Tobacco Health Document Submission

Extension

0910-0654

ABSTRACT FOR USE IN ICRAS

FDA guidance on this collection requested health documents that were created during the period of June 23, 2009, through December 31, 2009. FDA is in the process of revising the April 2010 guidance but will continue collecting documents created during the period of June 23, 2009 through December 31, 2009, from any manufacturers, importers, or their agents who still have documents to submit. The information collected will inform FDA's development of good manufacturing practices, review standards for new tobacco products, and regulation of modified risk tobacco products, among others. Respondents submit information through a facilitative electronic form or in paper form using Form FDA 3743. In both forms, FDA is requesting the following information: Submitter identification, submitter point of contact, submission format and contents (as applicable), confirmation statement, document categorization (as applicable), document readability and accessibility, and document metadata.

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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. Further, FDA stated it would publish a revised guidance specifying the timing of subsequent reporting. FDA is in the process of revising the April 2010 guidance but will continue collecting documents created during the period of June 23, 2009 through December 31, 2009, for any manufacturers, importers, or their agents who still have documents to submit.

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.

This information is not related to the American Recovery and Reinvestment Act of 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.

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. In the final guidance document associated with this information collection, FDA stated that it will publish additional guidance specifying the timing of subsequent submissions. Submitting the remaining documents on a biannual basis should be adequate to ensure FDA continues to receive them until the notice of a new collection is issued and the guidance is revised to support a new collection.

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

This section is not applicable.

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 04/10/2013 (78 FR 21379). FDA received five comments; some comments raised more than one issue. Comments relevant to the information request are addressed in this document.

(Comment 1) One comment indicated that the intent of the notice was unclear and suggested that FDA revise and republish the notice to provide clarity and allow stakeholders more opportunity to comment.

(Response) FDA published the 60-day information collection notice (78 FR 21379) to provide an opportunity for comment on its proposed extension of an existing collection of information. The collection includes health tobacco documents created during the period June 23, 2009, through December 31, 2009, that have not been submitted to FDA. FDA does not believe that revision of the April 2013 notice would add clarity or provide a more meaningful opportunity to comment. FDA has met the requirements for the proposed extension of this collection of information.

(Comment 2) Another comment stated that FDA is outside its statutory authority in recommending coding/classification and places an unnecessary and unreasonable burden on the industry with no benefit to FDA in collecting this information.

(Response) Section 904(a)(4) of the FD&C Act grants FDA the authority to collect health document information as specified in this document. The classification and coding mentioned in this document are recommendations from the April 2010 guidance, and FDA will reevaluate and revisit this issue in developing future guidance.

(Comment 3) Two comments indicated that the timing and burden for this collection are underestimated.

(Response) The estimated burden of 50 hours per response is based on the average burden estimate among four respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 50 hours estimate because it is an average value. FDA notes that the number of documents received since the original collection period has decreased each year and is currently less to than 5 percent of the number received in the year following the Agency's original announcement. FDA expects that this collection of information will decrease by 7,600 hours because most documents created within the specified period have been submitted, and the number of respondents who still have documents to submit has decreased. Therefore, FDA estimates the biannual burden of the continuation of this collection to be, at most, 5 percent of the original burden.

(Comment 4) One comment indicated that the information requested in this collection is from too narrow a collection window, and another comment stated that the collection of 2009 information in 2013 is not necessary.

(Response) Section 904(a)(4) of the FD&C Act sets out an ongoing requirement for the submission of tobacco health documents. FDA is in the process of revising the April 2010 guidance to specify the timing of subsequent submissions. However, the Agency will continue collecting documents created during the period from June 23, 2009 through December 31, 2009, from any manufacturers, importers, or their agents who still have documents to submit.

(Comment 5) Several comments referred to the 2009 draft guidance (74 FR 68629, December 28, 2009) and to previously submitted comments on the 2009 draft guidance.

(Response) The 2009 draft guidance was superseded by publication of the April 2010 guidance. FDA considered comments on the 2009 draft guidance while developing the April 2010 guidance. Comments on Agency guidance are welcome at any time (21 CFR 10.115(g)(5)), and comments submitted on the April 2010 guidance will be considered when the guidance is revised.

