

holding a public meeting where stakeholders and other members of the public were given an opportunity to present their views on reauthorization (75 FR 49502, August 13, 2010). This meeting and written comments submitted to the docket have provided critical input as FDA prepares for reauthorization discussions. Section 738A(b)(3) of the FD&C Act further requires that FDA meet with patient and consumer advocacy groups at least once every month during negotiations with the regulated industry to continue discussions of their views on the reauthorization, and their suggestions for changes to the MDUFA program.

FDA is issuing this **Federal Register** notice to request that patient and consumer advocacy groups notify FDA of their intent to participate in periodic consultation meetings on reauthorization of MDUFA. FDA believes that consistent representation at these meetings will be important to ensuring progress in these discussions. If you wish to participate in this part of the reauthorization process, please designate one or more representatives from your organization who will commit to attending these meetings regularly and preparing for the discussions as needed. Patient and consumer advocacy groups who identify themselves through this notice will be included in all future patient and consumer advocacy group meetings while FDA negotiates with the regulated industry. If a representative of a patient and consumer advocacy group decides to participate in these monthly meetings at a later time, they may still participate in remaining monthly meetings by notifying FDA (*see ADDRESSES*). These meetings will satisfy the requirement in section 738A(b)(3) of the FD&C Act.

## II. Additional Information on MDUFA

There are several sources of information on FDA's Web site that may serve as useful resources for patient and consumer advocacy groups participating in the periodic consultation meetings:

- Information on the September 2010 public meeting on MDUFA Reauthorization, the **Federal Register** notice announcing the meeting, and the transcript of the meeting are available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm218250.htm>.

- FDA created a Webinar on the Medical Device User Fee program, medical device development, and FDA's medical device review in MDUFA. These presentations are available at

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm218250.htm>.

- Key **Federal Register** documents, MDUFA-related guidances, legislation, performance reports, and financial reports and plans are posted at <http://www.fda.gov/MDUFA>.

- FDAAA-specific information is available at: <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/SignificantAmendmentstotheFDCAAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm>.

## III. Notification of Intent To Participate in Periodic Patient and Consumer Advocacy Group Consultation Meetings

If you intend to participate in continued periodic patient and consumer advocacy group consultation meetings regarding MDUFA Reauthorization, please provide notification by e-mail to [MDUFAReauthorization@fda.hhs.gov](mailto:MDUFAReauthorization@fda.hhs.gov) by January 6, 2011. Your e-mail should contain complete contact information, including name, title, affiliation, address, e-mail address, telephone number, and notice of any special accommodations required because of disability.

Representatives of patient and consumer advocacy groups will receive confirmation and additional information about the first meeting once FDA receives their notification.

Dated: December 8, 2010.

**Nancy K. Stade,**

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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, Pub. L. 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 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) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (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: Retention Survey of NHSC Clinicians and Alumni/NHSC Site Administrators—

[NEW] The National Health Service Corps (NHSC) Loan Repayment and Scholarship Programs were established to assure an adequate supply of trained primary care health care professionals to provide services in the neediest Health Professional Shortage Areas (HPSAs) of the United States. Under these programs, the Department of Health and Human Services agrees to repay the educational loans of, or provide scholarships to, primary care health professionals. In return, the professionals agree to serve for a specified period of time in a Federally designated HPSA approved by the Secretary. The last survey conducted to analyze retention of NHSC clinicians is more than ten years old. There is a need to distribute a survey to reevaluate the personal/professional development of NHSC clinicians in an effort to retain the clinicians in service providing care for individuals residing in underserved areas. The survey will ask current and former NHSC clinicians questions regarding professional satisfaction, expectations of service in the NHSC, and their experiences at NHSC sites. The survey will also ask questions of NHSC site administrators about their locations and the attributes of current and former NHSC clinicians at these sites.

The estimated response burden for the survey is as follows:

SURVEY

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Survey of Site Administrator .....	2,000	1	2,000	.15	300
Survey of NHSC Clinicians in Service .....	6,500	1	6,500	.13	845
Survey of NHSC Alumni (Recent) .....	3,000	1	3,000	.20	600
Survey of NHSC Alumni (Remote) .....	1,143	1	1,143	.15	171
<b>Total</b> .....	<b>12,643</b>	<b>4</b>	<b>12,643</b>	<b>.63</b>	<b>1,916</b>

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the 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 8, 2010.

**Robert Hendricks,**  
 Director, Division of Policy and Information Coordination.

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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, Pub. L. 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, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (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: The Division of Independent Review Grant Reviewer Recruitment Form (OMB No. 0915-0295)—[Extension]**

HRSA's Division of Independent Review (DIR) is responsible for carrying

out the independent and objective review of all eligible applications submitted to HRSA. DIR ensures that the independent review process is efficient, effective, economical, and complies with statutes, regulations, and policies. The review of applications is performed by people knowledgeable in the field of endeavor for which support is requested and is advisory to individuals in HRSA responsible for making award decisions.

To streamline the selection and assignment of grant reviewers to objective review committees, HRSA utilizes a Web-based data collection form to gather critical reviewer information. The Grant Reviewer Form standardizes pertinent categories of reviewer information, such as: areas of expertise; occupations; work settings; reviewer experience; and allows maximum use of drop-down menus to simplify the data collection process. The Web-based system also permits reviewers to update their information as needed. HRSA maintains a pool of approximately 5,000 individuals that have previously served on HRSA objective review committees.

The estimated annual burden is as follows:

Grant recruitment form	Number of respondents	Responses per respondent	Total responses	Hours per Response	Total burden hours
New reviewer .....	1,380	1	1,380	45 min.	1,035
Updating reviewer information .....	4,255	1	4,255	30 min.	1,850
<b>Total</b> .....	<b>4,900</b>	<b>.....</b>	<b>4,900</b>	<b>.....</b>	<b>2,750</b>

E-mail comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the 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 8, 2010.

**Robert Hendricks,**  
 Director, Division of Policy and Information Coordination.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as