4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1109]

Tobacco Farm 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 Tobacco Farm Site Tours Program. This program is intended to give CTP staff an opportunity to visit farms that grow tobacco for sale to tobacco product manufacturers in order to gain a better understanding of tobacco farming and the processes involved in curing and preparing tobacco intended for sale to tobacco product manufacturers. This program is not an FDA regulatory inspection, and tobacco farms are not regulated entities unless they are also a tobacco product manufacturer or controlled by a tobacco product manufacturer. The purpose of this notice is to invite parties interested in participating in the Tobacco Farm 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 farm is interested in offering a site visit, please submit a request 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: Allison Hoffman, Office of Science, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, rm. 5426, Silver Spring, MD 20993-0002, 1-877-287-1373, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) 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 Tobacco Farm Site Tours Program to provide its staff an opportunity to visit farms that grow tobacco for sale to tobacco product manufacturers (a "tobacco product manufacturer" is defined as any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product, or imports a finished tobacco product for sale or distribution in the United States (section 900(20) of the FD&C Act (21 U.S.C. 387(20))). Although farms that grow tobacco are not FDA-regulated entities unless they are also a tobacco product manufacturer or controlled by a tobacco product manufacturer (see section 901(c)(2) of the FD&C Act (21 U.S.C. 387a(c)(2))), tobacco farm site visits will aid the Agency in gaining a better understanding of tobacco farming and the processes involved in curing and preparing tobacco leaf intended for sale to tobacco product manufacturers. The goal for the Tobacco Farm Site Tours Program is for CTP staff to gain firsthand exposure to tobacco farming practices, including cultivation, harvesting, curing, and preparation for sale of tobacco leaf to tobacco product manufacturers.

II. Description of Tobacco Farm Site Tours Program

In the Tobacco Farm Site Tours Program, small groups of CTP staff plan to observe the operations of farms that grow tobacco for sale to tobacco product manufacturers. Please note that FDA does not regulate these farms and the Tobacco Farm Site Tours Program is not an inspection of facilities to determine compliance with the FD&C Act; rather, this program is meant to educate CTP staff and improve their understanding of tobacco farming. It is anticipated that the tobacco farm site tours will take place in the fall of 2016.

III. Site Selection

CTP hopes to be able to tour small, medium, and large farms, and farms that grow tobacco for different kinds of tobacco products. 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 types of tobacco farms. FDA plans on visiting nine or fewer farms. All FDA travel expenses associated with the farm 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 farm, including the size of the farm;
- A list of the type(s) of tobacco grown and the kinds of tobacco product manufacturers to whom you sell tobacco;
- 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 Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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