

nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: July 11, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-16739 Filed 7-14-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0508]

#### Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.” This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

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

**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-2009-D-0508 for “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.” 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.

- *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.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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**FOR FURTHER INFORMATION CONTACT:** Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, email: [CTPRRegulations@fda.hhs.gov](mailto:CTPRRegulations@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a revised guidance for industry entitled, “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.” This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate given the requirement that registration and listing submissions be submitted by December 31, 2016 (§ 10.115(g)(2)). We made this determination because the guidance presents a less burdensome policy consistent with the public health. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA’s GGP regulation.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) added section 905 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387e), establishing requirements for tobacco product establishment registration and product listing.

FDA revised the registration and listing guidance to include newly deemed tobacco products. Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C Act, including section 905, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a) grants FDA authority to deem those products subject to chapter IX of the FD&C Act. Pursuant to that authority, FDA issued a proposed rule seeking to deem all other products that meet the statutory definition of tobacco product, set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) (except for accessories of those products) (79 FR 23142). After review and consideration of comments on the proposed rule, FDA published the final rule on May 10, 2016 (81 FR 28974) (“the deeming rule”) and it will become effective on August 8, 2016. As a result, owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products subject to the deeming rule are now required to comply with chapter IX of the FD&C Act, including the establishment registration and product listing requirements in section 905.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on registration and product listing for owners and operators of domestic tobacco product establishments. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 time required to complete this information collection is estimated to average 3.75 hours per response, including the time to review

instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to: Food and Drug Administration, Center for Tobacco Products, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910–0650 (expires June 30, 2019).

## IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: July 11, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Council on Graduate Medical Education; Request for Nominations

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on the Council on Graduate Medical Education (COGME). COGME is authorized by Section 762 of the Public Health Service (PHS) Act (42 U.S.C. 294o), as amended. The Advisory Council is governed by the provisions of the Federal Advisory Act (FACA) (5 U.S.C. Appendix 2), as amended, which sets forth standards for the formation and use of advisory committees, and applies to the extent that the provisions of FACA do not conflict with the requirements of PHS Act Section 762.

**DATES:** The agency will receive nominations on a continuous basis.

**ADDRESSES:** All nominations should be submitted to Advisory Council Operations, Bureau of Health Workforce, HRSA, 11W45C, 5600

Fishers Lane, Rockville, Maryland 20857. Mail delivery should be addressed to Advisory Council Operations, Bureau of Health Workforce, HRSA, at the above address, or via email to: [BHWAdvisoryCouncilFRN@hrsa.gov](mailto:BHWAdvisoryCouncilFRN@hrsa.gov).

**FOR FURTHER INFORMATION CONTACT:** Joan Weiss, Ph.D., RN, CRNP, FAAN, Designated Federal Official, COGME at 301–443–0430 or email at [jweiss@hrsa.gov](mailto:jweiss@hrsa.gov). A copy of the current committee membership, charter, and reports can be obtained by accessing the Web site <http://www.hrsa.gov/advisorycommittees/bhpradvisory/COGME/index.html>.

**SUPPLEMENTARY INFORMATION:** COGME provides advice and makes policy recommendations to the Secretary of the U.S. Department of Health and Human Services (Secretary) and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the U.S. House of Representatives Committee on Energy and Commerce on matters concerning the supply and distribution of physicians in the United States, physician workforce trends, training issues, and financing policies. Meetings are held twice a year.

Specifically, HRSA is requesting nominations for voting members of COGME representing: Practicing primary care physicians, national and specialty physician organizations, foreign medical graduates, medical student and house staff associations, as well as representatives of schools of medicine, schools of osteopathic medicine, public and private teaching hospitals, health insurers, business, and labor. Among these nominations, medical students, residents, and/or fellows from these programs are encouraged to apply.

The Department of Health and Human Services (HHS) will consider nominations of all qualified individuals with the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership. Nominations shall state that the nominee is willing to serve as a member of COGME and appears to have no conflict of interest that would preclude COGME membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of COGME to permit evaluation of possible sources of conflicts of interest.