

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. FDA-2010-N-0646]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Tobacco Products, Exemptions From Substantial Equivalence Requirements**
**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Tobacco Products, Exemptions From Substantial Equivalence Requirements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On June 1, 2011, the Agency submitted a proposed collection of information entitled "Tobacco Products, Exemptions From Substantial Equivalence Requirements" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0684. The approval expires on August 14, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: September 6, 2011.

**Leslie Kux,**
*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-23184 Filed 9-9-11; 8:45 am]

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**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 13, 2011, from 8 a.m. to 6 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, 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 20993-0002, 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 13, 2011, the committee will discuss, make recommendations, and vote on information related to the premarket approval application (PMA) for the Cook, Inc., ZILVER-PTX Drug-Eluting Stent. The ZILVER-PTX Stent is a self-expanding nitinol stent coated on its outer surface with the cytotoxic drug paclitaxel without any polymer, binder, or excipient at a dose density of 3 micrograms/square millimeter. The ZILVER-PTX Stent is available in diameters ranging from 5 to 10 millimeters (mm) and lengths of 20 to 80 mm and are pre-loaded onto 6 or 7 Fr<sup>1</sup> (diameter of 2 or 2.3 mm) delivery systems. Upon deployment, the ZILVER-PTX Stent expands to establish and maintain patency in the stented region. The proposed indications for use are: treatment of de novo or restenotic symptomatic vascular disease of the above-the-knee femoropopliteal arteries

<sup>1</sup> "Fr" stands for French. It is a term that defines the diameter of a catheter.

having reference vessel diameter from 4 mm to 9 mm and total lesion lengths per patient of 280 mm.

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 5, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on October 13, 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 September 28, 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 September 30, 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 at 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/ucm11462.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 6, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-23130 Filed 9-9-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0128]

#### Prescription Drug 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 Prescription Drug User Fee Act (PDUFA), which authorizes FDA to collect user fees and use them for the process for the review of human drug applications for fiscal years (FYs) 2013 through 2017. The legislative authority for PDUFA expires in September 2012. At that time, new legislation will be required for FDA to collect prescription drug user fees for future fiscal years. Following discussions with the regulated 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 October 24, 2011, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by October 10, 2011. See section IV.B of this document for information on how to register for the meeting. Submit either electronic or written comments by October 24, 2011.

**ADDRESSES:** The meeting will be held at FDA's White Oak Campus, 10903 New

Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD, 20993.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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 (see section IV.C of this document).

#### FOR FURTHER INFORMATION CONTACT:

Sunanda Bahl, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 1168, Silver Spring, MD 20993, 301-796-3584, fax: 301-847-8443, [PDUFAreauthorization@fda.hhs.gov](mailto:PDUFAreauthorization@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

FDA is announcing a public meeting to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA), which authorizes FDA to collect user fees and use them for the process of the review of human drug applications for FYs 2013 through 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process. Section 736B(d)(4) (21 U.S.C. 379h-2(d)(4)) of the FD&C Act requires that after FDA holds negotiations with regulated industry and periodic consultations with stakeholders, we do the following: (1) Present recommendations to congressional committees, (2) publish recommendations in the **Federal Register**, (3) provide a period of 30 days for the public to provide written comments on the recommendations, (4) hold a meeting at which the public may present its views, and (5) after consideration of public views and comments, revise the recommendations as necessary.

This notice, the 30-day comment period, and the public meeting will satisfy some of these requirements. After the public meeting, we will revise the recommendations as necessary and present our proposed recommendations to the congressional committees.

The purpose of the meeting is to hear the public's views on the proposed recommendations for the reauthorized program (PDUFA V). The following

information is provided to help potential meeting participants better understand the history and evolution of the PDUFA program and the current status of the proposed PDUFA V recommendations.

## II. The PDUFA Program

### A. What is PDUFA? What does it do?

FDA considers the timely review of the safety and effectiveness of new drug applications (NDAs) and biologics license applications (BLAs) to be central to the Agency's mission to protect and promote the public health. Prior to enactment of PDUFA in 1992, FDA's drug review process was not very predictable and was relatively slow compared to other countries. As a result of concerns expressed by both industry and patients, Congress enacted PDUFA, which provided the added funds through user fees that enabled FDA to hire additional reviewers and support staff and upgrade its information technology systems. At the same time, FDA committed to complete reviews in a predictable timeframe. These changes revolutionized the drug approval process in the United States and enabled FDA to speed the application review process for new drugs and biologics without compromising the Agency's high standards for demonstration of safety, efficacy, and quality of new drugs prior to approval.

### B. PDUFA Achievements

PDUFA has produced significant benefits for public health, providing patients faster access to over 1,500 new drugs and biologics since enactment in 1992, including treatments for cancer, infectious diseases, neurological and psychiatric disorders, and cardiovascular diseases. The United States now leads the world in the first introduction of new active drug substances.<sup>1</sup> Since PDUFA was enacted, the median approval time of original NDAs and BLAs has been reduced by about 50 percent for standard applications (25.6 months in FY 1992 versus 13 months in FY 2009) and 55 percent for priority applications (19.9 months in FY 1992 versus 9 months in 2009).

Increased resources provided by user fees have also enabled FDA to provide a large body of technical guidance to industry that has clarified the drug development pathway for many diseases. These resources have also enhanced FDA's ability to meet with companies during drug development to

<sup>1</sup> Scrip NCE Review/Scrip Yearbook/Scrip Magazine (1982-2005), PharmaProjects R&D Annual Review (2006-2009).