Information Request Regarding Dissolvable Tobacco Products

0910-NEW

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 (the Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FFDCA) by adding 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.

Section 917 of the Tobacco Control Act required the Secretary to establish a Tobacco Products Scientific Advisory Committee (TPSAC), which was formed on March 22, 2009. Section 907(f) of the Tobacco Control Act requires the following:

''(1) REFERRAL; CONSIDERATIONS.—The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 917(c)(4), the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).

''(2) REPORT AND RECOMMENDATION.—Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

Subsections 904(b)(1) and 904(b)(3) of the FFDCA, as amended by the Tobacco Control Act, state that the Secretary may require each tobacco product manufacturer or importer to submit:

"(1) Any or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiological effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives."

"(3) Any or all documents (including underlying scientific or financial information) relating to marketing research involving the use of tobacco products or marketing practices and the effectives of such practices used by tobacco manufacturers and distributors."

FDA is requesting OMB approval of an information collection pursuant to subsections 904(b)(1) and 904(b)(3) an of the FFDCA, as amended by the Tobacco Control Act.

To report accurately on the impact of the use of dissolvable tobacco products on the public health, TPSAC requires information from the tobacco industry manufacturers. FDA will be requesting this information through a letter sent to all manufacturers of tobacco products. This information will include information requests about research pursuant to sections 904(b)(1) and 904(b)(3) of the Tobacco Control Act as well as voluntary information requests beyond the inquiries described in section 904(b).

The letter will request the following information:

Documents and underlying scientific information or financial information relating to the following topics:

1. Marketing research involving the use of dissolvable tobacco products..
2. Marketing practices used by tobacco manufacturers and distributors for dissolvable tobacco products.
3. The effectiveness of marketing practices used by tobacco manufacturers and distributors.

Documents and underlying scientific information relating to the following topics:

4. The health effects of dissolvable tobacco products.
5. The toxicological effects of dissolvable tobacco products.
6. The behavioral effects of dissolvable tobacco products.
7. The physiologic effects of dissolvable tobacco products.

To provide additional background information for the TPSAC review, beyond the section 904(b) request, CTP also is asking for the following information:

8. A complete description of the composition and design of each dissolvable tobacco product.
9. A one to five page summary of the process, criteria and considerations utilized in selecting the form (e.g. size, color, shape), flavoring, and sugar content of each dissolvable tobacco product.
10. A one to five page summary of marketing research on the use of dissolvable tobacco products, e.g. by age, type of prior tobacco use (if any), and by interest in quitting cigarette smoking or traditional smokeless tobacco use. Among other things, address consumer perceptions of taste, impact, nicotine strength, and product harm.
11. A one to five page summary of marketing practices (e.g. by age, type of prior tobacco use if any, and by interest in quitting cigarette smoking or traditional smokeless tobacco use) used by tobacco manufacturers and distributors for dissolvable tobacco products.
12. A one to five page summary of the effectiveness of marketing practices (e.g. by age, type of prior tobacco use if any, and by interest in quitting cigarette smoking or traditional smokeless tobacco use) used by tobacco manufacturers and distributors.

13. A one to five page summary of research results on health effects of dissolvable tobacco products.
14. A one to five page summary of research results on toxicological effects of dissolvable tobacco products.
15. A one to five page summary of research results on behavioral effects of dissolvable tobacco products among users and non-users of other tobacco products regarding appeal, use, initiation, cessation, switching between cigarettes and dissolvable tobacco products, switching between traditional smokeless and dissolvable tobacco products, and dual use of cigarettes and dissolvable tobacco products. Summarize these results for users of different ages.
16. A one to five page summary of research results on physiological effects of dissolvable tobacco products on users and non-users of other tobacco products, including but not limited to chemosensory effects and abuse liability.

2. Purpose and Use of the Information Collection

This is a new collection of information for FDA. TPSAC will require the 904(b) information to assess and report accurately on the impact of the use of dissolvable tobacco products on the public health. The other requested information will provide a scientific framework and basis for TPSAC to develop the report required by the Tobacco Control Act. Individuals from CTP have previously reviewed all of the available published literature on dissolvable tobacco products and presented that information to the TPSAC members. However, there is limited information in the published literature and the Committee specifically identified the topics that are included in the information request as information that is important for them to develop a report and recommendations. TPSAC will use this information to better understand and report on the impact of the use of dissolvable tobacco products on the public health in developing the statutorily required report due on March 22, 2012.

The respondents to this collection of information are from the private sector, and are business and other for-profit institutions who manufacture or import tobacco products.

3. Use of Improved Information Technology and Burden Reduction

FDA is encouraging respondents to submit their response in an electronic format on CD-ROM or DVD. The information request provides guidance for preparing the submission. FDA estimates that approximately 80% of the respondents will submit their response using this format.

4. Efforts to Identify Duplication and Use of Similar Information

Section 904(a)(4) of the act (tobacco health document submission) 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.” Since the tobacco health document submission requirement pertains only to documents developed after June 22, 2009, most of the requested

documents under this 904(b) information collection will not be duplicate documents requested under section 904(a)(4).

