

matter; (3) a list of documents in the administrative file, or additional copies of such documents, that are deemed necessary for resolution of the issue(s); and (4) a statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information that the Agency suggests submitting with a formal request for dispute resolution consists of: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA's experience with dispute resolution, the Agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the Agency. Consequently, FDA anticipates that the collection of

information attributed solely to the guidance will be minimal.

**Description of respondents:** A sponsor, applicant, or manufacturer of a drug or biological product regulated by the Agency under the Federal Food, Drug and Cosmetic Act or section 351 of the Public Health Service Act (42 U.S.C. 262) (Pub. L. 99-660) who requests formal resolution of a scientific or procedural dispute.

**Burden Estimate:** Provided below is an estimate of the annual reporting burden for requests for dispute resolution. Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately nine sponsors and applicants (respondents) submit requests for formal dispute resolution to CDER annually and approximately one respondent submits requests for formal dispute resolution to CBER annually. The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests

for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 18 requests annually and CBER receives approximately 1 request annually. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the Agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 152 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Requests for formal dispute resolution	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER .....	9	2	18	8	144
CBER .....	1	1	1	8	8
Total .....					152

Dated: March 15, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-6690 Filed 3-19-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0389]

#### Medical Device User Fee Act; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Act (MDUFA) for fiscal years (FYs) 2013 through 2017. MDUFA authorizes FDA to collect user fees and use them for the process for the review of medical device applications. The

current legislative authority for MDUFA expires on October 1, 2012. New legislation will be required for FDA to collect medical device user fees for future FYs. Following discussions with the device industry and periodic consultations with public stakeholders, the Federal Food, Drug, and Cosmetic Act (FD&C Act) directs FDA to publish the recommendations for the reauthorized program in the **Federal Register**, hold a meeting at which the public may present its views on such recommendations, and provide for a period of 30 days for the public to provide written comments on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

**DATES:** The public meeting will be held on March 28, 2012 from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by March 26, 2012. Submit either electronic or written comments by April 16, 2012.

**Location:** The meeting will be held at the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. For directions

and metro information please visit the following Web site: <http://www.hhs.gov/about/hhhmap.html>. The public meeting will also be available to be viewed online via webcast. Registration is required to view the webcast.

**Contact Person:** Cindy Garris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 4459, Silver Spring, MD 20993, 301-796-5861, FAX: 301-847-8142, email: [MDUFAReauthorization@fda.hhs.gov](mailto:MDUFAReauthorization@fda.hhs.gov).

**Registration and Oral Presentations:** If you wish to attend and/or speak at the meeting or view the webcast, please register by March 26, 2012. To register for the meeting, please visit <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (or go to the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public meeting from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and phone number. Registrants wishing to speak during the open comment period should note that when registering. We

will try to accommodate all persons who wish to speak. The time allotted for an individual to speak may depend on the number of persons who wish to speak. Registration is free and will be on a first-come, first-served basis, with the following exception. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will not be available.

If you need special accommodations due to a disability, please contact Cindy Garris (email: [MDUFARauthorization@fda.hhs.gov](mailto:MDUFARauthorization@fda.hhs.gov) or 301-796-5861) at least 2 days before the meeting.

**Comments:** FDA is holding this public meeting to hear stakeholders' views on the draft recommendations for the reauthorized user fee program (MDUFA III), including suggestions for any changes that FDA should consider. FDA policy issues are beyond the scope of the user fee program. Accordingly, the public comments should focus on MDUFA III draft recommendations.

Regardless of attendance at the public meeting, interested persons may submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number found in brackets in the heading of this document. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Introduction**

FDA is announcing its intention to hold a public meeting to discuss proposed recommendations for the reauthorization of the Medical Device User Fee Amendments of 2007 (MDUFA), which authorizes FDA to collect user fees and use them for the process for the review of device applications until October 1, 2012. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the medical device review process.

