rule on Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. The collections of information in the final rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of the information collection provisions elsewhere in this issue of the **Federal Register** and has submitted them for OMB approval.

This guidance also refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3520). The collections of information in section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) have been approved under OMB control number 0910–0673; the collections of information in sections 904(a)(1), (c) and 905(b), (c), (d), (h), (i) of the FD&C Act have been approved under OMB control number 0910–0650; the collections of information in section 904(a)(4) of the FD&C Act have been approved under OMB control number 0910–0654; the collections of information in 21 CFR 1107.1(b) and (c), 21 CFR 25.40, and section 905(j)(1)(A)(ii) of the FD&C Act have been approved under OMB control number 0910–0684; the collections of information in sections 904(a)(3) and 904(c)(1) of the FD&C Act have been approved under OMB control number 0910–0732; and the collections of information in section 910 have been approved under OMB control number 0910–0775.

III. 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: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10690 Filed 5–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2014–N–0189]

The Food and Drug Administration Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements; Small Entity Compliance Guide.'' This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the deeming regulation and to help small businesses understand and comply with the regulation.

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–2014–N–0189 for ''FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements; Small Entity Compliance Guide.'' 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, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., 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.

FOR FURTHER INFORMATION CONTACT: Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–2000, 1–877–287–1373, email: *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements, Small Entity Compliance Guide.'' This guidance is intended to help small businesses understand and comply with FDA's implementation of the final rule entitled ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (Deeming rule), which is published elsewhere in this edition of the **Federal Register**. Specifically, this guidance is intended to help small businesses understand how to comply with FDA's final rule deeming tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act (''FD&C Act''), as amended by the Family Smoking Prevention and Tobacco Control Act (''Tobacco Control Act''). The Deeming rule extends FDA's authority in Chapter IX of the FD&C Act to include all tobacco products, except accessories of newly deemed tobacco products. The Deeming rule also prohibits the sale of covered tobacco products to individuals under the age of 18, prohibits vending machine sales unless sold in adult-only facilities, and requires the display of health warning statements on cigarette tobacco, roll-your-own tobacco, and covered tobacco product packages and in advertisements.

In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121), FDA is making available this SECG stating in plain language the legal requirements of the Deeming final rule, set forth in 21 CFR parts 1100, 1140, and 1143.

II. Significance of Guidance

FDA is issuing this SECG as a level 2 guidance, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public unless specific regulatory or statutory requirements are cited. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. 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: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10684 Filed 5–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1140, and 1143

[Docket No. FDA–2015–D–2496]

Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems.'' Given the relatively new presence of electronic nicotine delivery systems (ENDS) on the U.S. market and FDA's final rule deeming these products to be subject to the tobacco product authorities in the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA expects to receive premarket tobacco product application (PMTA) submissions from manufacturers of ENDS. This draft guidance is intended to assist persons with their PMTA submissions for ENDS products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 11, 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