

Administration for Community Living, Washington, DC 20201, Attention: Susan Jenkins.

FOR FURTHER INFORMATION CONTACT:

Susan Jenkins, Administration for Community Living, Washington, DC 20201, 202-795-7369 or by email: Susan.Jenkins@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites

comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Evidence Based Program Fidelity Surveys will be used by ACL to evaluate the fidelity with which ACL's grantee organizations, under the Older Americans Act, implement the required evidence-based programs. States that receive Older Americans Act funds under Title III-D are required to spend those funds on evidence-based programs to improve the health and well-being of their clients and to reduce disease and

injury. Since 2003, the aging services network has been steadily moving towards wider implementation of disease prevention and health promotion programs that are based on scientific evidence and demonstrated to improve the health of older adults. The FY 2012 Congressional appropriations law included, for the first time, an evidence-based requirement related to Title III-D funds.

The results of this information collection will be used by ACL/AoA to:

- Effectively report its results to the President, to Congress, to the Department of Health and Human Services and to the public.
- Assess the effectiveness of ACL and its grantees in monitoring program fidelity.
- Aid in program refinement and continuous improvement.

To comment on this information collection please visit the ACL website: <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
Grantee: Program selection process and survey	103	1	2.00	206
Local Implementation Organization Survey	412	1	0.67	275
Total	515	1	0.93	481

Dated: July 6, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-1997]

Food and Drug Administration Oversight of Food Products Covered by Systems Recognition Arrangements; Draft Guidance for Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for FDA staff entitled "FDA Oversight of Food Products Covered by Systems Recognition Arrangements." This draft guidance provides recommendations related to the FDA's regulatory oversight activities for food products imported from countries whose food safety systems the FDA has recognized in Systems Recognition Arrangements (SRAs).

DATES: Submit either electronic or written comments on the draft guidance by September 10, 2021 to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance.

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-1997 for “FDA Oversight of Food Products Covered by Systems Recognition Arrangements; Draft Guidance for FDA Staff.” 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 between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

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

Submit written requests for a single hard copy of the draft guidance entitled “FDA Oversight of Food Products Covered by Systems Recognition Arrangements” to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Building, Rm. 4148, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Marla Hallacy, Office of Regulatory Affairs, Division of Operational Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-6674.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for FDA staff entitled “FDA Oversight of Food Products Covered by Systems Recognition Arrangements; Draft Guidance for FDA Staff.” The draft guidance is part of FDA’s larger effort to take a risk-based approach to food safety to include ensuring the safety of imported food, consistent with the FDA Food Safety Modernization Act. The guidance covers FDA’s regulatory oversight activities for food products covered by SRAs between FDA and its foreign regulatory counterparts. Currently, the FDA has signed SRAs with food safety agencies in Australia, Canada, and New Zealand.

The draft guidance is being issued 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 the topic of Systems Recognition Arrangement implementation. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>.

Dated: July 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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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 (Revised); Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised final guidance for industry entitled “Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).” This is a revision to the third edition of this final guidance, which issued in February 2021, and is intended to assist those required to submit cigarette plans for cigarette packages and cigarette advertisements by providing content, timing, and other recommendations related to those submissions. FDA is revising this guidance to reflect the May 21, 2021, court order that postponed the effective date of the final rule entitled “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements” to July 13, 2022. Pursuant to the court order, this revised guidance strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event, by the recommended submission date, which is currently September 13, 2021.