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 act) by adding, among other things, a new chapter granting FDA important new 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 creates many new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amends the act by adding, among other things, new section 904(a)(4).

Section 904(a)(4) of the 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"). Information required under section 904(a)(4) must be submitted to FDA beginning December 22, 2009.

FDA is collecting the information submitted pursuant to section 904(a)(4) through an electronic portal and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic portal. In the electronic portal and paper form FDA is requesting the following information:

- Submitter identification
  - Submitter type, company name, address, country, company headquarters Dun and Bradstreet D-U-N-S number, and company headquarters 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
- Metadata: document date of creation, 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 portal and paper form, 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 to the electronic portal.

2. Purpose and Use of the Information Collection

The information collected under this provision of the 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 an electronic portal (whereby 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 portal. In the latter case, the submitter may provide electronic documents (digital production on a hard drive, CD, or DVD) or paper documents along with the paper form. We estimate that approximately 20% 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 the primary federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. Therefore, no duplication of data exists.

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 all owners and operators of a tobacco product establishment. FDA is providing an alternative paper form for those individuals who are unable, or choose not to, use the electronic portal. 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.

FDA aids small business in dealing with the information submission requirements of section 904 by providing guidance, which will further describe 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 act to begin on December 22, 2009, but does not specify the frequency of submission for this ongoing requirement. The draft guidance document associated with this information collection provided for a quarterly schedule for document production. FDA determined that a quarterly basis for submission would allow the agency to have a manageable volume of documents to review while not overburdening entities with more frequent submissions. In the final guidance document associated with this information collection, FDA stated that it will publish additional guidance specifying the timing of subsequent submissions. We have retained the quarterly schedule for purposes of this information collection request.

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

FDA received one comment in response to the 60-day notice soliciting public comment on the extension of OMB approval for this information collection. The comment stated that the classification/coding recommendations will impose burdens that significantly exceed the burden estimate of 200 hours and will likely inundate FDA with information with little incremental value. The estimated 200 hours per response burden is based on the average burden estimate among all 10 respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 200 hours estimate since it is an average value. FDA currently is evaluating the classification/coding recommendations and will revisit this issue in future guidance.

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 act may include, but is not limited to, a company's non-public trade secret or confidential commercial information. Several laws govern the confidentiality of ingredient information submitted under section 904 of the act, including sections 301(j) and 906(c) of the 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 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 act and, when relevant, in any proceeding under the tobacco products chapter of the act. Section 301(j) of the 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 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

FDA received one comment on the burden hours and costs in response to the 60-day notice soliciting public comment on the extension of OMB approval for this information collection. The comment stated that the classification/coding recommendations will impose burdens that significantly exceed the burden estimate of 200 hours and will likely inundate FDA with information with little incremental value. The estimated 200 hours per response burden is based on the average burden estimate among all 10 respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 200 hours estimate since it is an average value. FDA currently is evaluating the classification/coding recommendations and will revisit this issue in future guidance. FDA, therefore, is retaining the burden hours and costs provided in the 60-day notice.

12a. *Hour Burden Estimate*
FDA estimates the burden for this information collection as follows:

Estimated Annual Reporting Burden

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Tobacco Health Document Submission and form FDA 3743	10	4	40	200	8,000

FDA estimates that a tobacco health document submission as required by section 904(a)(4) of the act will take 200 hours per submission. The agency estimates that approximately 10 submissions will be submitted on a quarterly basis. The agency bases its estimate on the total number of tobacco firms it is aware of and its experience with document production.

12b. *Reporting Cost Burden Estimate*

The annual reporting cost to respondents for submitting health documents is $ 440,000. This figure was derived by multiplying the total reporting burden hours by an hourly rate of $55. This hourly rate is based on a 2,080 annual work hours and at an annual salary rate of $116,000. This health care professional salary rate includes salary, benefits, overhead, technical staff, support staff, etc. This annual rate was determined by the Agency's current estimates of staff expenses.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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 portal. Estimating these costs is problematic because the costs would 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 or DVD) chosen to submit the documents. Currently we cannot identify how many health documents will be submitted per response.

Some sample postage costs are shown for different types of packages:

- 10 compact disks (CDs) in a flat envelope weighing 30 ounces: approximately $8.00 using first class business mail
- Five pound parcel containing paper documents: approximately $12 using business parcel post mail and delivering to the furthest delivery zone
- Ten pound parcel containing paper documents: approximately $17 using business parcel post mail and delivering to the furthest delivery zone
- Fifty pound parcel containing paper documents: approximately $52 using business parcel post mail and delivering to the furthest delivery zone

We estimate the capital costs associated with an average health document submission to be $828. This estimate is based upon 32 submissions (80% of 40 total submissions) being submitted via mail with (a) 60% of the 32 submissions mailing an average of 10 CDs per envelope and (b) 40% of the 32 submissions 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:

Staff Costs

Full time Equivalents = 6

Annual Cost per FTE=$116,000

Annual Cost = $696,000

Employing contractors to assist in the review of health document submissions = $5,000,000

Total annual cost to the Federal Government = $5,696,000

15. Explanation for Program Changes or Adjustments

Based on comments indicating that the burden estimate was too low, FDA adjusted its original burden estimate from 1.0 hour per response to 200 hours per response. FDA also increased the annual frequency per response from 1 to 4 (quarterly). FDA is maintaining the original estimate of the number of respondents at 10. FDA is basing its estimates on the total number of tobacco firms it is aware of, its experience with document production, and comments received in response to the draft guidance document published on December 28, 2009.

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.