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

The estimated 50 hours per response burden is based on the average burden estimate among all 4 respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 50 hours estimate because it is an average value. FDA currently is evaluating the classification/coding recommendations and will revisit this issue in future guidance. However, 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. Therefore, FDA estimates the biannual burden of the continuation of this collection to be, at most, 5 percent of the original burden.

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 per Response	Total Annual Responses	Hours per Response	Total Hours
Tobacco Health Document Submissions and Form FDA 3743	4	2	8	50	400

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	400	$19.22	$7,688

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 $208. This estimate is based upon 6 submissions (80 percent of 8 total submissions) being submitted via mail with (a) 50 percent of the 6 submissions (3 submissions total) mailing an average of 10 CDs per envelope and (b) 50 percent of the 6 submissions (3 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

This is an extension with adjustments due to OPDIV Estimate.

Because the number of documents received each year has fallen to less than 5 percent of what was approved by OMB in 2010, FDA estimates adjustments in the ICR as follows:

- A decrease of 824 total annual responses (from 832 to 8 total annual responses) due to an error in entering the original submission into ICRAS in July 2010, and an adjustment in

the estimate of how many remaining responses are expected to be collected for this information collection. The last submission was approved by OMB on October 11, 2010. In that ICR, FDA entered erroneously the total number of responses as 800 instead of 8. This is substantiated by the submission's supporting statement Item 12, which indicates that a total of 40 total annual responses were to be approved by OMB. Also, Item 3 further substantiates this figure because it indicates that 20% of responses were expected to be submitted electronically. Twenty percent of the 40 responses in that collection is 8. For this submission, FDA estimates that out of the original responses collected, only 8 may still have to submit information, so the number of responses is expected to decrease from the revised 40 submissions to 8 for this submission.

- A decrease of 7,600 total annual burden hours (from 8,000 to 400 total annual burden hours) due to FDA's estimate that the number of documents expected to be submitted each year since the original collection has fallen to less than 5 percent of the original submission. We expect this decrease because FDA estimates that 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 most documents created within the specified period (June-December 2009) have already been submitted. To be conservative, FDA estimates that the total number of burden hours will fall to 5 percent of what was originally approved by OMB, or 400 hours (8,000 x 0.05).

- A decrease of $620 annual cost burden (from $828 to $208 annual cost) due to a decrease in the number of submissions and an increase in the amount of shipping cost per item. In the last submission, FDA estimated that $828 in capital costs were incurred based upon 32 submissions being submitted via mail. FDA estimated that (a) 60% of the 32 submissions were mailed with an average of 10 CDs per envelope (at $8 each envelope or 19 submissions x $8 = $152 total) and (b) 40% of the 32 submissions were mailed with a package of paper documents weighing an average of 50 pounds total (at an average of $52 each package or 13 submissions x $52 = $676 total). Capital costs are expected to decrease during this submission to $208, as the number of submissions is expected to decrease due to a decrease in the overall hourly burden (mentioned above), and a slight increase in the cost of mailing each submission. FDA estimates that 80% of the 8 submissions (or 6 submissions) are expected to be submitted via mail. FDA also estimates that (a) 50% of the 6 submissions will be mailed with an average of 10 CDs per envelope (at $9.35 each envelope or 3 submissions x $9.35 = $28 total) and (b) 50% of the 6 documents mailed using a package of paper documents weighing an average of 50 pounds total (at an average of $60 each package or 3 submissions x $60 = $180 total.) Therefore, the total decrease in capital costs for this collection is expected to be $620 ($828 - $208).

Therefore, the total number of annual responses is expected to decrease to 8 (from 832), the total number of annual burden hours is expected to decrease to 400 (from 8,000), and the total capital cost is expected to decrease to $208 (from $828).

	Requested	Due to New Statute	Due to OPDIV Discretion	Due to Adjustment in OPDIV Estimate	Change Due to Violation	Currently Approved
Annual Number of Responses	8	0	0	-824	0	832
Annual Hour Burden	400	0	0	-7,600	0	8,000
Annual Cost Burden	$ 208	$ 0	$ 0	$ -620	$ 0	$ 828

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.