

United States Food and Drug Administration

Tobacco Health Document Submission

OMB Control No. 0910-0654—EXTENSION

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) guidance. The Federal Food, Drug, and Cosmetic Act (the 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.

Tobacco products are governed by chapter IX of the FD&C Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387u). Section 201(rr) of the FD&C Act, as amended, defines a tobacco product as “any product made or derived from tobacco or containing nicotine from any source that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).”

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” 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-revised) requests tobacco health document submissions from manufacturers and importers of tobacco products based on statutory requirements and compliance dates. 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 (Tobacco Control Act) (Public Law 111-31; 123 Stat. 1776). 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 for current or future finished tobacco products 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. 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.

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 & Bradstreet Data Universal Numbering System (D-U-N-S®) number, and FDA assigned Facility Establishment Identifier (FEI) number
- Authorized representative identification
- Contact prefix, name, position title, email, telephone, fax, company name, address, and country
- Submission format and contents (as applicable)
- Electronic documents: media type, media quantity, size of submission, quantity of documents, file type, file software, and any special instructions
- Paper documents: quantity of documents, quantity of volumes, and quantity of boxes
- Declaration of not having health documents and anticipate not having health documents in the future
- Confirmation statement
- Identification and signature of authorized representative or U.S. agent 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
- 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 the document

(e.g., attachment to a submitted email), document type, and whether the document is present in the University of California San Francisco's Truth Tobacco Documents database

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 extended 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.

The Consolidated Appropriations Act of 2022 (the Appropriations Act) (Pub. L. 117-103), enacted on March 15, 2022, amended the definition of the term "tobacco product" in section 201(rr) of the FD&C Act to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (e.g., products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022, including the requirement of health document collection for tobacco products.

We therefore request extension of OMB approval of the information collection provisions found in the guidance, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Respondents are firms engaged in the manufacture, preparation, compounding, or processing of tobacco products including those products containing NTN. The information collected under this provision of the FD&C Act will inform FDA's development of good manufacturing practices, review standards for new tobacco products, and regulation of modified risk tobacco products, among others.

3. Use of Improved Information Technology and Burden Reduction

To make reporting requirements for this collection easier for respondents, FDA offers respondents the ability to provide their health document submissions electronically through new web forms within the CTP Portal Next Generation (NextGen), or via paper forms available for download from FDA. In the latter case, the submitter may provide electronic documents (digital production on a hard drive, CD, DVD, USB drive) or paper documents along with the paper form. FDA estimates that 90 percent of the respondents will use an electronic means to provide information.

FDA strongly encourages electronic submission by uploading documents via the FDA's CTP Portal NextGen. The CTP Portal NextGen web application requires that an organization request an Industry Account Manager (IAM) role be set up for an individual of the organization to act as an administrator for all of the organization's CTP Portal NextGen accounts. Once the IAM account is created by CTP, the IAM can create, manage, and set roles for all of the organization's employees' CTP Portal NextGen user accounts. Users may then prepare submissions on behalf of their organization using the FDA's eSubmitter tool for supported submission types and can send these submissions to CTP directly from CTP Portal NextGen. Instructions on requesting a free IAM account for CTP Portal NextGen are available at www.fda.gov/tobacco-products/manufacturing/request-industry-account-manager-iam-ctp-portal-next-generation.

Respondents may access the electronic form at www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal-next-generation 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.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

All domestic manufacturers and importers of tobacco products subject to regulation under chapter IX of the FD&C Act are affected by this rule, including small businesses. It is likely that about 85 percent of the affected entities would be considered small tobacco product manufacturers under the definition included in section 900 of the FD&C Act.¹

The information submission requirements in section 904(a)(4) do not fall disproportionately upon small businesses. The Tobacco Control Act requires the submission of this information from each tobacco product manufacturer or importer, or agent thereof. FDA is providing an alternative paper form for those individuals who are unable to, or choose not to, use the electronic form submission option. FDA continues to pursue means of reducing the reporting burden for both small and large respondents and will continue to employ the latest technology for receiving these submissions, consistent with the intent of the legislation.

Experience gained from the initial and ongoing collection indicates that few small firms have documents to report and those that did report documents had substantially fewer documents than large firms.