As required by section 738A(b)(2), (3), and (6) of the FD&C Act (21 U.S.C. 379j-1(b)(2), (3), and (6)), FDA obtained prior public input and negotiated an agreement with regulated industry

while periodically consulting with patient and consumer advocacy groups and making minutes of negotiation and stakeholder meetings publicly available (Ref. 1). Section 738A(b)(4) of the FD&C Act, requires that, after holding negotiations with regulated industry and before transmitting the Agency's final recommendations to Congress for the reauthorized program (MDUFA III), we do the following: (1) Present the draft recommendations to the Committee on Energy and Commerce of the U.S. House of Representatives and the Committee on Health, Education, Labor, and Pensions of the U.S. Senate; (2) publish the draft recommendations in the **Federal Register**; (3) provide a period of 30 days for the public to provide written comments on the draft recommendations; (4) hold a meeting at which the public may present its views on the draft recommendations; and (5) after consideration of public views and comments, revise the draft recommendations as necessary. This notice, the 30 day comment period, and the public meeting will satisfy certain of these requirements. After the public meeting, we will revise the draft recommendations as necessary. In addition, the Agency will present the draft recommendations to the Congressional committees.

The purpose of the meeting is for the public to present its views on the draft recommendations for the reauthorized program (MDUFA III). In general, the meeting format will include a brief presentation by FDA, but will focus on hearing from different stakeholder interest groups (such as patient advocates, consumer advocates, industry, health professionals, and academic researchers). The Agency will also provide an opportunity for individuals to make presentations at the meeting and for organizations and individuals to submit written comments to the docket before and after the meeting. The following information is provided to help potential meeting participants better understand the history and evolution of the medical device user fee program and the current status of the MDUFA III draft recommendations.

##### **II. What is the medical device user fee program? What does it do?**

In the years preceding enactment of Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107-250), FDA's medical device program suffered a long-term, significant loss of resources that undermined the program's capacity and performance. MDUFMA was enacted "in order to provide the Food and Drug

Administration (FDA) with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier time, and to ensure that reprocessed medical devices are as safe and effective as original devices" (H.R. Rep. No. 107-728, at 21 (2002)). MDUFMA had a 5-year time frame and contained two particularly important features which relate to reauthorization:

- *User fees* for the review of medical device premarket applications, reports, supplements, and premarket notification submissions provided additional resources to make FDA reviews more timely, predictable, and transparent to applicants. MDUFMA fees and increased appropriations for the medical device program helped FDA expand available expertise, modernized its information management systems, provided new review options, and provided more guidance to prospective applicants. The ultimate goal was for FDA to approve and clear safe and effective medical devices more rapidly, benefiting applicants, the health care community and, most importantly, patients.

- *Negotiated performance goals* for many types of premarket reviews provided FDA with benchmarks for measuring review improvements. These quantifiable goals became more demanding each year and included FDA decision goals and cycle goals (cycle goals refer to FDA actions prior to a final action on a submission). Under MDUFMA, FDA also agreed to several commitments that did not have specific time frames or direct measures of performance, such as expanding the use of meetings with industry, maintenance of current performance in review areas where specific performance goals had not been identified, and publication of additional guidance documents.

Medical device user fees and increased appropriations were essential to support high-quality, timely medical device reviews, and other activities critical to the device review program.

MDUFMA provided for fee discounts and waivers for small businesses. Small businesses make up a large proportion of the device industry, and these discounts and waivers helped reduce the financial impact of the user fees on this sector of the device industry, which plays an important role in fostering innovation.

FDA provided periodic reports on its progress towards meeting these performance goals and commitments to stakeholders and Congress. FDA also

provided an annual financial report to Congress, which provided transparency and accountability regarding the Agency's use of the additional resources provided by MDUFMA. Although FDA made progress towards achieving MDUFMA's central objectives, progress was limited by financial shortfalls and unpredictable fee revenues caused by variability in pre-market submission quantities.

