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Dated: August 6, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on October 17, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a

previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 203858, lomitapide capsules, by Aegerion Pharmaceuticals, Inc. The proposed indication (use) is as an adjunct to a low-fat diet and other lipid-lowering drugs with or without low-density lipoprotein (LDL) apheresis to reduce LDL cholesterol, total cholesterol, apolipoprotein B, and triglycerides in patients with homozygous familial hypercholesterolemia. (Apheresis is a laboratory technology used to remove LDL from the bloodstream.)

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 2, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 24, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will

notify interested persons regarding their request to speak by September 25, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-20013 Filed 8-14-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0853]

Tobacco Product Manufacturing Facility Visits

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 Tobacco Product Manufacturing Facility Visits. This program is intended to give FDA staff an opportunity to visit facilities involved in the manufacturing of tobacco products, including any related laboratory testing, and observe the manufacturing operations of the tobacco industry. The purpose of this notice is to invite parties interested in participating in Tobacco Product Manufacturing Facility Visits to submit requests to CTP.

DATES: Submit either an electronic or written request for participation by October 15, 2012. See section IV of this document for information on requests for participation.

ADDRESSES: If your facility is interested in participating in Tobacco Product

Manufacturing Facility Visits, 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:

Lindsay Tobias, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 877-287-1373, email: lindsay.tobias@fda.hhs.gov

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Public Law 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. The new provisions include, among other things, the authority to issue regulations related to tobacco product manufacturing practice in order to protect the public health and to assure that tobacco products are in compliance with the FD&C Act. Specifically, section 906(e) of the FD&C Act (21 U.S.C. 387f(e)) provides that “in applying manufacturing restrictions to tobacco, the Secretary shall * * * prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology.”

CTP is instituting Tobacco Product Manufacturing Facility Visits to provide FDA staff with the opportunity to:

- Observe tobacco product manufacturing operations—from the receipt of raw materials to the distribution of finished products, and
- Learn about the manufacturing practices and processes unique to your facility and regulated tobacco products.

This program will also inform FDA staff as they implement the tobacco provisions of the FD&C Act.

II. Description of the Tobacco Product Manufacturing Facility Visits

In this program, groups of FDA staff plan to observe the following facilities and their operations:

- Manufacturing facilities, including facilities that process, package, label,

and distribute different types of regulated tobacco products (cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products),

- Laboratory facilities that perform tobacco testing (whether third-party or in-house),
- Manufacturing facilities for components, parts, and accessories (including, but not limited to, cigarette paper, tipping paper, filters), and
- Manufacturing facilities for materials used for further processing in finished tobacco products (including, but not limited to, flavors, casings).

Please note that Tobacco Product Manufacturing Facility Visits are not intended to include or replace official FDA inspections of facilities to determine compliance with the FD&C Act; rather, these facility visits are meant to educate FDA staff and improve their understanding of the tobacco industry and its manufacturing operations.

III. Site Selection

CTP plans to select one or more of each of the following:

- Cigarette manufacturers,
- Cigarette tobacco and roll-your-own tobacco manufacturers,
- Smokeless tobacco manufacturers,
- Tobacco laboratories,
- Importers of finished tobacco products,
- Distributors and wholesalers of regulated tobacco products,
- Manufacturers of components, parts, accessories, and
- Manufacturers of materials used for further processing in finished tobacco products.

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, as 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 will be engaged in active manufacturing or processing during the proposed time of the visit. All travel expenses associated with Tobacco Product Manufacturer Facility Visits will be the responsibility of CTP.

IV. Requests for Participation

The request for participation should include the following identification information:

- The name and contact information (including address, phone number, and email) of your point of contact for the request,
- The physical address(es) of the site(s) for which you are submitting a request,

- The type of processes (e.g., manufacturing, laboratory practices, packaging, labeling, and distribution activities) performed at your facility,
- The type of tobacco products tested, processed, or manufactured at your facility, and
- A proposed program agenda.

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: August 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health/National Institute of Environmental Health Sciences

Proposed Collection; Comment Request; The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The Sister Study: A Prospective Study of the Genetic and Environmental Risk Factors for Breast Cancer. *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* This is to continue the Phase II follow-up of the Sister Study—a study of genetic and environmental risk factors for the development of breast cancer in a high-risk cohort of sisters of women who have had breast cancer. The etiology of breast cancer is complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. By focusing on genetically susceptible subgroups, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible.