

## II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, or <https://www.regulations.gov>.

Dated: August 20, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–N–0377]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Health Document Submission

**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 Tobacco Health Document Submissions.

**DATES:** Submit either electronic or written comments on the collection of information by October 22, 2018.

**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 October 22, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 22, 2018. 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–2013–N–0377 for “Tobacco Health Document Submission.” 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, [PRStaff@fda.hhs.gov](mailto:PRStaff@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.

### Tobacco Health Document Submission

*OMB Control Number 0910-0654—Extension*

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a new chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Additionally, section 101 of the Tobacco Control Act amended the FD&C Act by adding, among other things, new section 904(a)(4) (21 U.S.C. 387d(a)(4)).

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives" (herein referred to as "tobacco health documents").

FDA announced the availability of a guidance on this collection in the **Federal Register** of April 4, 2010 (75 FR 20606) (revised December 5, 2016 (81 FR 87565) and August 10, 2017 (82 FR 37459) (extending compliance dates)), and requested health documents that were created during the period of June 23, 2009, through December 31, 2009 based on the statutory requirements. The guidance stated that information required under section 904(a)(4) of the FD&C Act must be submitted to FDA beginning December 22, 2009. However, FDA also explained that it did not intend to enforce the December 22, 2009, deadline provided that the documents were submitted by April 30, 2010, for all health documents developed between June 23, 2009 and December 31, 2009. Further, FDA stated it would publish a revised guidance specifying the timing of subsequent reporting.

FDA has been collecting the information submitted pursuant to section 904(a)(4) of the FD&C Act through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. On both forms, FDA is requesting the following information from firms that have not already reported or still have documents to report:

- Submitter identification
- Submitter type, company name, address, country, company headquarters Dun and Bradstreet D-U-N-S number, and FDA assigned Facility Establishment Identifier (FEI) number
- Submitter point of contact
- Contact name, title, position title, email, telephone, and fax
- Submission format and contents (as applicable)
- Electronic documents: Media type, media quantity, size of submission, quantity of documents, file type, and file software
- Paper documents: Quantity of documents, quantity of volumes, and quantity of boxes
- Whether or not a submission is being provided
- Confirmation statement
- Identification and signature of submitter including name, company name, address, position title, email, telephone, and fax
- Document categorization (as applicable): Relationship of the document or set of documents to the following:
  - Health, behavioral, toxicological, or physiological effects
  - Uniquely identified current or future tobacco product(s)

- Category of current or future tobacco product(s)
- Specific ingredient(s), constituent(s), component(s), or additive(s)
- Class of ingredient(s), constituent(s), component(s), or additive(s)
  - Document readability and accessibility: Keywords; glossary or explanation of any abbreviations, jargon, or internal (e.g., code) names; special instructions for loading or compiling submission.

- Document metadata: Date document was created, document author(s), document recipient(s), document custodian, document title or identification number, beginning and ending Bates numbers, Bates number ranges for documents attached to a submitted email, document type, and whether the document is present in the University of California San Francisco's Truth Tobacco Documents database.

In addition to the electronic and paper forms, FDA issued guidance documents intended to assist persons making tobacco health document submissions (draft guidance: December 28, 2009 (74 FR 68629); final guidance: April 20, 2010 (75 FR 20606); revised December 5, 2016 (81 FR 87565) and August 10, 2017 (82 FR 37459) (extending compliance dates)). For further assistance, FDA is providing a technical guide, embedded hints, and a web tutorial on the electronic portal.

FDA issued a final rule to deem products meeting the statutory definition of "tobacco product" to be subject to the FD&C Act on May 10, 2016 (81 FR 28973), which became effective on August 8, 2016. The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. This final rule extends the Agency's "tobacco product" authorities to all other categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such deemed tobacco products.

For tobacco products subject to the deeming rule, FDA understands "current or future tobacco products" to refer to products commercially distributed on or after August 8, 2016, or products in any stage of research or development at any time after August 8, 2016, including experimental products and developmental products intended for introduction into the market for consumer use. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco, FDA understands "current or future tobacco products" to refer to products commercially distributed on or after

June 23, 2009, or products in any stage of research or development at any time after June 23, 2009, including experimental products and developmental products intended for introduction into the market for consumer use.