In August 2005, Congress enacted the Medical Device User Fee Stabilization Act (Pub. L. 109–45) (MDUFSA), which modified several provisions of MDUFMA. MDUFSA: (1) Repealed the appropriations trigger for FY 2003 and FY 2004 and allowed for tolerances of up to 1 percent of the appropriations trigger for FY 2005–2007; (2) provided for predictable application fees by establishing fixed annual fees for FY 2006 and FY 2007, although at a lower rate of increase than under the original legislation; and (3) expanded the definition of “small business” for FY 2006 and FY 2007. However, MDUFSA did not address the issue of ensuring predictable revenues for FDA.

In 2007, Congress reauthorized medical device user fees through FY 2012 under the Medical Device User Fee Amendments of 2007 (MDUFA II) (title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85).

Under MDUFA II, the user fee program remained intact, with a few significant modifications to the program. The user fee framework was changed to provide a more reliable and stable funding stream. Specifically, MDUFA II included establishment registration as a new fee type that provided a more predictable amount of funds to be collected by the Agency in any given year. MDUFA II also included changes to the performance goals. Compared to MDUFMA, there were fewer performance goals under MDUFA II, yet the goals were more demanding. FDA published the commitment letter outlining the goals in the last reauthorization, as well as a number of reports that provide the public with useful background on MDUFMA, FDAAA, and MDUFA II (Ref. 2). FDA also posted video presentations on the medical device user fee program to give the public more background information on the program (Ref. 3).

### **III. Proposed MDUFA III Recommendations**

In preparing the proposed recommendations to transmit to Congress for MDUFA reauthorization, we have conducted discussions with the device industry, and we have consulted

with stakeholders as required by law. We began the MDUFA reauthorization process with a public meeting held on September 14, 2010 (75 FR 49502, August 13, 2010). The meeting included presentations by FDA and a series of panels representing different stakeholder groups, including patient advocates, consumer groups, the device industry, health care professionals, and scientific and academic experts.

From January 2011 through February 2012, FDA conducted negotiations with representatives of the device industry: The Advanced Medical Technology Association (AdvaMed); the Medical Device Manufacturers Association (MDMA); the Medical Imaging and Technology Alliance (MITA); and, the American Clinical Laboratory Association (ACLA). FDA also held monthly consultations with public stakeholders during that time period. As directed by Congress, FDA posted minutes of these discussions on its Web site (Ref. 4).

The proposed recommendations for MDUFA III address many of the priorities and concerns identified by public stakeholders and the device industry, and many of the important challenges identified by FDA. Each recommendation is briefly described with reference to the applicable section of the draft commitment letter (Ref. 5).

In conjunction with the proposed enhancements and performance goals outlined in the draft commitment letter, FDA is proposing new user fees and several statutory changes. The specific proposals are briefly described with reference to the applicable section of the draft legislative language (Ref. 6).

#### **A. Process Improvements**

FDA is proposing several process improvements designed to increase the consistency, predictability, transparency, and efficiency of the device review program.

##### **1. Pre-Submissions**

A Pre-Submission provides the opportunity for an applicant to obtain FDA feedback prior to submission of an investigational device exemption or marketing application. Although no specific resources are being allocated through the proposed MDUFA III user fees for the Pre-Submission program, FDA is proposing that we will institute a structured process for managing Pre-Submissions, as resources permit, and not to the detriment of meeting the quantitative review timelines in this proposal and statutory obligations. FDA is proposing to issue a draft guidance document and final guidance document on Pre-Submissions. The draft

commitment letter includes additional details on the manner in which FDA intends to manage Pre-Submissions. These details can be found in section I.A of the draft commitment letter.

##### **2. Submission Acceptance Criteria**

FDA is proposing to implement revised submission acceptance criteria through the publication of guidance. These revised criteria are intended to ensure that FDA is only reviewing complete submissions. The guidance will outline electronic copy of submissions (e-Copy) and objective criteria for revised “refuse to accept/refuse to file” checklists. This recommendation can be found in section I.B of the draft commitment letter. FDA is also proposing corresponding statutory language mandating e-Copy of submissions; this statutory requirement would be implemented through the guidance described in this paragraph. (See section III.L of this document for further information about this proposed statutory change).

