

**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.*

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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