I. Background

FDA is announcing the availability of a draft guidance for industry entitled “DEMS Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for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.


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
that if you include your name, contact
information, or other information that
identifies you in the body of your
comments, that information will be
• 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–
2015–D–2496 for “Premarket Tobacco
Product Application for Electronic
Nicotine Delivery Systems.” 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 draft 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
20993–2000. Send one self-addressed
adhesive label to assist that office in
processing your request or include a fax
number to which the draft guidance
may be sent. See the
SUPPLEMENTARY INFORMATION
section for information on
electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance:
Colleen Lee, 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,
AskCTP@fda.hhs.gov.

With regard to the proposed collection of
information: FDA PRA Staff, Office
of Operations, Food and Drug
Administration, 8455 Colesville Rd.,
COLE–14526, Silver Spring, MD 20993–
0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of
a draft guidance for industry entitled
“Premarket Tobacco Product
Applications for Electronic Nicotine
Delivery Systems.”

On June 22, 2009, the President
signed the Family Smoking Prevention
and Tobacco Control Act (Tobacco
The Tobacco Control Act amended the
Federal Food, Drug, and Cosmetic Act
(the FD&C Act) and granted FDA
authority to regulate the manufacture,
marketing, and distribution of tobacco
products to protect public health
generally and to reduce tobacco use by
minors. Under section 901(b) of the
FD&C Act (21 U.S.C. 387a(b)), FDA’s
tobacco product authorities in chapter
IX of the FD&C Act apply to all
cigarettes, cigarette tobacco, roll-your-
own tobacco, and smokeless tobacco
and to any other tobacco products that
the Secretary of Health and Human
Services by regulation deems to be
subject to chapter IX. Concurrently with
issuing this draft guidance, FDA is
publishing elsewhere in this issue of the
Federal Register, its final rule,
“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) to deem all products
meeting the statutory definition of
“tobacco product” in section 201(rr) of
the FD&C Act (21 U.S.C. 321(rr)), except
accessories to newly deemed tobacco
products, to be subject to chapter IX of
the FD&C Act (21 U.S.C. 387 through
387a).

Under section 910 of the FD&C Act
(21 U.S.C. 387)), persons seeking to
market a new tobacco product (as
defined in section 910(a)(1) of the FD&C
Act) must first submit a PMTA to FDA
and obtain a marketing authorization
order, unless FDA has issued an order
that the new tobacco product is
substantially equivalent to a tobacco
product commercially marketed in the
United States as of February 15, 2007,
or the new tobacco product is exempt
from demonstrating substantial
equivalence pursuant to the reasons
outlined in section 905(j)(3) of the FD&C
Act (21 U.S.C. 387(e)(j)(3)). The ENDS
products that are the subject of this draft
guidance likely would be considered
new tobacco products.

Given the relatively new presence of
ENDS on the U.S. market, FDA
anticipates that many manufacturers of
these new tobacco products will seek a
marketing authorization order by filing
a PMTA. This draft guidance explains,
among other things, products to which
the guidance applies, when a PMTA is
required, general procedures for review of
an ENDS PMTA, what information
the FD&C Act requires applicants to
submit in a PMTA, and what
information FDA recommends
applicants submit in an ENDS PMTA to
show whether permitting such new
tobacco product to be marketed is
appropriate for the protection of the
public health.

II. Significance of Draft Guidance

FDA is issuing this draft guidance
consistent with FDA’s good guidance
practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on PMTAs for ENDS. 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 draft guidance refers to collections of information described in FDA’s Deeming rule, which this draft guidance is intended to interpret. The collections of information in the Deeming 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.

IV. Electronic Access

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


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–10687 Filed 5–5–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1150


Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products; 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 revised guidance for industry entitled “Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products; Small Entity Compliance Guide” for the final user fees rule published July 10, 2014, and for the new user fees regulation. This revised guidance, a small entity compliance guide (SECG), replaces the SECG of the same name published on July 16, 2014. The revised SECG is intended to set forth in plain language the requirements of the user fee regulations and to help small businesses understand and comply with the regulations.

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–D–0917 for “Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products.” 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 docket, 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