Information Request Regarding Menthol in Cigarettes

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 requires the Secretary to establish a Tobacco Products Scientific Advisory Committee (TPSAC). Section 907(e) of the Tobacco Control Act requires the following:

> ''(1) REFERRAL; CONSIDERATIONS.—Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under section 917(a), the Secretary shall refer to the Committee for report and recommendation, under section 917(c)(4), the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsections (a)(3)(B)(i) and (b).
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> ''(2) REPORT AND RECOMMENDATION.—Not later than 1 year 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."
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> "(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 menthol in cigarettes on the public health, TPSAC is requesting information from cigarette 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).

For the purposes of this section 904(b) request, the cigarette manufacturer is to submit documents and underlying scientific information relating to the following topics:

1. Dose-response relationships for the physiologic effects of mentholated tobacco smoke.
2. Chemosensory effects of menthol compounds in tobacco smoke, including effects at thermal and trigeminal receptors.
3. Impact of menthol on the neurobiology of tobacco dependence.
4. Dose-related interactions between menthol and nicotine on a) consumer perception of nicotine strength and b) uptake and metabolism of nicotine.
5. Correlations between menthol content and consumer perceptions regarding a) taste, b) impact, c) nicotine strength, and d) product harm.

In accordance with FDA's request under section 904(b) of the act, the cigarette manufacturer is also to submit documents and underlying scientific information developed since January 1, 1990 relating to the following topics:

6. Consumer perception studies around advertising and packaging of menthol cigarettes.
7. Marketing strategies by brand/subbrand of menthol cigarettes, including a) strategies targeted to particular demographic groups, b) strategies aimed at tobacco-naïve consumers, and c) strategies aimed at recruitment of former tobacco users.
8. Rates of users switching from menthol to nonmenthol cigarettes and vice versa.
9. Comparative rates of initiation for menthol and nonmenthol cigarettes.
10. Comparative rates of cessation for users of menthol and nonmenthol cigarettes.

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

11. Quantities of menthol and nicotine in the cigarette by brand/subbrand and by year between 2000 and 2010. Each brand/subbrand should be identified as a menthol or nonmenthol product.

12. Quantities of menthol and nicotine in the cigarette smoke, as measured using the FTC and Canadian Intense methods, by brand/subbrand and by year between 2000 and 2010.
13. Description of the manufacturing process by which menthol is introduced into their menthol cigarettes, including a) the source and type of menthol used, b) the presence or use of any menthol analogs, and c) the manufacturing stage at which menthol is introduced (e.g., placed on the foil in contact with the tobacco product, introduced as a flavor into the reconstituted tobacco).
14. Threshold (e.g., menthol content) at which the firm identifies and markets a product by reference to its menthol flavoring or characteristics.
15. Rationale for adding menthol to cigarettes not marketed as menthol cigarettes, and criteria for determining amount of menthol to be added.
16. Research on other chemical compounds structurally or functionally similar to menthol, including the rationale for identifying and using such compounds in cigarettes.

We are requesting emergency processing of this information collection regarding the public health impact of menthol in cigarettes. As described above, section 907(e) of the act requires TPSAC to study "the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities," and to provide CTP with a report and recommendations. To ensure a comprehensive review of this issue, CTP is requesting tobacco industry data and information to support the work of TPSAC. Pursuant to section 907(e), TPSAC must submit its report and recommendations to the Secretary of Health and Human Services within one year of its formation, or March 23, 2011. We are requesting emergency processing and clearance of this information collection by May 17, 2010, so that FDA can issue the letter to industry requesting this information soon thereafter. This timeframe will enable FDA to receive information by July, 2010 in order for TPSAC to have this information for its analysis and review for developing its report and recommendations.

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 menthol cigarettes 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 menthol (more than 300 articles) 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 menthol in cigarettes on the public health in developing the statutorily required report due on March 23, 2011.

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. We estimate that approximately 80% of the respondents will submit their response using this format.

4. Efforts to Identify Duplication and Use of Similar Information

To avoid the inefficiencies associated with submitting, receiving and reviewing duplicative documents or substantively identical documents, FDA requests only final document versions, or in the absence of a final version, the most recent draft of each document. This request specifically excludes a) past iterations of a completed or more recent document, b) document duplicates, or c), near duplicates that only vary in minor ways (e.g. differences in addressee or changes in letterhead).

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). However, the letter to industry requesting this information will state that if information responsive to this 904(b) request has been previously provided to FDA under the 904(a)(4) requirement to submit certain tobacco health documents, such documents do not have to be re-submitted as long as the document can be fully referenced (e.g., by the file name and file extension, Bates number (begin Bates number to end Bates number), the date of submission, and relevant page numbers). However, information sufficient to fully identify the document must be provided in lieu of reproducing the document under this 904(b) submission.

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 added menthol to their cigarettes 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. The letter to industry requesting menthol-related documents provides instructions on how to comply with the information collection request.

6. Consequences of Collecting the Information Less Frequently

The members of TPSAC require the requested information in order to draft a report, which the Tobacco Control Act requires them to complete within one year of the committee's formation.

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 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. We are also drawing on our experience with tobacco health document submissions under section 904(a)(4) of the Act to inform the burden estimates associated with this information collection.

Upon renewal of this emergency clearance in six months, FDA will publish a 60-day notice to solicit public comment on the burden estimates contained in this emergency clearance.

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 has not yet sought comment on the burden hours and costs of this information request. However, FDA has based these burden hours and costs on estimates and comments received for similar information requests, including those under section 904(a)(4) (tobacco health document submission). In addition, these burden estimates are informed on current FDA reporting experience.

FDA estimates the burden for this information collection as follows:

12a. *Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Submission of menthol-related documents	116	1	116	140	16,240

Reporting Burden

FDA estimates that the submission of menthol-related documents will take approximately 140 hours per submission. The Agency estimates that approximately 116 submissions will be submitted in this one-time collection. The agency bases its number of respondents on the number of registered manufacturers of tobacco products.

12b. *Reporting Cost Burden Estimate*

FDA estimates the reporting cost to respondents is $893,200. 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 for mailing documents in electronic format. Estimating these costs is problematic because the costs would 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., 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.

We estimate the capital costs associated with this document submission to be $1940. This estimate is based upon (a) 93 submissions (80% of 116 submissions) being submitted by mailing an average of 10 CDs per envelope and (b) 23 submissions (20% of the 116 submissions) being submitted by 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 = 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 collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Section 907(3) requires TPSAC to produce its report one year after its formation, which is March 23, 2011.

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

We are 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.