

Dated: September 14, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-3998]

Flavor Developer and 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 Flavor Developer and Manufacturer Site Tours Program. This program is intended to give CTP staff an opportunity to visit companies that develop and/or manufacture flavors (including flavor mixtures) that are sold to tobacco product manufacturers in order to gain a better understanding of the development, testing, and production of flavors and flavor mixtures used in the manufacturing of tobacco products. The site tours in this program are not intended as regulatory inspections. The purpose of this notice is to invite parties interested in participating in the Flavor Developer and Manufacturer Site Tours Program to submit requests to CTP.

DATES: Submit either an electronic or written request for participation in this program by November 20, 2017. See section IV of this document for information on requests for participation.

ADDRESSES: If your company is interested in offering a site 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

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (the 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 (Pub. L. 111-31). 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 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 Flavor Developer and Manufacturer Site Tours Program to provide its staff an opportunity to visit companies that develop and/or manufacture flavors (including flavor mixtures) that are sold to tobacco product manufacturers. Flavor developers and manufacturers 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 development, testing, and production of flavors and flavor mixtures used in the manufacturing of tobacco products. The goal for the Flavor Developer and Manufacturer Site Tours Program is for CTP staff to gain firsthand exposure to how flavors are developed, tested, and produced.

II. Description of Flavor Developer and Manufacturer Site Tours Program

In the Flavor Developer and Manufacturer Site Tours Program, small groups of CTP staff will observe the operations of flavor developers and manufacturers, including the development, testing, and production of flavors that can be used by tobacco

product manufacturers. 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 flavors used in the manufacturing of tobacco products. It is anticipated that the site tours will take place in 2018.

III. Site Selection

CTP hopes to be able to tour small, medium, and large flavor developers and manufacturers, as well as companies that develop and/or manufacture flavors that are used for different categories of tobacco products (e.g., cigarettes, cigars, smokeless tobacco, waterpipe tobacco, e-liquids). 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 flavor developers and manufacturers. All FDA travel expenses associated with the Flavor Developer and 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 flavors your company develops and/or manufactures and the categories of tobacco product (e.g., cigarettes, cigars, smokeless tobacco, waterpipe tobacco, e-liquids) for which your flavors are typically used;
- The physical address(es) of the site(s) for which you are submitting a request; and
- A proposed 1-day tour agenda.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as