

April 29 to 30, 2008, workshop on hemoglobin based oxygen carriers; (2) July 10 to 11, 2008, blood establishment computer software conference; (3) the development of an automated Biologics License Application submission system; and (4) Draft Guidance for Industry: Re-qualification Method for Re-entry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc). Following these updates, the Committee will discuss options for blood donor screening and re-entry for malaria. 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/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and 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 September 2, 2008. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:30 a.m. and between approximately 4 p.m. and 4:30 p.m. on September 10, 2008, and between approximately 9:15 a.m. and 9:45 a.m. and between approximately 1:30 p.m. and 2 p.m. on September 11, 2008. 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 participants, and an indication of the approximate time requested to make their presentation on or before August 22, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 25, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee

meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Pearline K. Muckelvene at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 17, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

Risk Communication Advisory Committee; 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. All attendees should bring some form of government-issued photo identification, such as a driver's license.

Name of Committee: Risk Communication Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on effective risk communication.

Date and Time: The meeting will be held on August 14, 2008, from 8 a.m. to 5 p.m. and August 15, 2008, from 8 a.m. to 2 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Lee L. Zwanziger, Office of the Commissioner, Office of Policy, Planning and Preparedness, Office of Planning (HFP-60), Food and Drug Administration, 5600 Fishers Lane (for express delivery: rm 15-22), Rockville, MD 20857, 301-827-2895, FAX: 301-827-3285, Food and Drug

Administration, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732112560. 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 August 14 and 15, 2008, the committee will meet for presentations and discussion of the scientific basis for translating principles of risk communication into practice in situations of emerging and uncertain risk.

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 or will be available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and 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 August 11, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on August 14th and 10:30 to 11:30 on August 15th. Those desiring to make formal oral presentations should notify the contact person and should submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 7, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will

notify interested persons regarding their request to speak by August 8, 2008.

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FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 17, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA)

publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail

paperwork@hrsa.gov or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Sickle Cell Disease Treatment Demonstration Program (SCDTDP), Health Resources and Services Administration (HRSA): NEW

In 2004 Congress enacted and the President signed into law Public Law 108-357, the American Jobs Creation Act of 2004. Section 712 of Public Law 108-357 authorized a demonstration program for the prevention and treatment of Sickle Cell Disease. The legislation was enacted to (1) create an optional medical assistance program for individuals with Sickle Cell Diseases for treatment and education, genetic counseling and other services to prevent mortality and decrease morbidity from Sickle Cell Disease, and (2) create a demonstration program, the SCDTDP, under HRSA. The SCDTDP provides grants to federally-qualified and nonprofit health care providers to establish geographically distributed regional networks that will work with comprehensive Sickle Cell Disease centers and community-based support organizations to provide coordinated, comprehensive, culturally competent,

and family-centered care to families with Sickle Cell Disease. In fiscal year 2006, HRSA awarded four, 4-year grants to the Illinois Sickle Cell Association Network, Alabama Network for Sickle Cell Care, Access, Prevention, and Education, Carolina Partnership for Sickle Cell Treatment Continuum of Care, and the Cincinnati Sickle Cell Network.

Under the authorizing legislation, a National Coordinating Center (NCC) was established to (1) collect, coordinate, monitor, and distribute data, best practices and findings regarding the activities of the demonstration program, (2) identify a model protocol for eligible entities with respect to the prevention and treatment of Sickle Cell Disease, (3) identify educational materials regarding the prevention and treatment of Sickle Cell Disease, and (4) prepare a final report on the efficacy of the demonstration program based on evaluation findings.

As part of the evaluation, pre and post utilization and satisfaction data and quality of life assessments will be collected from the demonstration clients during various phases of their participation. These data will be collected through medical record abstractions and self-report using hard copy questionnaires and submitted to the NCC for processing and analysis.

The total burden estimate per participant is shown below:

Type of respondent	Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Sickle Cell Disease clients or caregivers.	Utilization Questionnaire (pre-demonstration).	400	1	400	.75	300
Sickle Cell Disease clients or caregivers.	Utilization Questionnaire (post demonstration).	400	1	400	.50	200
Sickle Cell Disease clients or caregivers.	SF-36 Health Survey for adults over 18 years of age.	280	2	560	.25	140
Parents of Sickle Cell Disease clients.	PedsQL for parents	120	2	240	.25	60
Sickle Cell Disease clients age 18 and younger.	PedsQL for children and adolescents.	100	2	200	.25	50
Sickle Cell Disease clients or caregivers.	The Medical Home Family Index (Health Care Satisfaction).	400	2	800	.25	200
Total	500	2,600	950

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to

the desk officer for HRSA, either by e-mail to OIRA_submission@omb.eop.gov or by fax to 202-395-6974. Please direct

all correspondence to the "attention of the desk officer for HRSA."