Estimated Total Annual Burden Hours: 2,890,539.87

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, E-mail: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Dated: August 2, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2010–19268 Filed 8–4–10; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0348]**

### Center for Devices and Radiological Health 510(k) Working Group Preliminary Report and Recommendations, and Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations; Availability; Request for Comments

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

**ACTION:** Notice; request for comment.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for public comment of a two-volume set of documents entitled "Center for Devices and Radiological Health Preliminary Internal Evaluations," which is comprised of the preliminary reports of two internal committees: The 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making. Volume I is entitled "510(k) Working Group Preliminary Report and Recommendations." Volume II is entitled "Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations." The recommendations contained in these reports are preliminary. FDA has not made any decisions on specific changes to pursue. FDA is soliciting public input on the recommendations discussed in these reports, including the feasibility of implementation and potential alternatives. Once its assessment of public input and other necessary reviews are completed, FDA will announce which improvements it will implement, as well as projected timelines for implementation.

**DATES:** Submit either electronic or written comments on the preliminary report by October 4, 2010.

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit electronic comments on the preliminary report 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. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5447, Silver Spring, MD 20993–0002, 301–796–5678.

**SUPPLEMENTARY INFORMATION:**

## I. Background

### *A. 510(k) Working Group*

The premarket notification (510(k)) process for the review of medical devices was established in 1976, under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). With the exception of certain low-risk devices that are exempt from premarket submission requirements, a medical device that is first introduced into the market after May 28, 1976 (a postamendment device) may be legally marketed without an approved premarket approval application (PMA) if FDA concludes through review of a 510(k) submission that the device meets the comparative standard of "substantial equivalence" to a "predicate" device. Substantial equivalence may be determined by a comparison to a device that was legally marketed prior to May 28, 1976 (a preamendment device), to a device that has been reclassified from class III (high-risk) to class II or class I (medium- to low-risk), or to a device that has previously been cleared through the 510(k) process.

Since its inception, the 510(k) process has undergone a number of statutory changes. In addition, FDA has modified its implementation of the process to adapt to changing circumstances and accommodate the evolving medical device landscape. The current 510(k) program reflects the current statutory framework and FDA's implementation of that framework through regulation, guidance, and administrative practice.

The 510(k) program, as it currently exists, is intended to support FDA's public health mission by meeting two important goals: making available to consumers devices that are safe and effective, and fostering innovation in the medical device industry. In recent years, concerns have been raised within and outside of FDA about whether the current 510(k) program optimally achieves these goals.

In September 2009, CDRH convened an internal 510(k) Working Group as part of a two-pronged, comprehensive assessment of the 510(k) process. The other component of this assessment is an ongoing independent study by the Institute of Medicine, which is expected to conclude in the summer of 2011. The 510(k) Working Group was charged to evaluate the 510(k) program and explore actions CDRH could take to strengthen the program and improve the consistency of its decision making, with a principal focus on actions the Center could take in the short term under its existing statutory authority.

### *B. Task Force on the Utilization of Science in Regulatory Decision Making*

CDRH uses science to guide its regulatory decision making across the total product life cycle of medical devices and radiation-emitting products. At any stage of that life cycle, CDRH may encounter new, unfamiliar, or unexpected information that may influence its thinking, expectations, and actions. To fulfill its mission to protect and promote the public health, CDRH must strike a balance between the ability to adapt its approach as necessary as new science emerges, and the desire to provide predictable regulatory pathways that foster innovation.

In September 2009, CDRH convened an internal Task Force on the Utilization of Science in Regulatory Decision Making to review how CDRH uses science in its regulatory decision making, and to make recommendations on how the Center can quickly incorporate new science—including

evolving information, novel technologies, and new scientific methods—into its decision making, while also maintaining as much predictability as practical.

*C. Preliminary Reports*

FDA is making available for public comment a two-volume set of documents entitled "Center for Devices and Radiological Health Preliminary Internal Evaluations." Volume I is entitled "510(k) Working Group Preliminary Report and Recommendations." This preliminary report is intended to communicate preliminary findings and recommendations regarding the 510(k) program and actions CDRH might take to address identified areas of concern. Volume II is entitled "Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations." This preliminary report is intended to communicate preliminary findings and recommendations regarding the incorporation of new scientific information into CDRH's decision making and actions CDRH might take to address identified areas of concern.

Interested persons are invited to comment on either or both of these preliminary reports. CDRH will consider comments received prior to finalizing the two reports and determining which, if any, recommendations to implement in their current or a modified form.

## II. 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.

## III. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.regulations.gov* or *http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/default.htm* (select appropriate option from the menu).

Dated: July 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–19339 Filed 8–4–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0001]**

### 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). The meeting will be open to the public.

*Name of Committee*: Tobacco Products Scientific 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 August 30, 2010, from 8:30 a.m. to 12 noon.

*Location*: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. The hotel telephone number is 301–590–0044.

*Contact Person*: Cristi Stark, 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), code 8732110002. 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 August 30, 2010, the committee will receive a report from the Tobacco Product Constituents Subcommittee and discuss a proposed initial list of harmful or potentially harmful constituents, the rationale for inclusion of each constituent, established analytical methods as well as the ancillary methods and normalization standards for the identified constituents.

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 August 23, 2010. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. Those desiring to make 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 August 13, 2010. 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 August 16, 2010.

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 Cristi Stark 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).