TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
80.22	32	185	5,920	0.05	296
Total					1,302

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
80.39	32	185	5,920	0.25	1,480
Total					1,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate on its review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 2,782 hours. The estimated reporting burden for this information collection is 1,302 hours and the estimated recordkeeping burden for this information collection is 1,480 hours. From FY 2008 to FY 2010, FDA processed an average of 5,932 responses (requests for certification of batches of color additives) per year. There were 32 different respondents, corresponding to an average of approximately 185 responses from each respondent per year. Using information from industry personnel, FDA estimates that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

FDA's Web-based color certification information system allows certifiers to request color certification online, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing certifiers to sell their certified color before receiving hard copy certificates. Any delays in the system result only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis. FDA has estimated a reduction in the hour burden for reporting from use of the Web-based system.

Dated: December 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31195 Filed 12–10–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0389]

Medical Device User Fee Program; Meetings on Reauthorization; Request for Notification of Patient and Consumer Advocacy Group Intention to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to request that patient and consumer advocacy groups notify FDA of their intent to participate in periodic consultation meetings on reauthorization of the Medical Device User Fee Amendments of 2007 (MDUFA) (the Food and Drug Administration Amendments Act of 2007). The statutory authority for MDUFA expires September 30, 2012. At that time, new legislation will be required for FDA to continue collecting user fees for the medical device program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next MDUFA program. The FD&C Act also requires that FDA hold continued discussions with representatives of patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these discussions by establishing consistent patient and consumer advocacy group representation.

DATES: Submit notification of intention to participate by January 6, 2011. The first patient and consumer advocacy group meeting will be held on January 13, 2011, from 9 a.m. to 11 a.m. Meetings will continue at least monthly during reauthorization negotiations with the regulated industry.

ADDRESSES: Submit notification of intention to participate in monthly patient and consumer advocacy group meetings by e-mail to *MDUFAReauthorization@fda.hhs.gov*. The first meeting will be held at the Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 B and C, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Cindy Garris, Food and Drug Administration, Center for Devices and Radiological Health 10903 New Hampshire Ave., Bldg. 66, rm. 4610, Silver Spring, MD 20993–0002, 301–796–5861, FAX: 301–847–8149.

SUPPLEMENTARY INFORMATION:

I. Introduction

The authority for MDUFA (Pub. L. 110–85) expires September 30, 2012. Without new legislation to reauthorize the program, FDA will no longer be able to collect user fees to fund the medical device program. Section 738A(b)(1) (21 U.S.C. 379j–1(b)(1)) of the FD&C Act requires that FDA consult with a range of groups in developing recommendations for the next MDUFA program, including scientific and academic experts, health care professionals, and representatives from patient and consumer advocacy groups. FDA initiated this process of consultation on September 14, 2010, by

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/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/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* 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,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–31160 Filed 12–10–10; 8:45 am]

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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: