4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0351]

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) 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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 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--Revision

This information collection supports FDA guidance. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 904(a)(4) of the FD&C Act ((21 U.S.C. 387d(a)(4)) 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" or "health documents").

The guidance document "Health Document Submission Requirements for Tobacco Products (Revised)" (2023) (www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-health-document-submission) requests tobacco health document submissions from manufacturers and importers of tobacco products based on statutory requirements and compliance dates.[1] We updated the guidance to reflect revised references to current FDA websites, which we will publish upon OMB approval. As indicated in the guidance, 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 Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31)). However, FDA generally does not intend to enforce the requirement at this time with respect to all such health documents, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, are provided at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce.

[1] FDA announced the availability of a guidance on this collection in the Federal Register on April 20, 2010 (75 FR 20606) [revised December 5, 2016 (81 FR 87565), August 10, 2017 (82 FR 37459), and March 20, 2023 (88 FR 16636)]

Thereafter, manufacturers should preserve all health documents, including those that relate to products for further manufacturing and those developed after December 31, 2009, for future submission to FDA. All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

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. You may access the electronic and paper forms on our website, at www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal and www.fda.gov/media/78652/download , respectively. In addition to the electronic and paper forms, FDA issued the guidance on this collection to assist persons making tobacco health document submissions. For further assistance, FDA has provided a technical guide, embedded hints, and a web tutorial on the electronic portal via www.fda.gov/media/78631/download?attachment , www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal#what%20can , and www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions .

In this information collection, FDA is proposing to continue its compliance plan and request all manufacturers and importers of tobacco products, if not previously submitted, at least 90 days prior to the delivery for introduction into interstate commerce. Thereafter, manufacturers should preserve all health documents, including those that relate to products for further manufacturing and those developed after December 31, 2009, for future submission to FDA.

In the *Federal Register* of June 27, 2025 (90 FR 27640), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. 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

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Since the publication of the 60-day Federal Register notice, FDA discovered that we erroneously omitted the discussion of the removal of a line item from the burden chart. As such, FDA estimates that a tobacco health document submission as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on FDA experience. To derive the number of respondents for this provision, FDA assumes that very few manufacturers or importers, or agents thereof, would have health documents to submit. We anticipate 32 document submissions will be submitted on an annual basis by 10 respondents for an average of 3.2 submissions per respondent. We anticipate that manufacturers without additional documents have already completed their notification through a single FDA Form 3743 submission. Conversely, our experience shows that manufacturers with additional documents generally make multiple submissions. FDA estimates the annual reporting burden for these manufacturers to be 1,600 hours.

FDA has adjusted its burden estimate by removing estimates of burden associated with tobacco health document submissions for NTN products because the compliance period for initial submission from NTN manufacturers has passed. This has resulted in a decrease of 200 hours and 100 respondents. With this revision, all tobacco product manufacturers are now accounted for under the single tobacco health document submissions information collection activity listed in Table 1.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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