##### **3. Interactive Review**

FDA is proposing to continue to incorporate an interactive review process to provide for, and encourage, informal communication between FDA and applicants to facilitate timely completion of the review process based on accurate and complete information. This recommendation can be found in section I.C of the draft commitment letter.

##### **4. Guidance Document Development**

FDA is proposing to apply user fee revenues to supplement the improvement of the process of developing, reviewing, tracking, issuing, and updating guidance documents. This recommendation can be found in section I.D of the draft commitment letter.

##### **5. Third Party Review**

Although no specific resources are being allocated through the proposed MDUFA III user fees for the Third Party Review program, FDA is recommending reauthorization of the program and will work with interested parties to strengthen and improve the current program as resources permit. This recommendation can be found in section I.E of the draft commitment letter.

##### **6. Patient Safety and Risk Tolerance**

FDA proposes to fully implement final guidance on factors to consider when making benefit-risk determinations in medical device

premarket review. FDA also proposes to meet with patient groups during MDUFA III to better understand the patient perspective on disease severity or unmet medical need. FDA also proposes to increase its utilization of FDA's Patient Representatives to provide patients' views early in the medical product development process. This recommendation can be found in section I.F of the draft commitment letter.

#### 7. Low Risk Medical Device Exemptions

FDA proposes to identify additional low risk medical devices to exempt from premarket notification. This recommendation can be found in section I.G of the draft commitment letter.

#### 8. Emerging Diagnostics

FDA proposes to work with industry to develop a transitional In Vitro Diagnostics (IVD) approach for the regulation of emerging diagnostics. This recommendation can be found in section I.H of the draft commitment letter.

#### *B. Review Performance Goals—Fiscal Years 2013 Through 2017 as Applied to Receipt Cohorts*

FDA is proposing to meet more rigorous goals for MDUFA III while streamlining management of the program. In making these proposals, we have taken into account efficiencies planned for in MDUFA III including: Additional scientific, regulatory, and leadership training; additional staff, including those with expertise demanded by increasingly complex device reviews; improved submission acceptance criteria; and information technology improvements that allow us to better track and manage the device review process.

FDA is proposing to eliminate the "two-tier" goal structure that we believe is an impediment to improving average total time to decision and to reaching the ultimate goal of the medical device user fee program—for safe and effective devices to reach patients and health care professionals more quickly. FDA is proposing a more simplified goal structure, which will be easier to implement and will improve predictability of the program, leaving the program less prone to unintended consequences. The simplified goal structure includes a single, high percentage goal for each performance metric. This provides more clarity to industry so applicants will know when to expect feedback from the Agency on their marketing submissions, and allows the Agency's review staff to better

manage their time. This structure also allows more flexibility in the Agency's management strategy, allowing for adjustments as needed to ensure achievement of the desired outcomes—specifically, reducing review cycles and reducing average total time to decision.

FDA is proposing decision goals of 180 FDA days for premarket approval applications (PMAs) that do not require Advisory Committee input and for 180-Day PMA Supplements, 320 FDA days for PMAs that do require Advisory Committee input, 90 FDA days for Real-Time PMA Supplements, and 90 FDA days for premarket notification (510(k)) submissions. FDA is proposing performance goals for Clinical Laboratory Improvement Amendments (CLIA) waiver applications: 210 FDA days for dual submission of a 510(k) and CLIA waiver application; 180 FDA days for a CLIA waiver application not requiring Advisory Committee input; and 330 FDA days for CLIA waiver applications that do require Advisory Committee input. For each of these decision goals, FDA is proposing to "ramp-up" the percentage of applications that will be completed within the goal time line during the 5-year time period to correspond with the timetable for additional staff to be hired during MDUFA III. The goal percentages will increase to 90 or 95 percent in the final years of the program, depending on the submission type. Additionally, FDA is proposing to institute an acceptance/filing communication and Substantive Interaction goal for several submission types, which will track the Agency's communication with the applicant at specified points during the review process. FDA is proposing to retain the existing goals for Biological Licensing Applications (BLAs) and their supplements. Additional details regarding all of the quantitative review performance goals can be found in section II of the draft commitment letter.

