4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0377]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0654. 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.

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 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 headquarter's Dun and Bradstreet D-U-N-S number, and FDA assigned Facility Establishment Identifier 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 on May 10, 2016 (81 FR 28973), which became effective on August 8, 2016, to deem products meeting the statutory definition of "tobacco product" to be

subject to the FD&C Act. 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 to May 8, 2018, for small-scale manufacturers in the areas impacted by recent natural disasters. 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.

In the *Federal Register* of August 23, 2018 (83 FR 42664), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related.

(Comment) FDA received one comment requesting that FDA exercise enforcement discretion by suspending the collection and utilizing the Agency's other authorities to inform regulatory decisions due to the associated burden of manufacturers to retain documents for future submission to FDA. Additionally, the commenter requests FDA to narrow the scope of the collection by defining key terms.

(Response) At this time, FDA does not intend to suspend the collection as respondents have the option to submit documents directly to FDA independent of the compliance policy. Additionally, at this time, FDA believes narrowly defining health effects could potentially exclude relevant scientific information from being retained by industry and subsequently submitted as part of future health document submissions.

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

Activity	No. of Respondents	No. of Responses per	Total Annual Responses	Average Burden per	Total Hours

		Respondent		Response	
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600

Table 1.--Estimated Annual Reporting Burden[1]

[1.] 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 that 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: May 14, 2019.
Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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