



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0889]

Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), Office of Science is announcing an invitation for participation in its Site Tours Program. This program is intended to give CTP staff an opportunity to visit facilities involved in the growing, processing, or manufacturing of tobacco or currently regulated tobacco products (i.e., cigarettes, roll-your-own, and smokeless tobacco). These visits are intended to provide CTP staff with the opportunity to gain a better understanding of the tobacco industry and its 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 alert parties interested in participating in the Site Tours Program to submit requests to CTP.

DATES: Interested parties should submit either an electronic or written request for participation 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 all tobacco products processed and/ or manufactured there. 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, you should submit a request to participate in the program either electronically to <http://www.regulations.gov> or in writing 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 continuing the Site Tours Program to provide its scientific and regulatory staff the opportunity to gain a better understanding of the tobacco industry and its operations, including tobacco product manufacturing and aspects of tobacco growing, processing, and storage that may affect the physical and chemical properties of tobacco. Although FDA generally does not regulate tobacco farms and tobacco warehouses, the Agency believes that gaining a better understanding of the operations performed at these facilities may be helpful. The goals of the Site Tours Program are to: (1) Provide CTP firsthand exposure to industry's manufacturing processes; (2) learn about control measures used by tobacco product manufacturers to ensure product consistency; (3) understand the processing of different forms of tobacco and the manufacturing processes used for various types of tobacco products and their

influences on product constituents; and (4) understand how growing conditions, curing, storage, and manufacturing processes might influence the levels of tobacco or tobacco smoke constituents.

II. Description of Site Tours Program

In the Site Tours Program, small groups of CTP staff plan to observe the operations of tobacco growers, tobacco warehouses, and tobacco product manufacturing facilities of cigarettes, roll-your-own, and smokeless tobacco companies, including the manufacturing of paper, filters, and pouch materials. Please note that the 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 the tobacco industry and its operations.

III. Site Selection

CTP plans to select one or more of each of the following types of facilities: A large cigarette manufacturing facility, a small cigarette manufacturing facility, a smokeless manufacturing facility, a burley tobacco farm, a flue-cured tobacco farm, a tobacco rolling paper facility, a tobacco warehouse and a tobacco processing facility. 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: (1) Compliance status of the requesting facility and affiliated firm, if applicable; (2) whether the requesting facility is in arrears for user fees; (3) whether the requesting facility or affiliated firm, if applicable, has a significant request or marketing application or submission pending with FDA; and (4) whether the requesting facility will be engaged in active manufacturing or processing during the proposed time of the visit.

IV. Requests for Participation

Requests are to be identified with the docket number found in brackets in the heading of this document. Requests received by the Agency 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: July 14, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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