FDA under section 911(g) (21 U.S.C. 387k(g)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) must be in effect with respect to the tobacco product. 21 U.S.C. 387k(a). Any person may submit an application seeking an order under section 911(g) of the FD&C Act.

Section 911(f) of the FD&C Act (21 U.S.C. 387k(f)) requires FDA to refer modified risk tobacco product applications to the Tobacco Products Scientific Advisory Committee (TPSAC) for its recommendations. TPSAC is required to report its recommendations on an application to FDA no later than 60 days after the date the application is referred to them. 21 U.S.C. 387k(f)(2). On April 30, 2013, FDA will present information to the committee on the process it will use to refer individual modified risk tobacco product applications to TPSAC.

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 meeting link.

Procedure: On April 30, 2013, from 8:30 a.m. to 3 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 April 23, 2013. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on April 30, 2013. 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 April 15, 2013. 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 April 16, 2013.

Closed Committee Deliberations: On April 30, 2013 from 3:30 p.m. to 5:30 p.m., 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)).

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: April 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08069 Filed 4–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0329]

Center for Devices and Radiological Health: Health of Women Program; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop: ''The Center for Devices and Radiological Health (CDRH) Health of Women (HoW) Program: Educate, Enable, Enlist and Explore—HoW to Improve the Health of Women.'' CDRH is developing the HoW Program to explore unique issues in the regulation of medical devices related to the health of women and seeks public input on the priority activities. The CDRH HoW program seeks to bring together industry, clinicians, researchers, academia, government agencies, and patient/advocacy groups in an effort to: (1) Highlight device-specific clinical Study recruitment and retention strategies; (2) improve analysis and communication of sex-specific findings to providers and patients; (3) develop a priority research road map for the HoW device ecosystem. The workshop focus will be device- and disease-specific, patient centered, and action oriented.

Dates and Times: The public workshop will be held on June 24, 2013, from 8 a.m. to 5 p.m. and June 25, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held on FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993.

Contact: Nada Hanafi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5422, Silver Spring, MD 20993–0002, 301–796–5427, *Nada.Hanafi@fda.hhs.gov;* or Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5568, Silver Spring, MD 20993–0002, 301–796–6349, *Kathryn.OCallaghan@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 5 p.m. on June 14, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration will be provided beginning at 7:30 a.m. on the day of the public workshop.

If you need special accommodations due to a disability, please contact Joyce Raines (*Joyce.Raines@fda.hhs.gov* or 301–796–5709) by 5 p.m. on June 14, 2013.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* and select this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone number and primary HoW Program area of expertise or interest. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the public workshop: The plenary portions of this

workshop will be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on June 14, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and connection access information after June 19, 2013. An archived file of the Webcast will be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list).

Workshop format: This workshop will begin with plenary sessions to outline the three primary areas of focus for the CDRH HoW Program. In each area, panels will examine major themes using data-driven case studies with a focus on practical strategies relevant to particular challenges in the medical device arena. Participants will then rotate through breakout sessions, collectively building an action plan for each activity area. The meeting will conclude with specific commitments by stakeholder groups to partner with CDRH and each other in a collaborative effort to educate, enable, enlist and explore, with a common goal of improving the health of women.

Comments: In order to permit the widest possible opportunity to obtain public information from interested persons on the workshop topics, FDA is opening the docket to gather electronic or written comments on the three areas of focus for the HoW workshop identified in section II. Comments received will be reviewed by FDA as part of this effort. The deadline for submitting comments related to this public workshop topic is July 31, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. 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. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section II, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The mission of the CDRH Health of Women (HoW) Program:

To improve the health of women by:

- Improving the availability, consistency, and communication of sex-specific information for the safe and effective use of medical devices in women;
- addressing identified gaps and unmet needs through targeted resources; and
- fostering the development of innovative strategies, technology, and clinical study paradigms.

A key priority in regulatory science for CDRH is improving the health of special populations and addressing their unique health-related issues.[1] CDRH recognizes women as a special population, and seeks to identify and address differences in the safety, effectiveness, and utilization of medical devices for women. There are unique issues in the regulation of medical devices for use by women, which include:

- Uncertainty about medical device performance in women due to inconsistent data analysis and under-representation of women in clinical trials
- Baseline differences in anatomy, physiology, risk factors, disease signs/symptoms, and comorbidities that may be associated with different outcomes of device use
- Potential differences in health communication/health seeking behavior that may impact FDA communication of medical device benefit-risk information to this population
- Different considerations regarding effects of hormones through life stages (first menstrual period (menarche) to menopause; hormone replacement therapy)
- Unique risks and needs related to medical device research involving women of childbearing potential
- Unique risks and needs for pregnant females associated with the use of medical devices, including risk of birth defects (teratogenicity) or complications of pregnancy arising from medical device components such as drugs, chemicals, and certain biomaterials

[1] Food and Drug Administration, ''Regulatory Science in FDA's Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health,'' *http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm274162.pdf*.

II. Topics for Discussion in the Docket and at the Public Workshop

Topics for discussion include:

1. Device-specific clinical study recruitment and retention strategies;
2. Analysis and communication of sex-specific findings to providers and patients; and
3. Priority research road map for the HoW device ecosystem.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08015 Filed 4–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

Information Collection Request Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR Part 60 Regulations and Forms OMB No. 0915–0126—Revision

Abstract: This is a request for a revision of OMB approval of the information collections contained in regulations found at 45 CFR part 60 governing the National Practitioner Data Bank (NPDB) and the forms to be used in registering with, reporting information to, and requesting information from the NPDB. Section 6403 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) Public Law 111–148 requires the transfer of all data in the Healthcare Integrity and Protection Data Bank