

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 October 26, 2011, the committee will discuss, make recommendations, and vote on information related to the premarket approval application sponsored by AtriCure, Inc., for the AtriCure Synergy Ablation System to be used for the treatment of atrial fibrillation in patients who are undergoing open concomitant cardiac surgery. The AtriCure Synergy Ablation System consists of the following:

- The AtriCure Isolator Synergy Handpieces (models OLL2 and OSL2), which resemble surgical clamps, include a syringe-type grip handle/actuator, connected by a cylindrical shaft to a pair of grasping jaws with electrodes on each jaw. The electrodes deliver radiofrequency (RF) energy to the tissue grasped by the jaws.
- The Ablation and Sensing Unit is an RF generator used to power the Isolator Synergy Handpieces.
- The Isolator Switch Matrix is an accessory interface module allowing the Isolator Synergy Handpieces to connect to the RF generator.

On October 27, 2011, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for the Medtronic Ablation Frontiers Cardiac Ablation System sponsored by Medtronic, Inc. The Medtronic Ablation Frontiers Cardiac Ablation System is a catheter-based device developed for the treatment of atrial fibrillation. The system consists of the following:

- The Pulmonary Vein Ablation Catheter, which is designed to create lesions in the left atrium via five pairs of electrodes to isolate the pulmonary veins. It has a deflectable distal end and bidirectional steering to aid in positioning the catheter appropriately.
- The Multi-Array Septal Catheter, which is designed to create lesions on the septal wall of the left atrium via six pairs of electrodes. It is not steerable and is intended to be used in a transeptal approach.
- The Multi-Array Ablation Catheter, which is designed to create "X"-like lesions in the left and/or right atrium via four pairs of electrodes. It has a deflectable distal segment and

bidirectional steering within a single plane.

- The GENius Multi-Channel RF Ablation Generator.

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/AdvisoryCommittees/Calendar/default.htm>. 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 October 19, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on October 26 and 27. Those individuals interested in making 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 October 11, 2011. 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 October 13, 2011.

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 AnnMarie Williams, Conference Management Staff, 301-796-5966, 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/AdvisoryCommittees/AboutAdvisoryCommittees/>

[ucm111462.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: September 13, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-23875 Filed 9-16-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0352]

Prescription Drug User Fee Act IV Information Technology Plan

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an updated information technology (IT) plan entitled "PDUFA IV Information Technology Plan" (updated plan) to achieve the objectives defined in the Prescription Drug User Fee Act (PDUFA) Performance Goals. This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the process for the review of human drug applications. The FDA is publishing the updated plan for comment to allow the public to provide feedback as the Agency moves towards a fully electronic standards-based submission and review environment.

DATES: Submit electronic or written comments on the updated plan by November 3, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2008-N-0352, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):*

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2008-N-0352. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Alfred Kempinski, Office of the PDUFA Business Program Manager, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1127, Silver Spring, MD 20993-0002, 301-796-1999.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an updated IT plan entitled "PDUFA IV Information Technology Plan." This plan will meet one of the performance goals agreed to under the 2007 reauthorization of PDUFA IV (Title I of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85)). Under section XIV of the PDUFA Performance Goals, FDA agreed to develop, periodically update, and publish for comment an IT plan for achieving the objectives defined in section XIV, Information Technology Goals, of the PDUFA Performance Goals (see <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119243.htm>). This plan is intended to provide regulated industry and other stakeholders with information on FDA's vision and plan for improving the automation of business processes and maintaining information systems that support the process for the review of human drug applications, to achieve the objectives defined in section XIV of the PDUFA Performance Goals. The objectives of the PDUFA IV IT Goals are to move FDA towards the long-term goal of an automated standards-based information technology environment for the exchange, review, and management

of information supporting the process for the review of human drug applications throughout the product life cycle.

In the **Federal Register** of June 30, 2008 (73 FR 36880), FDA issued a notice announcing the availability of an earlier version of the IT plan entitled "Prescription Drug User Fee Act (PDUFA) IV Information Technology Plan" (June 2008 plan). This updated plan revises the June 2008 plan; it communicates the progress and strategic changes for key initiatives that illustrate the accomplishment of near-term objectives and describes FDA's strategy for meeting the long-term goal of a fully electronic submission and review environment. The sections that have been revised are identified in the Revision Index (after the Table of Contents) in the updated plan.

FDA conducts an annual IT assessment to measure performance against the IT plan. The 2010 Annual IT Assessment is available at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm183308.htm>.

II. Electronic Access

Persons with access to the Internet may obtain the updated plan at <http://www.regulations.gov>.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. 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.

Dated: September 12, 2011.

Leslie Kux,

Acting Assistant 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, 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 or call the HRSA Reports Clearance Officer at (301) 443-0165.

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: Health Professions Student Loan (HPSSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy) (OMB No. 0915-0047)—[Extension]

The regulations for the Health Professions Student Loan (HPSSL) Program and Nursing Student Loan (NSL) Program contain a number of reporting and recordkeeping requirements for schools and loan applicants. The requirements are essential for assuring that borrowers are aware of rights and responsibilities, know the history and status of each loan account in order to pursue aggressive collection efforts to reduce default rates, and that they maintain adequate records for audit and assessment purposes. Schools are free to use improved information technology to manage the information required by the regulations.

The estimated total burden is 49,489 hours. The annualized burden estimates are as follows: