

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](mailto: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](mailto: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