Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0056, Report of Shipment, in all correspondence.

Dated: June 9, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–14119 Filed 6–14–16; 8:45 am]

BILLING CODE 6820–EP–P

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 newly deemed tobacco products and their components and parts, including any related laboratory testing, and to observe the manufacturing operations of the tobacco industry. The purpose of this document 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 August 15, 2016. 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: Matthew Brenner, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, email: *CTPRegulations@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. 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 newly deemed tobacco products, and
- Learn about the manufacturing practices and processes unique to your facility and newly deemed 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 establishments that process, package, label, and distribute different types of newly deemed tobacco products (*e.g.,* dissolvable products, gels, cigars, pipe tobacco, waterpipe tobacco products, and electronic nicotine delivery systems (ENDS) (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes) and liquid nicotine and flavors) (see 81 FR 28973, May 10, 2016),
- Laboratory facilities that perform tobacco testing (whether third-party or in-house), and
- Manufacturing facilities for tobacco products for further manufacturing into finished tobacco products (including, but not limited to, components, parts, flavors, casings, e-liquids).

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 sites from one or more of each of the following categories:

- Dissolvable products,
- Gels,
- Cigars,
- Pipe tobacco,
- Waterpipe tobacco products,
- ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes) and liquid nicotine and flavors,
- Tobacco laboratories,
- Importers of finished tobacco products,
- Distributors and wholesalers of regulated tobacco products, and/or
- Manufacturers of tobacco products for further manufacturing into finished tobacco products (including, but not limited to, components, parts, flavors, casings, e-liquids).

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 or affiliated firm, if applicable, has a significant request or marketing application or submission pending with FDA; 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, mixing, 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.

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: June 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14139 Filed 6–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 042

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 042'' (Recognition List Number: 042), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective June 15, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 042.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 042.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 042 is available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 042 modifications and other standards related information. Submit written requests for a single hard copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 042'' to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149.