#### *C. Shared Outcome Goals*

FDA and representatives of the device industry believe that the process improvements outlined in the draft commitment letter, when implemented by all parties as intended, should reduce the average Total Time to Decision for PMA applications and 510(k) submissions, provided that the total funding of the device review program adheres to the assumptions underlying the agreement. Reducing average total time to decision is an important aspect of the ultimate goal of the user fee program, so that safe and effective devices reach patients and health care professionals more quickly. FDA proposes to report, on an annual basis,

the average Total Time to Decision, as defined in the draft commitment letter, for PMA and 510(k) submissions, with shared goals for FDA and industry of 395 calendar days for PMAs and 135 calendar days for 510(k)s beginning with the FY 2013 receipt cohort, declining to 385 calendar days for PMAs and 124 calendar days for 510(k)s for the FY 2017 receipt cohort. Additional details regarding the shared outcome goals can be found in section III of the draft commitment letter.

#### *D. Infrastructure*

FDA is proposing to apply user fee revenues to improve scientific and regulatory review capacity by reducing the ratio of review staff to front line supervisors and enhancing and supplementing scientific review capacity. FDA is seeking to obtain streamlined hiring authority in order to accomplish this (see section III.M of this document). FDA is proposing to apply user fee revenues to supplement training programs. FDA is proposing to continue efforts to improve its IT systems. Additional details regarding the infrastructure proposals can be found in section IV of the draft commitment letter.

#### *E. Independent Assessment of Review Process Management*

In order to implement continued program improvements and efficiencies, FDA is proposing to conduct a comprehensive assessment of the process for the review of device applications. FDA is proposing to incorporate findings and recommendations of the independent assessment into its management of the premarket review program. Additional details regarding the independent assessment proposal can be found in section V of the draft commitment letter.

#### *F. Performance Reports*

FDA is proposing to report its progress toward meeting the goals in the draft commitment letter through quarterly and annual reporting. The proposed reporting structure includes more detailed reporting than the Agency agreed to provide during MDUFA II. Additional details regarding the performance reporting structure can be found in section VI of the draft commitment letter.

#### *G. MDUFA III Inflation and Fee Adjustments*

In calculating user fees for each new FY in MDUFA III, FDA proposes to adjust the base revenue amount by inflation. This methodology is specified in the draft legislative language. The

inflation adjuster accounts for changes in FDA's costs related to payroll compensation and benefits as well as changes in non-payroll costs through use of the Consumer Price Index. This weighted composite inflation adjuster will provide a degree of assurance that fees during MDUFA III keep pace with FDA's costs. Additionally, FDA proposes to adjust establishment registration fees annually, as needed, to account for any unanticipated variations in submission and registration quantities that are likely to result in FDA collecting more or less than the authorized amount of fees each year (as adjusted for inflation). Additional details regarding the annual fee setting and adjustments can be found in section 738(c) of the draft legislative language.

#### *H. Impact of MDUFA III Enhancements on User Fee Revenue*

Implementing the proposed enhancements discussed in the previous sections of this document will require approximately \$595 million, before adjustments for inflation, in device user fee revenue over the course of the 5-year MDUFA III period, FY 2013 through FY 2017. Proposed user fee collections, before adjustments for inflation, are: \$97,722,301 in FY 2013; \$112,580,497 in FY 2014; \$125,767,107 in FY 2015; \$129,339,949 in FY 2016; and \$130,184,348 in FY 2017. This user fee revenue will support approximately 208 additional full-time equivalent (FTE) staff by the end of the MDUFA III period. In addition, these fee levels will support the continued funding of approximately 32 FTEs over current staffing levels that FDA plans to hire by the end of FY 2012 under MDUFA II using currently authorized and appropriated user fees. Therefore, the net increase over current staffing levels will be approximately 240 FTEs as a result of this proposal. Collections slightly above proposed user fee spending in the early years of MDUFA III will ensure that funds are available to hire additional staff in order to meet the proposed commitments, and will be balanced by collections slightly below proposed user fee spending in the later years of MDUFA III. As in MDUFA II, the premarket application fee and the establishment registration fee are set during the annual fee setting, and other submission fees are determined as a percentage of the premarket application fee. In MDUFA III, the percentage associated with a premarket notification (510(k)) is being raised from 1.84 percent of a premarket application fee to 2.0 percent of a premarket application fee. All other percentages remain the same as during MDUFA II. Base fee

