ESTIMATED STATE MEDIAN INCOME FOR A FOUR-PERSON FAMILY, BY STATE, FOR FEDERAL FISCAL YEAR (FFY) 2012, FOR USE IN THE LOW INCOME HOME ENERGY ASSISTANCE PROGRAM (LIHEAP)—Continued

States	Estimated State median income for four-person families[1]	60 percent of estimated State median income for four-person families[2 3]
Pennsylvania	78,287	46,972
Rhode Island	87,669	52,601
South Carolina	64,228	38,537
South Dakota	68,064	40,838
Tennessee	63,480	38,088
Texas	65,508	39,305
Utah	70,322	42,193
Vermont	74,877	44,926
Virginia	85,546	51,328
Washington	81,788	49,073
West Virginia	58,739	35,243
Wisconsin	77,946	46,768
Wyoming	75,998	45,599

Note: FFY 2012 covers the period of October 1, 2011, through September 30, 2012. The estimated median income for four-person families living in the United States for this period is $74,985. These estimates become effective for LIHEAP at any time between the date of this publication and October 1, 2011, or the beginning of a LIHEAP grantee's fiscal year, whichever is later.

[1] Prepared by the U.S. Census Bureau, U.S. Department of Commerce (Census Bureau), from three-year estimates from the 2007, 2008 and 2009 American Community Surveys (ACSs). These estimates, like those derived from any survey, are subject to two types of errors: (1) Non-sampling Error, which consists of random errors that increase the variability of the data and non-random errors that consistently direct the data into a specific direction; and (2) Sampling Error, which consists of the error that arises from the use of probability sampling to create the sample.

[2] These figures were calculated by the U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services, Division of Energy Assistance (DEA) by multiplying the estimated State median income for a four-person family for each State by 60 percent.

[3] To adjust for different sizes of family, 45 CFR 96.85 calls for multiplying 60 percent of a State's estimated median income for a four-person family by the following percentages: 52 percent for one person, 68 percent for two persons, 84 percent for three persons, 100 percent for four persons, 116 percent for five persons, and 132 percent for six persons. For each additional family member above six persons, 45 CFR 96.85 calls for adding 3 percentage points to the percentage for a six-person family (132 percent) and multiply the new percentage by 60 percent of a State's estimated median income for a four-person family.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0214]

Guidance for Industry on How To Write a Request for Designation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "How to Write a Request for Designation (RFD)." This guidance is intended to clarify the type of information the Office of Combination Products (OCP) recommends that a sponsor include in a Request for Designation (RFD). This final guidance supersedes the previous RFD guidance document issued August 2005.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristina Lauritsen, Office of Combination Products, Food and Drug Administration, Bldg. 32, rm. 5132, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8936.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "How to Write a Request for Designation (RFD)." This guidance addresses 21 CFR 3.7 and is intended to clarify the type of information OCP recommends that a sponsor include in an RFD. The goal of this guidance is to help a sponsor understand what information FDA needs to determine the regulatory identity or classification of a product as a drug, device, biological product, or combination product, and to assign the product to the appropriate Agency component for review and regulation. This final guidance supersedes the previously issued RFD guidance document which was published on FDA's Web site on August 2005.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on how to write an RFD. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 3 have been approved under OMB control number 0910–0523.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/RegulatoryInformation/Guidances/ucm122047.htm* or *http://www.regulations.gov.*

Dated: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9261 Filed 4–15–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0240]

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 a notice 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 tobacco products. These visits are intended to provide CTP staff with the opportunity to gain a better understanding of the tobacco industry and its operations. 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 June 17, 2011. 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: Lucinda Miner, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 877–287–1373, *e-mail: lucinda.miner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31; 123 Stat. 1776) 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. This includes, among other things, the authority to issue regulations related to health warnings, tobacco product standards, good manufacturing practices, as well as tobacco product constituents, ingredients, and additives.

CTP is instituting 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 manufacturing facilities of cigarette, roll-your-own, and smokeless tobacco companies. 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; 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 tobacco manufacturing facility, a burley tobacco farm, a flue-cured tobacco farm, a tobacco rolling paper facility, and a tobacco warehouse. 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: April 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Noncompetitive Program Extension Supplemental Awards

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.