Tobacco Health Document Submission

0910-0654

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) 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 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 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
    - Specific current or future tobacco product(s)
    - Class 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, and Bates number ranges for documents attached to a submitted email.

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)). For further assistance, FDA is providing a technical guide, embedded hints, and a web tutorial on the electronic portal.

The Food and Drug Administration (FDA) issued a final rule to deem products meeting the statutory definition of “tobacco product” to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act) May 10, 2016. The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, 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 newly deemed tobacco products. This final rule also prohibits the sale of "covered tobacco products" to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. The rule also provides that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco products (in addition to cigarettes and smokeless tobacco) they manufacture, label, advertise, package, distribute, import, sell, or otherwise hold for sale comply with all applicable requirements. FDA is taking this action to reduce the death and disease from tobacco products.

Although section 904(a)(4) sets out an ongoing requirement to submit tobacco health documents developed after June 22, 2009 (the date of enactment of the Tobacco Control Act), FDA generally does not intend to enforce the requirement with respect to all such documents at this

time, so long as a specified set of documents are submitted by the effective date of the final rule plus 6 months. FDA issued a revised draft guidance in September and has finalized that guidance with a the same six month submission date compliance policy for newly deemed tobacco products that exists for currently regulated tobacco products - June 2009-December 2009. .

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 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 by providing guidance that further describes the statutory requirement for submitting this information.

Small businesses that manufacture newly deemed products, those with 150 or fewer employees and a annual revenues under $5 million dollars, will be provided an addition 6 months to provide health document submissions to FDA.

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 of April 25, 2014 (79 FR 23142). FDA has responded to the comments received in the preamble to the final rule, and the supporting statement for the Deeming information collections under OMB control number 0910-0768.

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:

Existing Burden

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Tobacco Health Document Submissions and Form FDA 3743	4	2	8	50	400

Deeming Burden

Table 2.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Cigar Manufacturers (Including Large and Small)	2	4	8	50	400
Pipe and Waterpipe Tobacco Manufacturers	1	4	4	50	200
Other Tobacco, E-	1	4	4	50	200

Cigarettes, and Nicotine Product Manufacturers ENDS					
Importers of Cigars and Pipe Tobacco Who Are Considered Manufacturers	1	4	4	50	200
Importers of other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers ENDS	1	4	4	50	200
Total Hours Health Document Submission					1,200

Final Burden

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

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 newly 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

The annual reporting cost to respondents for submitting health documents is $7,688, or 2 percent of the original 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. FDA is updating the guidance associated with this collection to include newly deemed products. The collection was previously updated to incorporate the burden for newly deemed products.

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.