U.S. Food and Drug Administration
Center for Tobacco Products
Tobacco Health Document Submission
OMB Control Number 0910-0654
Supporting Statement Part A

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us, or we) laws and guidance.

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) was enacted. 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, 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" or "health documents").

The guidance document "Health Document Submission Requirements for Tobacco Products (Revised)" (2017) (https://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. 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 Tobacco Control Act). 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. 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's proposed revisions to the guidance reflect that the deemed tobacco product compliance period has passed. Additional proposed revisions include clarifying and editorial changes to promote a better understanding of FDA's interpretation of the "health, toxicological, behavioral,

or physiologic" phrase, examples of health, toxicological, behavioral, or physiologic effects documents, and minor updates to the metadata list.

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
- 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. However, FDA generally does not intend to enforce the requirement at this time with respect to all such health documents for NTN manufacturers, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, are provided 6 months from the April 14, 2022, effective date (October 14, 2022). 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. While the scope of the collection is expanding to cover the submission by these products, the guidance does not include the updates at this time, FDA will include these changes in a later version of the guidance.

We request 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

FDA has chosen to collect the required information through a facilitative electronic form CTP Portal (documents are uploaded into an electronic system) and through a paper form (to identify and categorize the documents) for those individuals who choose not to use the electronic form. 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. We estimate that approximately a third (33%) of the respondents will use the electronic portal.

Respondents may access the electronic form and paper form on our website, at https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal and https://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 is providing 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. The Tobacco Control Act requires the submission of this information. FDA is the only Federal agency responsible for the collection of such information and is the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. Also, firms that have already provided notice or documents to the FDA will not need to respond again until they do have documents to report.

5. Impact on Small Businesses or Other Small Entities

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 facilitative form. 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 collection indicates that few small firms have documents to report and those that did report documents had substantially fewer documents than did 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.

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 intends to 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

This section is not applicable. 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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of February 25, 2022 (87 FR 10800). FDA received no comments.

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 6/24/22, and was assigned PIA ID 2060831.

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

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

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	Annual Frequency	Total Annual	Hours per Response	Total Hours

		per Response	Responses		
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600
Tobacco Health Document Submissions and Form 3743 for Non-Tobacco Nicotine Products	100	1	100	2	200
Total					1,800

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 documents will be submitted on an annual basis for a total of 10 respondents. FDA estimates the annual reporting burden for these manufacturers to be 1,600 hours.

As mentioned previously in this document, with the new authority provided to FDA, firms engaged in the manufacture, preparation, compounding, or processing of tobacco products containing NTN must provide health documents. Although these firms are unlikely to have health documents created within the specified period, we are estimating for this extension that we will receive 100 new NTN respondents who will be required to provide a declaration to such effect via Form 3743, which is expected to take 2 hours, for a total 200 burden hours. FDA estimates the total annual reporting burden to be 1,800 hours.

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $56,070 (1,800 hours x $31.15/hour The Bureau of Labor Statistics (BLS) May 2021 average (mean) hourly wage for all occupations - NAICS 312200 - Tobacco Manufacturing (https://www.bls.gov/oes/current/naics4_312200.htm).

Estimated Annual Cost Burden

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Tobacco Product Manufacturer, Importer, or Agent	1,800	$31.15	$56,070

13. Estimates of Other Total Annual Costs to Respondents and Record Keepers/Capital Costs

There are no additional capital costs associated with this collection of information.

14. Annualized Cost to the Federal Government

Our estimated cost to the Federal government reflects the allocation of 1 full-time equivalent (FTE) employees who will employ contractors to assist in the review of health document submissions. This cost includes a half FTE for document control room staff during receipt and processing and a half FTE of technical support and maintenance. Using as a basis salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov for a GS-13/4 employee, we calculate a total cost of $117,505 ($117,505 x 1).

15. Explanation for Program Changes or Adjustments

We have added 200 hours based on new authority provided by the Consolidated Appropriations Act, 2022. As a result, the FD&C Act now includes specific language that makes clear the U.S. Food and Drug Administration has the authority to regulate tobacco products containing nicotine from any source, which includes synthetic. On April 14, 2022, firms engaged in the manufacture, preparation, compounding, or processing of tobacco products containing NTN must therefore provide health documents. These firms are unlikely to have health documents created within the specified period and will be required to provide a declaration to such effect via Form 3743.

Additionally, we have removed the mailing costs that were assumed as capital costs as we no longer believe this is a capital cost. We now estimate the burden for this collection to be 1,800 hours.

In ROCIS, we are uploading the guidance as an instrument; for the previous ICR, the guidance had been uploaded as a supplementary document.

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 FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, 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 expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.