

business on (see **DATES**). All comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be posted without change, including any personal information provided. All comments received while the docket is open will be forwarded to the Science Board for their review. All comments will also be discussed at the next Science Board Advisory Committee meeting. A notice of the next Science Board Advisory Committee meeting will be published at a later date. See **SUPPLEMENTARY INFORMATION** section for electronic access.

**FOR FURTHER INFORMATION CONTACT:**

Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF-33), 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687, FAX: 301-827-3340, e-mail: [carlos.Peña@fda.hhs.gov](mailto:carlos.Peña@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On March 31, 2006, FDA charged the Science Board to conduct a broad review of FDA scientific capacities, processes, and infrastructure which support FDA's core regulatory functions including the following: (1) Premarket review and consultation during the development of new FDA-regulated products; (2) oversight of marketed product quality; and (3) postmarket product safety surveillance and risk management. The following is the Commissioner of Food and Drugs' charge to the Science Board: "Review and report the broad categories of scientific and technologic capacities that FDA needs to fully support its core regulatory functions and decisionmaking throughout the product life-cycle, today and over the next decade." Specifically:

(1) Are there any important gaps in current scientific capacities in which FDA should substantially increase efforts, to ensure that it can address current or expected scientific demands of FDA's regulatory mission? In what areas should the agency maintain or strengthen its current level of work and capacity?

(2) Are there areas of science in which the agency should consider refocusing its efforts in order to better address current or anticipated future scientific demands of FDA's regulatory mission?

(3) What opportunities exist to enhance the overall effectiveness of FDA's scientific and technologic

capacity through coordination of scientific activities and priority setting across FDA components?

(4) What opportunities exist to better leverage FDA's scientific capacity through collaboration with other public agencies and private organizations? Are there other approaches to resource leveraging that FDA could pursue to better support needed scientific capacities?

The review was initiated to obtain advice regarding current science-based capacities and the degree to which they can prepare FDA for anticipated changes in science, technology and population health needs.

To respond to this request from the agency, the Science Board established a subcommittee on science and technology to perform the review. The subcommittee was supported by 30 outside experts, who were drawn from government, academia, and industry. Their efforts culminated in a subcommittee report of findings and preliminary recommendations. The subcommittee report was presented and discussed at the December 3, 2007, Science Board Advisory Committee meeting, at which time the Science Board decided to obtain comments from the public on the subcommittee report (an electronic copy of the subcommittee report is available at [http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b\\_02\\_00\\_index.html](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html)).

**II. Request for Comments**

In accordance with 21 CFR 14.35, FDA is soliciting public comment on the subcommittee report, on behalf of the Science Board. Comments received while the docket is open will be forwarded to the Science Board for their review. Comments will also be discussed at the next Science Board Advisory Committee meeting. A notice of the next Science Board Advisory Committee meeting will be published in the **Federal Register** at a later date.

**III. Submission of Comments**

To help facilitate the public comment process upon the subcommittee report, FDA has established a public docket, on behalf of the Science Board. All comments submitted to the public docket are public information and may be posted to the FDA's Web site at: <http://www.fda.gov> for public viewing. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: December 28, 2007.

**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: Proposed Collection: Comment Request**

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**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 Pub. L. 108-

357, the American Jobs Creation Act of 2004. Section 712 of Pub. L. 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	Hours per response	Total burden hours
Sickle Cell Disease clients or caregivers.	Utilization Questionnaire (pre-demonstration).	400	1	.75 .....	300 hours.
Sickle Cell Disease clients or caregivers.	Utilization Questionnaire (post-demonstration).	400	1	.50 hours .....	200 hours.
Sickle Cell Disease clients or caregivers.	SF-36 Health Survey for adults over 18 years of age; PedsQL for children/adolescents 18 years or younger (Quality of Life).	400	2	.25 hours .....	200 hours.
Sickle Cell Disease clients or caregivers.	The Medical Home Family Index (Health Care Satisfaction).	400	2	.25 hours .....	200 hours.

The total burden is 900 hours or 2.25 hours per participant. This would be the maximum level of burden since some of the demonstration networks will be able to abstract medical records for some of the data collected on the Utilization Questionnaire.

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 27, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

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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, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to OMB for review under the Paperwork Reduction Act of 1995:

#### **Proposed Project: Application for the National Health Service Corps (NHSC) Scholarship Program (OMB No. 0915-0146): Reinstatement With Change**

The National Health Service Corps (NHSC) Scholarship Program's mission is to ensure the geographic distribution

of physicians and other health practitioners in the United States. Under this program, health professions students are offered scholarships in return for service in a federally designated Health Professional Shortage Area (HPSA). The Scholarship Program provides the NHSC with the health professionals it requires to carry out its mission of providing primary health care to HPSA populations in areas of greatest need. Students are supported who are well qualified to participate in the NHSC Scholarship Program and who want to assist the NHSC in its mission, both during and after their period of obligated service.

The application form is being revised to streamline the application process and collect the most relevant information necessary to make determinations of award. Scholars are selected for these competitive awards based on the information provided in the application and supporting documentation. Awards are made to applicants who demonstrate a high potential for providing quality primary health care services.

The estimated response burden is as follows: