DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0917]

Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a 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 a final rule published in the **Federal Register** of July 10, 2014. This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the regulation and to help small businesses understand and comply with the regulation.

DATES: Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, ATTN: Office of Small Business Assistance, 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.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nancy Boocker or Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 10, 2014 (79 FR 39302), FDA issued a final rule to add 21 CFR part 1150 to require domestic manufacturers and importers of tobacco products to submit to FDA information needed to calculate the amount of user fees assessed under the Federal Food, Drug, and Cosmetic Act. 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 July 10, 2014, final rule, set forth in 21 CFR part 1150.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

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/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: July 10, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–16590 Filed 7–15–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0018]

Agency Information Collection Activities: Application for Permission To Reapply for Admission Into the United States After Deportation or Removal, Form I–212; Revision of a Currently Approved Collection

ACTION: 60-Day notice.

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SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e., the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until September 15, 2014.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0018 in the subject box, the agency name and Docket ID USCIS–2008–0068. To avoid duplicate submissions, please use only one of the following methods to submit comments:

(1) *Online.* You may access the **Federal Register** Notice and submit comments via the Federal eRulemaking Portal Web site by visiting *www.regulations.gov.* In the search box either copy and paste, or type in, the e-Docket ID number USCIS–2008–0068. Click on the link titled Open Docket Folder for the appropriate Notice and supporting documents, and click the Comment Now tab to submit a comment;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov*;

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

SUPPLEMENTARY INFORMATION:

Comments: Regardless of the method used for submitting comments or