphrey Building, Room 738H, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690-5187.

SUPPLEMENTARY INFORMATION: The President's Council on Physical Fitness and Sports (PCPFS) was established originally by Executive Order 10673, dated July 16, 1956. PCPFS was established by President Eisenhower after published reports indicated that American boys and girls were unfit compared to the children of Western

Europe. The Council has undergone two name changes and several reorganizations. Authorization to continue Council operations has been given at appropriate intervals by subsequent Executive Orders. Authority to continue Council operations was most recently directed by Executive Order 13446, dated September 28, 2007. A program office to support PCPFS activities is located organizationally in the Office of Public Health and Science within the Office of the Secretary, DHHS.

On June 6, 2002, President Bush signed Executive Order 13265 to reestablish the PCPFS. Executive Order 13265 was established to expand the focus of the Council. This directive instructed the Secretary to develop and coordinate a national program to enhance physical activity and sports participation. The Council currently operates under the stipulations of the new directive. The primary functions of the Council include: (1) To advise the President, through the Secretary, on the progress made in carrying out the provisions of the enacted directive and recommend actions to accelerate progress; (2) to advise the Secretary on ways and means to enhance opportunities for participation in physical fitness and sports, and, where possible, to promote and assist in the facilitation and/or implementation of such measures; (3) to advise the Secretary regarding opportunities to extend and improve physical activity/fitness and sports programs and services at the national, state, and local levels; and (4) to monitor the need for the enhancement of programs and educational and promotional materials sponsored, overseen, or disseminated by the Council and advise the Secretary, as necessary, concerning such needs. The PCPFS holds at a minimum, one meeting in the calendar year to (1) assess ongoing Council activities and (2) discuss and plan future projects and programs.

Public attendance at the meeting is limited to space available. Individuals must provide a photo ID for entry into the building. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person.

Dated: April 18, 2008.

Melissa Johnson,

Executive Director, President's Council on Physical Fitness and Sports.

[FR Doc. E8-9232 Filed 4-25-08; 8:45 am]

BILLING CODE 4150-35-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-N-0154] (formerly Docket No. 2007N-0444)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Recordkeeping and Records Access Requirements for Food Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Recordkeeping and Records Access Requirements for Food Facilities" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 8, 2008 (73 FR 7564), 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 0910-0560. The approval expires on March 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: April 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-9155 Filed 4-25-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0240]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's current good manufacturing practice (CGMPs) regulations for finished pharmaceuticals.

DATES: Submit written or electronic comments on the collection of information by June 27, 2008.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44