maintain security in retirement and make better financial and healthcare choices. SMP team members provide one-on-one assistance, and when needed, serve as consumer advocates to resolve billing disputes/issues.

The SHIP–SMP Survey of One-on-One Assistance will gauge individuals' satisfaction with the services provided by SHIP and SMP team members. This survey is a renewal of the existing ''National Beneficiary Survey of State Health Insurance Assistance Program (SHIP)'', which received clearance on August 28, 2017, with ICR Reference Number 201702–0985–002 and OMB Control Number 0985–0057. That survey was conducted over a three-year period beginning on October 1, 2017, and will conclude on March 30, 2020. To date, this survey has generated over 2500 responses, all of which were submitted voluntarily.

ACL requests renewal of the survey to continue the collection performed in Fiscal Years 2018, 2019, and 2020. Reports developed for FY18 and FY19 participants have provided an overall measure of satisfaction with SHIP's one-on-one assistance services and have provided insight into the relationship between inputs (information provided, time between initial contact and services received) and overall satisfaction. The renewed collection will survey recipients of both SHIP and SMP one-on-one assistance but will not increase the number of surveys collected. The renewed survey will provide an annual collection at the national level, with an estimated collection of 800 responses per year. To generate a sample with a 95% confidence level at the national level 400 responses will be required from each program (n = 2,000,000 SHIP one-on-one assistance sessions in 2018; n = 275,000 SMP one-on-one assistance sessions in 2018).

ACL will draw a representative sample of customers who received assistance from each program by focusing only on non-redundant individuals (*i.e.,* a random sample without replacement of individuals who receive SHIP and/or SMP one-on-one assistance).

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Survey, Stratified Random Sample	800	1	6/60	80
Total	800	1	6/60	80

Dated: December 19, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–28101 Filed 12–27–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5364]

Submission of Plans for Cigarette Packages and Cigarette Advertisements; Draft 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 draft guidance for industry entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements.'' This guidance, when finalized, would assist those required to submit cigarette plans for cigarette packages and cigarette advertisements by providing recommendations related to those submissions, including information on what should be in a cigarette plan, who should submit a cigarette plan, and when to submit a cigarette plan.

DATES: Submit either electronic or written comments on the draft guidance by January 29, 2020.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2019–D–5364 for ''Submission of Plans for Cigarette Packages and Cigarette Advertisements.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 20993–0002. 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: Lauren Belcher or Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *AskCTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements.'' The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was enacted on June 22, 2009, and granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products. The Tobacco Control Act also amended section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) to direct FDA to issue regulations requiring each cigarette package and advertisement to bear a new textual warning label statement accompanied by color graphics depicting the negative health consequences of smoking (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the required warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act). The Tobacco Control Act also modified the requirements of the FCLAA regarding the submission of cigarette plans for the random and equal display and distribution of required warnings on cigarette packaging and quarterly rotation of required warnings in cigarette advertising. It also requires that such cigarette plans be submitted to FDA for review and approval, rather than to the Federal Trade Commission.

FDA issued a proposed rule entitled ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements'' on August 16, 2019 (84 FR 42754). The proposed rule, once finalized, would specify the color graphics that must accompany the new textual warning statements and establish marketing requirements for cigarette packages and advertisements. The marketing requirements would require, among other things, submission of a cigarette plan that provides for the random and equal display and distribution of the required warnings on cigarette packaging and quarterly rotation of the required warnings in cigarette advertising, as described under section 4 of FCLAA. This draft guidance provides recommendations related to preparing and submitting those cigarette plans.

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 regarding the submission of cigarette plans for cigarette packages and advertisements. 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 proposed collections of information described in FDA's August 16, 2019, proposed rule on ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements'', which this draft guidance is intended to interpret. The proposed collections of information in the proposed 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. 3501–3521). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule (84 FR 42754 at 42787) 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 *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: December 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27991 Filed 12–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0804]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the