DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Tobacco Products Scientific Advisory Committee (TPSAC).

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 2, 2011, from 9 a.m. to 5 p.m., and on November 3, 2011, from 8 a.m. to 5 p.m.

Location: Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd. rm. 020B, Rockville, MD 20850, 1–877–287–1373.

Contact Person: Caryn Cohen, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose option 4), e-mail: *TPSAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for 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: The committee will continue the discussions of issues related to the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children, as part of TPSAC's required report to the Secretary of Health and Human Services. Discussion will include such topics as the composition and characteristics of dissolvable tobacco products, product use, potential health effects, and marketing.

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: On November 2, 2011, from 1 p.m. to 5 p.m., and on November 3, from 8 a.m. to 5 p.m., the meeting is open to the public. 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 11 a.m. and 12 noon on November 3, 2011. 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 12, 2011.

Closed Committee Deliberations: On November 2, 2011, from 9 a.m. to 12 noon, the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). This portion of the meeting must be closed because the committee will be discussing trade secret and/or confidential data provided by the tobacco companies regarding dissolvable tobacco products.

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 Caryn Cohen 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. 2011–23868 Filed 9–16–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 26 and 27, 2011, from 8 a.m. to 6 p.m.

Location: Hilton Washington, DC, North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, e-mail: *james.swink@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for

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 transseptal 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):*