

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.

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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.

SUMMARY: The Health Resources and Services Administration (HRSA) will be issuing non-competitive supplemental funding to the Maternal Child and Health Bureau's (MCHB) Comprehensive Hemophilia Diagnostic and Treatment Centers. MCHB's Division of Children with Special Health Needs and the Genetic Services Branch are currently undergoing a strategic planning process. This will provide feasible time for the MCHB to

align fiscal resources and programmatic goals as determined by this strategic planning process with the least disruption to the States, communities, and constituencies that currently receive assistance and services from these grantees.

SUPPLEMENTARY INFORMATION: *Intended Recipient of the Award:* Comprehensive Hemophilia Diagnostic and Treatment Centers—12 Regional Centers (see table below).

Amount of the Award: 12 awards ranging from \$184,846 to \$595,453.

CFDA Number: 93.110.

Project Period: The period of supplemental support is from June 1, 2011, to May 31, 2012.

Authority: This activity is under the authority of Section 501(a) (2) of the Social Security Act, the Maternal and Child Health Federal Set-Aside Program: Special Projects of Regional and National Significance (SPRANS) (42 U.S.C. 701).

REGIONAL COMPREHENSIVE HEMOPHILIA DIAGNOSTIC AND TREATMENT CENTERS

Grantee	Grant No.	Region	FY 2010 Funding Level
University of Massachusetts	H30 MC00037–12–00.	Region 1	\$312,472
Mt. Sinai School of Medicine	H30 MC00019–20–00.	Region 2	595,453
Children's Hospital of Philadelphia	H30 MC09625–02–00.	Region 3	530,808
University of North Carolina	H30 MC05053–07–01.	Region 4–N	329,980
Hemophilia of Georgia	H30 MC00011–20–00.	Region 4–S	228,857
Hemophilia Foundation of Michigan	H30 MC00015–20–00.	Region 5–E	365,256
Great Lakes Hemophilia Foundation	H30 MC00032–21–02.	Region 5–W	446,520
University of Texas HSC at Houston	H30MC00029–20–06.	Region 6	455,871
Children's Mercy Hospital	H30 MC00040–10–00.	Region 7	371,228
University of Colorado	H30 MC00008–20–00.	Region 8	321,921
Children's Hospital of Orange County	H30 MC00036–12–00.	Region 9	714,832
Oregon Health and Science University	H30 MC00025–20–00.	Region 10	184,846

Justification for the Exception to Competition

Since the inception of HRSA's genetic services program, the landscape of our health care system has changed dramatically. In addition, our knowledge base for genetic medicine in general and blood disorders in particular has expanded. Unfortunately, the changes in our knowledge base and standards of care are not currently reflected in what we measure through this program nor how they are integrated into day to day activities that influence the health of individuals with hemophilia, thrombophilia and von Willebrand Disease and other congenital bleeding disorders.

To better reflect the current landscape, the MCHB is undertaking a strategic planning process this year. At the end of the process, we hope to have better defined measures that will reflect our new plan and the goals for the next 10 years. This will provide us with the basis to expand the applicant pool as

well as improve the evidence base for the utility of the National Hemophilia Program.

MCHB proposes this course of action for three reasons: (1) To appropriately respond to the directions that will be outlined after the strategic planning process, (2) to provide for sufficient fiscal resource to continue programmatic activities at current levels, and (3) to maintain MCH programmatic support with the least disruption to the State, community, and MCH constituencies who are currently receiving assistance and services from these grantees and the grantees themselves. Without this approach, the programmatic changes indicated through the strategic planning process will not be outlined nor implemented for another 3 years when the next competitive process will begin. Delaying the competition into mid fiscal year 2011 ensures continuity of funding for all eligible entities, with no eligible entity being harmed by the extension.

FOR FURTHER INFORMATION CONTACT: Sara Copeland, M.D., Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–8860, scopeland@hrsa.gov.

Dated: April 12, 2011.

Mary K. Wakefield,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

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