Tobacco Health Document Submission

0910-0654

SUPPORTING STATEMENT Part A

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding, among other things, a new chapter granting The Food and Drug Administration (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. The Tobacco Control Act created many new requirements for the tobacco industry. 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 2010 (75 R 20606), and requested health documents that were created during the period of June 23, 2009, through December 31, 2009. The guidance stated that information required under section 904(a)(4) 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) through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. In 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 presence of document in the University of California San Francisco 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 2016 (81 FR 87565) and October 2017 (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, 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 six 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.

2. Purpose and Use of the Information Collection

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 (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 20 percent of the respondents will use the electronic portal.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative. 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

There are no special circumstances.

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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER August 23, 2018 (83 FR 42664). FDA received one comment that was PRA related.

(Comment) FDA received one comment requesting that FDA exercise enforcement discretion by suspending the collection and utilize 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.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

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.

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:

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Tobacco Health	10	3.2	32	50	1,600

Document Submissions and Form FDA 3743					

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. Also, the number of respondents who still have documents to submit has decreased.

FDA estimates that a tobacco health document submission for cigars, pipe and waterpipe tobacco, electronic nicotine delivery systems (ENDS), and other tobacco 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 six submissions (two for cigar manufacturers, one for pipe and waterpipe tobacco manufacturers, one for other tobacco product manufacturers, and one for tobacco importers, and one 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 number of hours is 1,600 hours.

FDA estimates that a tobacco health document submission as required by section 904(a)(4) of the FD&C Act will take 50 hours per submission. The Agency estimates that approximately eight submissions will be submitted on a biannual basis each year. 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.

12b. Annualized Cost Burden Estimate

This figure was derived by multiplying the total reporting burden hours by an hourly rate of $19.22. This is the average hourly earnings for a manufacturing employee and is based on published data from the U. S. Bureau of Labor Statistics.

Estimated Annual Cost Burden

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Tobacco Product Manufacturer, Importer, or Agent	1,600	$19.22	$30,752

13. Estimates of Other Total Annual Costs to Respondents and Record Keepers/Capital Costs
Approximately 80 percent of the respondents will submit their tobacco health documents in paper form. The capital costs associated with this collection pertain to the postage cost for mailing the form and health documents for those individuals who choose not to use the electronic

form. These costs will vary depending on the size of the document production (e.g., 1 binder of documents vs. numerous boxes of paper) and the media type (e.g., CD, DVD, USB drive) chosen to submit the documents. Some sample postage costs are shown for different types of packages:

- 10 compact disks (CDs) in a flat envelope weighing 30 ounces: approximately $9.35 using first class business mail

- Five-pound parcel containing paper documents: approximately $14 using business parcel post mail and delivering to the furthest delivery zone

- Ten-pound parcel containing paper documents: approximately $20 using business parcel post mail and delivering to the furthest delivery zone

- Fifty-pound parcel containing paper documents: approximately $60 using business parcel post mail and delivering to the furthest delivery zone

Based on previous submissions, we estimate the capital costs associated with an average health document submission to be $902. This estimate is based upon 26 submissions (roughly 81 percent of 32 total submissions) being submitted via mail with (a) 50 percent of the 26 submissions (13 submissions total) mailing an average of 10 CDs per envelope and (b) 50 percent of the 26 submissions (13 submissions total) mailing a package of paper documents weighing an average of 50 pounds total.

14. Annualized Cost to the Federal Government

FDA anticipates that the Federal Government will incur the following costs. These costs have been reduced from the original collection because of the reduced burden and FDA now has a process and a system in place to manage these documents:

Staff Costs

Full Time Equivalents (FTEs) = 1 FTE at $116,000 each

Annual Cost = $116,000

In addition, FDA will employ contractors to assist in the review of health document submissions at a cost of $126,000. This cost includes a half FTE for document control room staff during receipt and processing and a half FTE of technical support and maintenance at an hourly rate of $126.

Total annual cost to the Federal Government = $116,000 + 126,000 = $242,000

15. Explanation for Program Changes or Adjustments

There are no changes in burden to this collection since the last approval. Capital costs associated with this collection haven't changed since last renewal – the increase reflected in ROCIS is correcting an error from last renewal.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

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

FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement were identified.