DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

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 Thursday, February 18, 2016, from 8 a.m. to 6 p.m.


Contact Person: Dimitrus Culbreath, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD, 20993, Dimitrus.Culbreath@fda.hhs.gov, 301–796–6872, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The Committee will discuss and make recommendations on clinical trial, postapproval study design, and physician training requirements for leadless cardiac pacemaker device technology. Specifically, the Committee will be asked to make recommendations on the acceptability of adverse event rates in acute and chronic timeframes as well as indications for use for this device type, given availability of other technologies with different adverse event profiles; required training and acceptability of observed learning curves for the new device type and necessary elements for postapproval study collection.

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: 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 February 11, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 February 3, 2016. 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 February 4, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Artair Mallett at 301–796–9638, 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: December 8, 2015.

Jill Hartzler Warner, Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–31372 Filed 12–11–15; 8:45 am]

BILLING CODE 4184–01–P
SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–0990–New–30D for reference.

Information Collection Request Title: Privacy and Security Capacity Assessment of the Title X Network

Abstract: The Office of the Assistant Secretary for Health Office of Population Affairs, (OPA) is requesting an approval by Office of Management and Budget (OMB) for a new information collection (Privacy and Security Capacity Assessment) which seeks to collect feedback from the Title X network regarding Title X grantees’ and service sites’ current privacy and security capabilities for health information exchange. This voluntary form will be administered at most annually and enable the Title X network to share important information to critically inform OPA’s development of Family Planning Annual Report (FPAR 2.0), as well as to identify any training assistance and inform guidance that OPA may offer in the future. OPA will solicit feedback from Title X agencies to advise our work on privacy and security, and proposes to make this data collection form available for up to 3 years so that OPA can accept feedback from the network regarding any changes or trends that might alter our approach to privacy and security as we proceed through the design and build process for the planned FPAR 2.0 data repository. Likely Respondents: Title X Grantees, Subrecipients, and Service Sites.

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<th>Number of responses per respondent</th>
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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Customs Brokers User Fee Payment for 2016


ACTION: General notice.

SUMMARY: This document provides notice to customs brokers that the annual user fee of $138 that is assessed for each customs broker permit. This document notifies customs brokers that for calendar year 2016, the due date for payment of the user fee is February 26, 2016. It is anticipated that for subsequent years, the annual user fee for customs brokers will be due on the last business day of February of each year.

FOR FURTHER INFORMATION CONTACT: Julia Peterson, Broker Management Branch, Office of International Trade, (202) 863–6601.

SUPPLEMENTARY INFORMATION: Pursuant to section 111.96 of title 19 of the Code of Federal Regulations (19 CFR 111.96(c)), U.S. Customs and Border Protection (CBP) assesses an annual user fee of $138 for each customs broker district and national permit held by an individual, partnership, association, or corporation. CBP regulations provide that this fee is payable for each calendar year in each broker district where the broker was issued a permit to do business by the due date. See 19 CFR 24.22(h) and (i)(9). Broker districts are defined in the General Notice entitled, “Geographic Boundaries of Customs Brokerage, Cartage and Lighterage Districts,” published in the Federal Register on March 15, 2000 (65 FR 14011), and corrected, with minor changes, on March 23, 2000 (65 FR 15686) and on April 6, 2000 (65 FR 18151).

As required by 19 CFR 111.96, CBP must provide notice in the Federal Register no later than 60 days before the date that the payment is due for each broker permit. This document notifies customs brokers that for calendar year 2016, the due date for payment of the user fee is February 26, 2016. It is anticipated that for subsequent years, the annual user fee for customs brokers will be due on the last business day of February of each year.

Dated: December 9, 2015.

Brenda B. Smith,
Assistant Commissioner, Office of International Trade.

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[DOCKET ID FEMA–2015–0001]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRM)s and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency’s (FEMA’s) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of April 5, 2016 which has been established for the