

and spousal support above a threshold to the Department of State, which will then deny passports to these individuals. On an ongoing basis, child support enforcement agencies submit to OCSE the names, Social Security numbers, and the amount(s) of past-due child and spousal support of noncustodial parents who are delinquent in making payments.

The information collection activities pertaining to the Federal Tax Refund Offset, Administrative Offset, and Passport Denial programs are authorized by: (1) 42 U.S.C. 652(b), 42 U.S.C. 664, 26 U.S.C. 6402(c), 31 CFR 285.3, 45 CFR

302.60, and 45 CFR 303.72, which require state child support agencies to submit information pertaining to past-due support cases meeting specific criteria for the offset of the federal tax refund of the noncustodial parent; (2) 31 U.S.C. 3701 *et seq.*, 31 U.S.C. 3716(h), and 31 CFR 285.1, which require state child support agencies to submit information pertaining to past-due support cases meeting specific criteria for the administrative offset of federal payments other than federal tax refunds of the noncustodial parent; (3) 42 U.S.C. 652(k), 42 U.S.C. 654(31), and 22 CFR 51.60, which require state child support

agencies to submit information to OCSE pertaining to past-due support cases meeting specific criteria for the denial, revocation, restriction, or limitation of the passport of the noncustodial parent; and (4) 42 U.S.C. 654(31), 42 U.S.C. 664, 31 CFR 285.1, and 31 CFR 285.3, which require state child support agencies to submit the Annual Certification Letter to OCSE asserting that each case submitted for the Federal Tax Refund Offset, Administrative Offset, and Passport Denial programs meets federal requirements.

*Respondents:* Child Support Enforcement Agencies

ANNUAL BURDEN ESTIMATES

Information collection instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Input Record .....	54	52	.3	842.4
Output Record .....	54	52	.46	1291.7
Payment File .....	54	52	.135	379.1
Certification Letter .....	54	1	.4	21.6
Portal Processing screens .....	173	280.65	.01	485.52

*Estimated Total Burden Hours:* 3,020.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attention Reports Clearance Officer. All requests should be identified by the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**.

Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2012-N-0977]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) 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 **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection for the regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents.

**DATES:** Submit either electronic or written comments on the collection of information by July 16, 2019.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 16, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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-2012-N-0977 for “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- **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.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.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. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical

utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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.

#### Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents—21 CFR 1140.30

##### OMB Control Number 0910-0312—Extension

This is a request for an extension of OMB approval for the information collection requirements contained in FDA’s regulations for cigarettes and smokeless tobacco containing nicotine. The regulations that are codified at 21 CFR part 1140 are authorized by section 102 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31). Section 102 of the Tobacco Control Act required FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the regulation issued by FDA in 1996 (61 FR 44396, August 28, 1996), with certain specified exceptions including that subpart C (which included 21 CFR 897.24) and 897.32(c) be removed from the reissued rule (section 102(a)(2)(B)). The reissued final rule was published in the **Federal Register** of March 19, 2010 (75 FR 13225).

This collection includes reporting information requirements for § 1140.30 which directs persons to notify FDA if they intend to use a form of advertising that is not addressed in the regulations and not originally described in the March 19, 2010, final rule. Section 1140.30 requires manufacturers, distributors, and retailers to (1) observe certain format and content requirements for labeling and advertising and (2) notify FDA if they intend to use an advertising medium that is not listed in the regulations. The concept of permitted advertising in § 1140.30 is sufficiently broad to encompass most forms of advertising.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1140.30—Scope of permissible forms of labeling and advertising .....	25	1	25	1	25

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden hour estimates for this collection of information were based on industry-prepared data and information regarding cigarette and smokeless tobacco product advertising expenditures.

FDA estimates that approximately 25 respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice. Therefore, FDA estimates that the total time required for this collection of information is 25 hours.

We have adjusted our burden estimate to approximately 25 notifications annually, which more accurately reflects the current number of submissions under this regulation. This is a decrease to the currently approved burden. The decrease in notifications is not unexpected given that the regulation applies to cigarettes and smokeless tobacco and many of the alternative media notifications have been made in previous years.

Dated: May 14, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-3031]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 17, 2019.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0749. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products**

*OMB Control Number 0910-0749—Extension*

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (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.

FDA issued a final rule that requires domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the FD&C Act ([https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-](https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10688.pdf)

[10688.pdf](https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10688.pdf)). FDA expanded its authority over tobacco products by issuing another 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), deeming all products that meet the statutory definition of “tobacco product,” except accessories of the newly deemed tobacco products, to be subject to the FD&C Act (<https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf>). The Deeming rule, among other things, subjected domestic manufacturers and importers of cigars and pipe tobacco to the FD&C Act’s user fee requirements. Consistent with the Deeming rule and the requirements of the FD&C Act, the user fee final rule requires the submission of the information needed to calculate user fee assessments for each manufacturer and importer of cigars and pipe tobacco to FDA.

As noted, FDA issued a final rule that requires domestic tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the FD&C Act. The U.S. Department of Agriculture (USDA) had been collecting this information and provided FDA with the data the Agency needed to calculate the amount of user fees assessed to tobacco product manufacturers and importers. USDA ceased collecting this information in fiscal year 2015 (October 2014). USDA’s information collection did not require OMB approval, per an exemption by Public Law 108-357, section 642(b)(3). Consistent with the requirements of the FD&C Act, FDA requires the submission of this information to FDA now instead of USDA. FDA took this action to ensure that the Agency continues to have the information needed to calculate, assess, and collect user fees from domestic manufacturers and importers of tobacco products.

Section 919(a) of the FD&C Act (21 U.S.C. 387s(a)) requires FDA to “assess user fees on, and collect such fees from,