amounts for premarket applications, prior to adjustments for inflation, are proposed as: \$248,000 in FY 2013; \$252,960 in FY 2014; \$258,019 in FY 2015; \$263,180 in FY 2016; and \$268,443 in FY 2017. Base fee amounts for establishment registration, prior to annual adjustments, are proposed as: \$2,575 in FY 2013; \$3,200 in FY 2014; \$3,750 in FY 2015; \$3,872 in FY 2016; and \$3,872 in FY 2017. Additional details regarding the MDUFA III fees can be found in section 738(a) and (b) of the draft legislative language.

#### *I. Establishment Registration Fee Exemptions*

The proposed legislative language eliminates exemptions under MDUFA II that allowed certain types of establishments to meet their requirement to register without incurring a fee. This amendment will increase the base of establishments paying registration fees. Additional details regarding this modification can be found in section 737(13) of the draft legislative language.

#### *J. Fee Waiver or Reduction Authority*

FDA is proposing a provision for the Secretary of Health and Human Services (Secretary), in the Secretary's sole discretion, to grant a waiver or reduction of fees if the Secretary finds that such waiver or reduction is in the interest of public health. Additional details regarding this provision can be found in section 738(f) of the draft legislative language.

#### *K. Appropriations and Spending Triggers*

FDA is proposing to update the appropriations trigger and the spending trigger to FY 2009 levels. This will provide assurance to industry that user fees will be additive to Budget Authority appropriations, as was the original intent of the user fee program and of the appropriations and spending triggers. Additional details regarding these updates can be found in section 738(h)(1)(A) and (i)(2)(A)(ii) of the draft legislative language.

#### *L. Electronic Copy of Submissions*

In order to implement revised submission acceptance criteria, FDA is proposing statutory language requiring an electronic copy (e-Copy) to be provided with any pre-submission or submission for devices. The proposed language provides that implementation of this requirement would occur following issuance of final guidance providing standards for such electronic copy. Additional details regarding this provision can be found under the

heading "Subchapter D—Information and Education" in the draft legislative language.

#### *M. Streamlined Hiring Authority*

In order to facilitate the steep ramp-up in hiring necessary to accomplish the goals agreed to in the draft commitment letter, FDA is proposing statutory language that would grant streamlined hiring authority to FDA for the first 3 years of MDUFA III. Additional details regarding this provision can be found under the heading "STREAMLINED HIRING AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION TO SUPPORT ACTIVITIES RELATED TO THE PROCESS FOR THE REVIEW OF DEVICE APPLICATIONS" in the draft legislative language.

#### **IV. References**

The following references have been placed on display in the Division of Dockets Management (see Comments) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. The minutes from FDA's negotiation and stakeholder meetings are available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm236902.htm>.

2. The MDUFA II commitment letter, key **Federal Register** documents, MDUFA II-related guidance documents, legislation, performance reports, and financial reports and plans are available at [www.fda.gov/MDUFA](http://www.fda.gov/MDUFA).

3. The pre-recorded video presentations are available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109316.htm>. FDAAA-specific information is available at <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendments/totheFDCA/FoodandDrugAdministrationAmendmentsActof2007/default.htm>.

4. The minutes from FDA's negotiation and stakeholder meetings are available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm236902.htm>.

5. Further information can be found on FDA's Web site at <http://www.fda.gov/MedicalDevices/NewsEvents/>

*WorkshopsConferences/ucm292860.htm.*

6. Further information can be found on FDA's Web site at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm292860.htm>.

## V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm292860.htm>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at <http://www.regulations.gov> approximately 30 days after the public meeting.

