performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Pub. L. 105–285, [42 U.S.C. 604 note].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–10863 Filed 5–23–19; 8:45 am]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1281]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of April 24, 2019. The amendment is being made to reflect a change in the **DATES** portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993, 301–796–6875, *Patricio.garcia@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 24, 2019 (84 FR 17173), FDA announced that a meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee would be held on May 30, 2019, from 10 a.m. to 4 p.m. On page 17173, in the third column, in the **DATES** section, the sentence ''The meeting will be held on May 30, 2019, from 10 a.m. to 4 p.m. and on May 31, 2019, from 8 a.m. to 4 p.m.'' is changed to read as follows:

The meeting will be held on May 30, 2019, from 9 a.m. to 4 p.m. and on May 31, 2019, from 8 a.m. to 4 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: May 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10900 Filed 5–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2037]

Electronic Nicotine Delivery System Device and E-Liquid Manufacturer Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is announcing an invitation for participation in its voluntary Electronic Nicotine Delivery System (ENDS) Device and E-Liquid Manufacturer Site Tours Program. This program is intended to give CTP staff an opportunity to visit facilities that develop, manufacture, or test ENDS devices or e-liquids (including pods or cartridges) to gain a better understanding of the processes involved in the development, manufacturing, and testing of ENDS devices and e-liquids. The site tours in this program are not intended as regulatory inspections. The purpose of this document is to invite ENDS device or e-liquid manufacturers that can demonstrate assembly process and present supply chain information, and laboratories that conduct ENDS aerosol and e-liquid testing, that are interested in participating in the ENDS Device and E-Liquid Manufacturer Site Tours Program to submit requests to CTP.

DATES: Submit either an electronic or written request for participation in this program by July 23, 2019. See section IV of this document for information on requests for participation.

ADDRESSES: If your facility is interested in participating in a facility visit, please submit a request either electronically to *https://www.regulations.gov* or in writing to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Karla Price, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) by, among other things, adding a new chapter (chapter IX) granting FDA the authority to regulate tobacco product manufacturing, distribution, and marketing. The Tobacco Control Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law.

On May 10, 2016, FDA published a final rule entitled ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (81 FR 28974), which became effective on August 8, 2016. Under this rule, all products, such as ENDS, that meet the statutory definition of ''tobacco product'' set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), including components and parts, but excluding accessories of newly deemed products, are now subject to chapter IX of the FD&C Act.

CTP's Office of Science is conducting the ENDS Device and E-Liquid Manufacturer Site Tours Program to provide its staff an opportunity to visit facilities that develop, manufacture, or test ENDS devices or e-liquids (including pods or cartridges). The ENDS device and e-liquid facilities are regulated by FDA if they, among other things, manufacture products that meet the statutory definition of a ''tobacco product'' set forth in section 201(rr) of the FD&C Act. The site tours will aid the Agency in gaining a better understanding of the processes involved in developing, manufacturing, and

testing ENDS devices and e-liquids (including pods or cartridges).

II. Description of ENDS Device and E-Liquid Manufacturer Site Tours Program

In the ENDS Device and E-Liquid Manufacturer Site Tours Program, CTP staff will observe the operations of ENDS device and e-liquid manufacturers, including the development, manufacturing, and testing of ENDS devices and e-liquids. The site tours in this program are not intended as regulatory inspections; rather, the program is meant to educate CTP staff and improve their understanding of ENDS devices and e-liquids. It is anticipated that the site tours will take place in 2020.

III. Site Selection

CTP hopes to be able to tour the facilities of different size manufacturers of ENDS devices, as well as facilities that develop or manufacture e-liquids (including pods and cartridges). This includes laboratories that test e-liquids or aerosols. Final site selections will be based on the availability of funds and resources for the relevant fiscal year as well as the desire to visit a wide variety of ENDS device and e-liquid manufacturers. FDA plans on visiting five or fewer ENDS device or e-liquid manufacturers. All travel expenses associated with the ENDS Device and E-Liquid Manufacturer site tours will be the responsibility of FDA.

IV. Requests for Participation

To aid in site selection, your request for participation should include the following information:

- A description of your company, including the size of the organization;
- A list of the ENDS devices and e-liquids your company develops or manufactures, including whether the company performs e-liquid and aerosol testing;
- The name and contact information (including address, phone number, and email) of your point of contact for the request;
- The physical address(es) of the site(s) for which you are submitting a request; and
- A proposed 1-day agenda that will aid with planning travel, indicating start and end times and provides addresses of all sites during the tour.

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–10898 Filed 5–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–E–5055]

Determination of Regulatory Review Period for Purposes of Patent Extension; EDWARDS INTUITY ELITE AORTIC VALVE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for EDWARDS INTUITY ELITE AORTIC VALVE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by July 23, 2019. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 20, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 23, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 20, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–E–5055 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; EDWARDS INTUITY ELITE AORTIC VALVE.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two