5. Impact on Small Businesses or Other Small Entities

   This information collection does not fall disproportionately upon small businesses. The letter requesting this information will be sent to all manufacturers of tobacco products. The agency expects that small businesses will have limited studies on many of the topics, except possibly on their manufacturing processes and marketing practices. Therefore, the burden on small businesses may actually be smaller. Moreover, some small companies may have never manufactured dissolvable tobacco products and their only burden will be to let us know that fact.

   FDA is encouraging respondents to submit their response in an electronic format on CD-ROM or DVD; submission through an electronic portal is not required. The information request provides detailed guidance for preparing the submission. FDA continues to pursue means of reducing the reporting burden for both small and large respondents.

6. Consequences of Collecting the Information Less Frequently

   Respondents to this collection of information are expected to respond to the data collection once. The members of TPSAC require the requested information in order to draft a report, which the Tobacco Control Act requires them to complete within two years of the committee's formation, or March 22, 2012. If this information is not collected, TPSAC will be unable to draft their report and will miss the deadline imposed by statute.

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

   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 that published in the FEDERAL REGISTER of October 25, 2010 (75 FR 65490). FDA received 8 comments from 7 commenters; 6 comments pertaining to the notice, and two comments pertaining to the information collection.
   Six comments were beyond the scope of this information request (e.g., tobacco is dangerous, dissolvable tobacco products are appealing to children, FDA should let the market prevail, FDA reviewers and TPSAC are not impartial). Comments relevant to the information request are addressed below.

   One commenter suggested that they would like to withhold proprietary information or have FDA mark the information received as "confidential and proprietary", and would like FDA to explicitly state in the letter that FDA does not require nor accept publically available information. The commenter would like FDA to accept submission of lists, summaries, and abstracts as a first pass so FDA could then decide which documents it really needs, and would like FDA to better explain what it is looking for with regard to

internal reports. The commenter would like FDA to restrict submissions to primary research data, and would like FDA to provide specific instructions for the citing of previously submitted documents so they can be fully referenced. FDA's response is that, with regard to confidential and proprietary information, documents submitted under section 904(b) of the FD&C Act may include, but are not limited to a company's non-public, trade secret, or confidential commercial information. FDA also notes that several laws govern maintaining the confidentiality of new tobacco product information submitted under section 904(b), 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. FDA's general regulations concerning the public availability of FDA's records are contained in 21 CFR Part 20. With regard to the submission of summary lists instead of documents, it is the responsibility of manufacturers and importers to identify and submit all documents that are responsive to a request under section 904(b). Information which could be responsive to this section 904(b) request that has been previously provided to FDA does not have to be re-submitted as long as the document is fully referenced with information including file name and file extension, Bates number (begin Bates number to end Bates number), the date of submission, and relevant page numbers. If the documents were previously submitted to FDA under the sections 904(a)(1), 904(c)(1), 904(c)(2) or 904(c)(3) requirement to submit listings of ingredients in tobacco products, FDA asks that the respondent please provide the date of submission, section under which the document was submitted, and the tobacco product brand/subbrand name and product identification number.

One commenter indicated that they bear responsibility for coordinating the implementation of the Tobacco Control Act for itself and its subsidiaries, and that they had already provided FDA with substantial information regarding dissolvable tobacco products in response to a February 1, 2010 request from FDA for this information. They also are concerned that FDA does not appear to give meaningful consideration to the burden imposed by FDA's requests, or to respondent's ideas for more efficient collections of information. The commenter hoped that FDA will consider the comments received as it continues to formulate future document and information collection requests and realize that FDA has seriously underestimated the time and cost burden to gather, review, and produce the requested documents. In addition, the commenter felt that FDA did not adequately explain how it calculated the estimated burden for respondents, as the 230 burden hours listed in the 60 Day Federal Register notice may be accurate for manufacturers conducting peripheral research, but may not be that accurate for a large tobacco manufacturer. The commenter stated that they estimate it will take10,000 hours to produce the documents the FDA requested related to dissolvable tobacco products. The commenter stated that FDA has exhibited a pattern of underestimating burden associated with document production requests in the past, and that this collection runs counter to the Paperwork Reduction Act of 1995 because the collection does not minimize respondent burden, and will have no practical utility to the FDA. The commenter also asked that FDA, rather than respondents, identify previously submitted documents because they should be able to produce this information using commonly available commercial software. The commenter re-emphasized that FDA and TPSAC would be unable to process the sheer volume of this information, so it has little practical

utility and does not minimize paperwork burden in violation of the PRA. They ask that FDA revise its estimated time and burden on manufacturers, allow time for meaningful review, and maximize the practical utility of this collection. FDA responded that in estimating the initial burden for this collection, FDA utilized its staff expertise and previous experience with similar types of agency collections to determine the burden. While FDA understands that there appears to be a large discrepancy in burden between this commenter's estimate and FDA's estimate, FDA did follow a methodology to determine as accurate an estimate as possible. However, due to the comments received for this information collection and other comments submitted by stakeholders, FDA has revised the burden for this collection. Information received by the public directly and in response to requests for comments will assist FDA in determining more accurate burden estimates in the future. With regard to the submission of documents previously, FDA maintains that it is the responsibility of manufacturers and importers to identify and submit all documents that are responsive to a request under section 904(b). As stated in the 60 Day Federal Register notice and letter, information responsive to this section 904(b) request which has been previously submitted to FDA under the Tobacco Control Act does not have to be re-submitted as long as the document is fully referenced.