FDA aids small business in dealing with the information submission requirements of section 904(a)(4) by providing guidance that further describes the statutory requirement for submitting this information.

¹ This estimate is based on counts of tobacco product manufacturer and importer EINs from 2023 TTB data and Census Bureau 2021 Statistics of U.S. Business data (www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html) on establishments with 500 or fewer employees (the closest reported threshold to the small tobacco product manufacturer 350 employee threshold).

6. Consequences of Collecting the Information Less Frequently

The Tobacco Control Act requires the health document submission under section 904(a)(4) of the FD&C Act to begin on December 22, 2009, but does not specify the frequency of submission for this ongoing requirement. FDA is taking an incremental approach to enforcement of this provision with respect to the periods of time for which documents must be submitted. Within the next few years, FDA may expand its enforcement beyond the short time period laid out. This expanded enforcement will enable FDA to more fully accomplish the important public health goals of this provision. Until the notice of a new collection is issued, and the guidance is revised to support a new collection FDA does not expect yearly submissions once an entity has responded.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

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

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Information submitted under section 904 of the FD&C Act may include, but is not limited to, a company's nonpublic trade secret or confidential commercial information. Several laws govern the confidentiality of ingredient information submitted under section 904 of the FD&C Act, including sections 301(j) and 906(c) of the FD&C Act (21 U.S.C. 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as FDA's implementing regulations.

Section 906(c) of the FD&C Act prohibits FDA from disclosing any information reported to or otherwise obtained by FDA under section 904, among other provisions, if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers or employees concerned with carrying out the tobacco products chapter of the FD&C Act and, when relevant, in any proceeding under the tobacco products chapter of the FD&C Act. Section 301(j) of the FD&C Act generally prohibits release of trade secret information obtained by FDA under section 904, among other provisions, outside of the Department of Health and Human Services, except to courts when relevant in any judicial proceeding under the FD&C Act and to Congress in response to an authorized congressional request.

CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. CTP consulted with FDA's Privacy office, which conducted a Privacy Impact Assessment (PIA). The PIA was approved on 8/10/2023 and was assigned PIA ID FDA2107988.

FDA's general regulations concerning the public availability of FDA records are contained in 21 CFR part 20.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 1.—Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600
Total					1,600

The total annual responses 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. 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.

12b. Annualized Cost Burden Estimate

The estimated annualized reporting cost to all respondents for submitting tobacco health documents is \$112,800. This estimate assumes that the tobacco manufacturing industry (all occupations) labor category will account for the health document submissions at an average (mean) hourly wage of \$35.25 (Department of Labor’s Bureau of Labor Statistics, May 2024 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 312200 – Tobacco Manufacturing, data.bls.gov/oes/#/industry/312200). We double this to account for benefits and overhead, yielding an hourly wage rate of \$70.50.

Table 2.—Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco Product Manufacturer, Importer, or Agent	1,600	\$70.50	\$112,800

13. Estimates of Other Total Annual Costs to Respondents and Recordkeepers or Capital Costs
There are no additional capital, start-up, or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

The estimated total annualized cost to the federal government for this information collection is \$132,638. Our estimated cost reflects the allocation of one (1) federal full-time equivalent (FTE) employee who will employ contractors to assist in the review of health document submissions. Using 2025 salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/25Tables/pdf/DCB.pdf for a GS-13, Step 4 employee, we calculate a total annual federal staff cost of \$132,638 (\$132,638 x 1).

15. Explanation for Program Changes or Adjustments

FDA has adjusted its burden estimates to remove the 200 hours that were associated with anticipated initial submission of health documents from NTN products, based on new authority provided by the Consolidated Appropriations Act, 2022. This appropriations statute revised the FD&C Act to include language that made clear the FDA has the authority to regulate tobacco products containing nicotine from any source, which includes synthetic nicotine. Therefore, as of April 14, 2022, firms engaged in the manufacture, preparation, compounding, or processing of tobacco products containing NTN were required to provide health documents to FDA or provide a declaration that they do not have health documents via Form FDA 3743. Because the compliance period for NTN manufacturers to either submit health documents or provide the declaration has passed, FDA has removed the estimated annual burden associated with these tobacco product manufacturers (100 respondents and 200 hours). We now estimate the annual burden for this collection to be 1,600 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

Consistent with established practice, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current information collection expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.