

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

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

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
80.21 and 80.22; Request for certification accompanied by sample.	67	112	7,504	0.22 (13 minutes) .....	1,651

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
80.39; Record of distribution .....	67	112	7,504	0.25 (15 minutes) .....	1,876

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

We base our estimate on our review of the certification requests received over the past 3 years. Using information from industry personnel, we estimate that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

Based on a review of the information collection since our last request for OMB approval, we have slightly decreased our burden estimate based on our experience with this program. As a result, although the number of respondents increased, the number of responses per respondent decreased.

Dated: October 13, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–D–4128]

#### Guidance Documents Referencing Pre-Existing Tobacco Products; Guidance for Industry; Availability; Withdrawal

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of revised final guidances for industry entitled “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions,” and

“Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.” Following the issuance of the final rules entitled “Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports” (SE) and “Pre-market Tobacco Product Applications and Recordkeeping Requirements” (PMTA), FDA has made minor updates to these guidances for consistency with the terminology used in those rules. FDA is also announcing the withdrawal of the final guidances entitled “Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products,” and “Investigational Use of Deemed, Finished Tobacco Products That Were on the U.S. Market on August 8, 2016, During the Deeming Compliance Periods,” and a draft guidance entitled “Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product,” which are obsolete due to the issuance of the SE final rule or the end of the compliance period for deemed, finished tobacco products that were on the U.S. market on August 8, 2016.

**DATES:** The announcement of the guidance is published in the **Federal Register** on October 18, 2023.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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–2023–D–4128 for “Guidance Documents Referencing Pre-Existing Tobacco Products.” 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 single copies of these guidances to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, 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 guidances may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance documents.

**FOR FURTHER INFORMATION CONTACT:** Natalie Gibson, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 877–287–1373, email: [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On June 22, 2009, the Family Smoking Prevention and Tobacco

Control Act (Pub. L. 111–31) (Tobacco Control Act) was signed into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by youth. FDA is announcing the availability of revised final guidances for industry, collectively entitled “Guidance Documents Referencing Pre-Existing Tobacco Products.”

In the PMTA final rule (86 FR 55300, October 5, 2021) and the SE final rule (86 FR 55224, October 5, 2021), FDA has changed the term “grandfathered tobacco product” to “pre-existing tobacco product” because it more appropriately describes these products. Specifically, FDA considers a “pre-existing tobacco product” to mean a tobacco product that was commercially marketed in the United States as of February 15, 2007. FDA also made other minor changes to the revised guidances to reflect updated terminology used in the SE final rule, when appropriate. Details of the changes are described in the revision history page included with each guidance.

FDA is also withdrawing three guidances that are obsolete due to the issuance of the SE final rule or due to the end of the compliance period for deemed, finished tobacco products that were on the U.S. market on August 8, 2016. The guidances along with their docket numbers and status are listed in table 1.

TABLE 1—REVISED AND WITHDRAWN GUIDANCES

Title	Docket No.	Status
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.	FDA–2011–D–0147 ....	Revised.
Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.	FDA–2011–D–0125 ....	Revised.
Investigational Use of Deemed, Finished Tobacco Products That Were on the U.S. Market on August 8, 2016, During the Deeming Compliance Periods.	FDA–2016–D–3276 ....	Withdrawn.
Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products .....	FDA–2010–D–0635 ....	Withdrawn.
Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product, Draft Guidance.	FDA–2014–D–0800 ....	Withdrawn.

The revised final guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115) and represent the current thinking of FDA on, among other things, the incorporation of the term “pre-existing tobacco product.” They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**II. Paperwork Reduction Act of 1995**

While these guidances contain no collections of information, they do refer to previously approved FDA collections of information. The previously approved collections of information 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). The collections of information in FDA’s guidance entitled “Establishing That a

Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007” have been approved under OMB control number 0910–0775.

**III. Electronic Access**

Persons with access to the internet may obtain an electronic version of the guidances at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/TobaccoProducts/>

*Labeling/RegulationsGuidance/default.htm*, or <https://www.regulations.gov>.

Dated: October 13, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-3595]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification

**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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed information collection entitled “Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.”

**DATES:** Either electronic or written comments on the collection of information must be submitted by December 18, 2023.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. eastern time at the end of December 18, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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-2023-N-3595 for “Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.” 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, 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.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, [PRStaff@fda.hhs.gov](mailto:PRStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), 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 before submitting the collection to OMB for approval. To comply with this