FDA has collaborated with and will continue to collaborate with National Institutes of Health (NIH) in conducting preliminary data analysis. FDA has also requested data from the Federal Trade Commissions (FTC) and will partner with the Centers for Disease Control and Prevention (CDC) for purposes of data analysis. FDA is also drawing on its experience with tobacco health document submissions under section 904(a)(4) of the Act to inform the burden estimates associated with this information collection.

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 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 of 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 estimates the burden for this information collection as follows:

12a. *Hour Burden Estimate*

FDA estimates the burden for this collection of information as follows:

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Large Tobacco Manufacturers or Importers	3	1	3	7,500	22,500
Small to Medium Tobacco Product Manufacturers or Importers	7	1	7	230	1,610
Submission of Letter indicating no documents available	110	1	110	1	110
Total	120		120		24,220

FDA has adjusted the burden for this information collection based on stakeholder and public comments received for this collection. Originally, FDA estimated that 10 tobacco manufacturers would be responsible for submitting documents, and that their burden would average 230 hours each. After reviewing comments, FDA still maintains that 10 tobacco manufacturers will be responsible for submitting documents, and has now broken the burden into three tiers – Large manufacturers and importers, small to medium manufacturers and importers, and manufacturers who are only required to submit a letter indicating that they have no tobacco documents to submit.

As shown in the table above, FDA now estimates that 3 large manufacturers are estimated to take approximately 7,500 hours apiece to provide dissolvable tobacco product documents, 7 small to medium manufactures are estimated to take approximately 230 hours apiece to provide dissolvable tobacco product documents, and 110 other manufacturers who do not have documents, do not manufacture dissolvable tobacco products, or do not anticipate manufacturing dissolvable tobacco products will take approximately 1 hour to draft and send a letter to FDA indicating that they do not have documents to submit. These estimates were derived based upon FDA experience and feedback provided by public and stakeholder comments.

12b. *Reporting Cost Burden Estimate*

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco manufacturers	24,220	$55.00	1,332,100

FDA estimates the reporting cost to respondents is $1,332,100. This figure was derived by multiplying the total reporting burden hours (24,220) 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.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

The capital costs associated with this collection pertain to the postage for mailing documents in electronic or paper formats. Estimating these costs is problematic because the costs will vary depending on the size of the document production (e.g. one binder of documents vs. numerous boxes of paper) and the media type (e.g., paper, CD, or DVD) chosen to submit documents. Currently, we cannot identify how many 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 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.

FDA estimates the capital costs associated with this document submission to be $924. The capital costs determined by this estimate are based upon 3 submissions for large manufacturers, 7 submissions for small to medium manufacturers, and 110 submissions of one letter apiece for those who do not either manufacture dissolvable tobacco products or have documents pertaining to the manufacture of dissolvable tobacco products.

For the 3 large manufacturers, it is estimated that each manufacturer will submit their documents electronically on the equivalent of one (1) 500gb external hard drive of data. This is estimated to cost approximately $125 per drive, and $20 to ship the drive, for a total of $435 (3 manufacturers x [$125 + $20]).

For the 7 small to medium sized manufacturers, it is estimated that 5 manufacturers (about 71%) will submit their documents electronically on the equivalent of 10 CD-ROMs. This is estimated to cost $20 for the 10 CD-ROM spindle, and $8 to ship each group of 10 CD's per envelope for a total of $140 (5 manufacturers x [$20 + $8]). The remaining 2 manufacturers will submit their documents via paper, which is estimated to cost $184 (2 manufacturers x [$40 cost of the box of paper + $52 to ship the box of paper]). The total capital cost for small to medium manufacturers, therefore, is estimated to be $324 ($140 + $184).

For the remaining 110 manufacturers who must only submit a letter to FDA indicating that they do not have any documents, it is estimated that each manufacturer will use $1 of paper products and pay postage approximating a rounded figure of $0.50 for a total of $165 (110 manufacturers x [$1.00 + $0.50]).

Therefore, FDA estimates the total capital costs associated with this collection of information to be $924 ($435 + $324 + $165=$924.)

14. Annualized Cost to the Federal Government

FDA anticipates that the Federal Government will incur the following costs:

Staff Costs

Full time Equivalents = 5 for 8 months.

Annual Cost per FTE = $116,000

Total Cost = approximately $387,000

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Section 907(3) requires TPSAC to produce its report two years after its formation, which is March 22, 2012.

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

    FDA is not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    No exceptions to the certification statement were identified.