Dated: March 15, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-6707 Filed 3-15-12; 4:15 pm]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Request for Comments on the Update of the Scholarships for Disadvantaged Students Program

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) updates and clarifies the implementation of the Scholarships for Disadvantaged Students (SDS) program under authority of Section 737 of the Public Health Service Act (PHS Act). The publication of the final notice will supersede all previous notices regarding the SDS program.

**DATES:** *Effective Date:* The program clarifications described in this notice will be implemented in fiscal year (FY) 2012 and beyond and will become effective for SDS funds awarded to schools in FY 2012 and beyond.

*Purpose:* HRSA is updating the SDS program to increase the impact of the program in the areas addressed in the program's authorizing statute. Specifically, the authorizing statute allows the Secretary to make grants to eligible entities that are carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups. (PHS Act, Sec. 737(d)(1)(B)). In addition, grantees provide scholarships to individuals who meet the following requirements: (1) are from disadvantaged backgrounds; (2) have a financial need for a scholarship; and (3) are enrolled (or accepted for enrollment) at an eligible health professions or nursing school as a full-time student in a program leading to a degree in nursing or a health profession. (PHS Act, Sec. 737(d)(2)(A-C)). Under the statute, priority is given to eligible entities based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities. (PHS Act, Sec. 737(c)).

*Current Program:* To be eligible, at least 10 percent of a school's enrollment and graduates must be disadvantaged individuals, and eligible entities must be carrying out a recruitment and retention program for students from disadvantaged backgrounds. For the purposes of the SDS program, an individual from a disadvantaged background is defined as one who: (1) Comes from an environment that has inhibited the individual from obtaining the knowledge, skills, and abilities required to enroll in and graduate from a health profession or nursing school, or from a program providing education or training in allied health professions; or (2) comes from a family with an annual income below the established Census Bureau low-income thresholds, adjusted by the Secretary for health professions and nursing programs eligibility. Eligible entities are: schools of allopathic and osteopathic medicine; dentistry; optometry; pharmacy; podiatric medicine; veterinary medicine; nursing (associate, diploma, baccalaureate, and graduate degree); public health; chiropractic; allied health (baccalaureate and graduate degree programs of dental hygiene, medical laboratory technology, radiology technology, speech pathology, audiology, registered dietitians, and occupational therapy and physical therapy); mental and behavioral health (graduate degree programs in clinical

psychology, clinical social work, professional counseling, marriage and family therapy); and physician assistant training. (PHS Act, Sec. 737(d)(1)(A)). Grant awards are determined by formula with the three priority areas based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities. There is also a requirement to award at least 16 percent of the available funds to nursing students (PHS Act Section 740(a)). The amount of the scholarship may not exceed a recipient's cost of tuition expenses, other reasonable educational expenses and reasonable living expenses incurred in attendance at such a school. The scholarship may be expended by the student only for such expenses. The average annual student award is \$2,300.

*Issues:* First, the SDS program grantee population has grown from 401 schools in FY 2000 to almost 700 health profession schools in FY 2011. Since all SDS eligible schools receive grant awards, the funding has been divided into ever decreasing amounts per school over the years. Many of the schools, in an effort to provide funding to each of their disadvantaged students, spread the award equally among the disadvantaged students and the smaller school award amounts result in smaller student scholarship amounts. While the student scholarship amounts have been decreasing, the tuition rates have been increasing. For many students with insufficient financial resources, the small award size is unlikely to provide enough funds to continue in school. Second, the primary care and underrepresented minority student priority weights currently used are too small to adequately incentivize and reward schools that are successful in graduating primary care underrepresented minority students or have excellent plans to improve their programs to recruit and retain students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups. Also, the primary care weights are not enough to incentivize schools to increase the proportion of graduating students going into primary care. Third, the practice of awarding grants for one year at a time does not allow the schools to select financially disadvantaged applicants with the assurance that a student will receive SDS financial aid for the entire time the student is enrolled.

#### *Proposed Changes:*

To provide larger award amounts to schools and to increase the retention and graduation of underrepresented