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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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.

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