All manufacturers and importers of tobacco products are now subject to the FD&C Act and are required to comply with section 904(a)(4), which requires immediate and ongoing submission of health documents developed after June 22, 2009 (the date of enactment of the Tobacco Control Act). However, FDA generally does not intend to enforce the requirement at this time with respect to

all such health documents relating to the deemed tobacco products, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, were submitted by February 8, 2017, or in the case of small-scale deemed tobacco product manufacturers (small-scale manufacturers), by November 8, 2017 (81 FR 28974 at 29008–09). Additionally, FDA extended the compliance deadlines by an additional 6 months for small-scale manufacturers in the areas impacted by recent natural disasters to May 8, 2018. Thereafter, FDA’s compliance plan requests

deemed manufacturers provide tobacco health document submissions from the specified period, at least 90 days prior to the delivery for introduction into interstate commerce of tobacco products to which the health documents relate. Manufacturers or importers of cigarettes, cigarette tobacco, RYO, or smokeless tobacco products must provide all health documents developed between June 23, 2009, and December 31, 2009, at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce. FDA estimates the burden of this collection of information as follows:

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743 .....	10	3.2	32	50	1,600

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

The number of documents received each year since the original collection period has fallen to less than 5 percent of what was received in the original collection period. FDA expects this is because documents created within the specified period should have already been submitted. The Agency bases this estimate on the total number of tobacco firms it is aware of and its experience with document production and the number of additional documents that have been reported each year since the original estimate of the reporting burden.

FDA estimates that a tobacco health document submission for cigars, pipe and waterpipe tobacco, electronic nicotine delivery systems (ENDS), and other tobacco products as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on the existing collection that applies to tobacco products currently subject to the FD&C Act and FDA experience. To derive the number of respondents for this provision, FDA assumes that very few manufacturers or importers of deemed tobacco products, or agents thereof, would have health documents to submit. In addition to the existing 4 respondents, the Agency estimates that approximately 6 submissions (2 for cigar manufacturers, 1 for pipe and waterpipe tobacco manufacturers, 1 for other tobacco product manufacturers, 1 for tobacco importers, and 1 for importers of ENDS who are considered manufacturers) will be submitted on an

annual basis for a total of 10 respondents. FDA estimates the total annual reporting burden to be 1,600 hours.

Based on a review of the information collection of our current OMB approval, we have made no adjustments to our burden estimate.

Dated: August 17, 2018.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2018–D–2776]

**Evaluating Inclusion and Exclusion Criteria in Clinical Trials; Workshop Report; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency is announcing the availability of a summary report of a public workshop that was held on April 16, 2018, entitled “Evaluating Inclusion and Exclusion Criteria in Clinical Trials.” The FDA Reauthorization Act of 2017 (FDARA) requires that the Agency convene a public workshop to discuss clinical trial eligibility criteria to inform a guidance

on this subject and to publish a report summarizing the topics discussed within 90 days of the public workshop. This summary report fulfills FDA’s mandate under FDARA.

**ADDRESSES:** For persons without internet access, copies of the summary report can be requested from the Division of Drug Information, Food and Drug Administration, by mail: 10001 New Hampshire Ave, Silver Spring, MD 20993–0002, or toll free telephone: 855–543–3784.

**FOR FURTHER INFORMATION CONTACT:**

Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 51, Rm. 3326, Silver Spring, MD 20993, 301–796–2500, *Dianne.Paraoan@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Section 610 of FDARA requires that FDA convene a public workshop to discuss clinical trial eligibility criteria to inform a guidance on this subject and to publish a report summarizing the topics discussed within 90 days of the public workshop (Pub. L. 115–52). On April 16, 2018, FDA convened the public workshop required by FDARA entitled “Evaluating Inclusion and Exclusion Criteria in Clinical Trials.” This notice announces the availability of the report required by FDARA that summarizes the major points explored with stakeholders during the public workshop. The report is intended only as a summary of the workshop