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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1208]

Laboratory Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Tobacco Products' (CTP) Office of Science is announcing an invitation for participation in its Laboratory Site Tours Program. This program is intended to give CTP staff an opportunity to visit facilities involved in the testing and analysis of tobacco products and tobacco smoke. These visits are intended to provide CTP staff with the opportunity to gain a better understanding of tobacco science and laboratory operations and are not intended as regulatory inspections or facility visits for the purposes of developing Tobacco Product Manufacturing Practice regulations. The purpose of this notice is to invite parties interested in participating in the Laboratory Site Tours Program to submit their 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]. The request should include a description of your facility, including, as applicable, a list of the types of testing and analyses of tobacco products and tobacco smoke performed. Please specify the physical address(es) of the site(s) for which you are submitting a request, along with a proposed 1-day tour agenda.

ADDRESSES: If your facility is interested in offering a site visit, submit either an electronic request to http://www.regulations.gov or a written request to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carolyn Dresler, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, rm. G335, Silver Spring, MD 20993-0002, 240-402-4067, carolyn.dresler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Public Law 111-31) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing.

CTP's Office of Science is conducting the Laboratory Site Tours Program to provide its scientific and regulatory staff the opportunity to gain a better understanding of tobacco science and laboratory operations, to include tobacco product testing and analysis. CTP's goal for the Laboratory Site Tours Program is for its staff to gain: (1) Firsthand exposure to laboratories that perform tobacco product testing and (2) knowledge of product analyses used by tobacco product manufacturers to ensure product consistency.

II. Description of Site Tours Program

In the Laboratory Site Tours Program, small groups of CTP staff plan to observe the operations of laboratories that perform testing and analyses of tobacco products and tobacco smoke relative to analytical chemistry, microbiology, toxicology, biomarkers of exposure or risk,

and analytical method development. Please note that the Laboratory Site Tours Program is not intended to include official FDA inspections of facilities to determine compliance with the FD&C Act or for the purposes of developing Tobacco Product Manufacturing Practice regulations; rather, the program is meant to educate CTP staff and improve their understanding of laboratory testing and analyses used by the tobacco industry.

III. Site Selection

CTP plans to select a wide variety of laboratories that include academic, private, and those affiliated with tobacco manufacturers. All travel expenses associated with the site tours will be the responsibility of CTP. Final site selections will be based on the availability of CTP funds and resources for the relevant fiscal year, as well as the following factors, if applicable: (1) Compliance status of the requesting facility and affiliated firm, (2) whether the requesting facility is in arrears for user fees, and (3) whether the requesting facility or affiliated firm has a significant request or marketing application or submission pending with FDA.

IV. Requests for Participation

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 Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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