Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

0910-0671 -Extension
SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of the Information Necessary[1]
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. Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section 3(b)(3)(A) of the Smokeless Tobacco Act requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by, FDA.

2. Purpose and Use of the Information Collection

This information collection--the submission to FDA of warning plans for smokeless tobacco products--is statutorily mandated. The warning plans will be reviewed by FDA, as required by the Smokeless Tobacco Act, to determine whether the companies' plans for the equal distribution and display of warning statements on packaging and the quarterly rotation of warning statements in advertising for each brand of smokeless tobacco products comply with section 3 of the Smokeless Tobacco Act, as amended.

3. Use of Improved Information Technology and Burden Reduction

The Smokeless Tobacco Act does not specify the means for submission of warning plans. There are three ways to submit warning plans: electronic format submitted via the FDA Electronic Submission Gateway; electronic format submitted on physical media (e.g., CD or DVD); or paper format. FDA estimates 90 percent will submit electronically.

4. Efforts to Identify Duplication and Use of Similar Information

FDA knows of no other regulations addressing this subject area or requiring disclosure of similar information. Although the warning statement requirements

[1] OMB review is sought only for the requirement to submit warning plans to FDA. FDA does not seek clearance for the requirement to display warning statements on smokeless tobacco products because the information (i.e., the warnings supplied by the Federal Government to the recipient for the purpose of disclosure to the public) does not constitute the "collection of information" as that term is defined in the regulations implementing the Paperwork Reduction Act (5 CFR 1320.3(c)(2)).

for smokeless tobacco products are similar to those applicable to cigarettes under the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), as amended by the Tobacco Control Act, no other statute provides for warning statements on the packaging or advertising of smokeless tobacco products. Furthermore, except as provided in the Tobacco Control Act, no statement relating to the use of smokeless tobacco products and health, other than the four warning statements required by the Smokeless Tobacco Act, shall be required by any Federal, State, or local statute or regulation to be included on the package or in an advertisement of a smokeless tobacco product. See section 7(a) of the Smokeless Tobacco Act, as amended (15 U.S.C. 4406).

5. Impact on Small Businesses or Other Small Entities

   The requirement for submission of warning plans does not fall disproportionately upon small businesses. The Smokeless Tobacco Act requires the submission of this information from manufacturers, distributors, importers, and retailers that manufacture, package, sell, offer to sell, distribute or import for sale or distribution smokeless tobacco products within the United States. Retailers may be exempt from this requirement under certain circumstances.

   CTP has issued guidance to assist small businesses and other persons required to submit warning plans under the Smokeless Tobacco Act.

6. Consequences of Collecting the Information Less Frequently

   Submission of warning plans for smokeless tobacco products to FDA is required so FDA can review and ensure the plan complies with the requirements set forth in the Smokeless Tobacco Act.

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 March 18, 2013 (78 FR 16678). No comments were received.

   The Federal Trade Commission (FTC) originally implemented the warning plan requirements in 1986 and thus had 24 years of experience in this area. In 2010, when FDA first estimated the burdens associated with the submission of warning plans for smokeless tobacco products, FDA staff reviewed the FTC's 2007 information collection notice.

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 3 of the Smokeless Tobacco Act may include, but is not limited to, a company's non-public trade secret or confidential commercial information. Certain laws govern the confidentiality of warning plan information, including 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 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

In the FEDERAL REGISTER of August 7, 2007 (72 FR 44138), the FTC published a 30-day notice announcing an opportunity for public comment and that the information collection would be sent to OMB for review. Based on the FTC's previous experience with the submission of warning plans and FDA's experience with smokeless tobacco companies (e.g., correspondence associated with user fees under section 919 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act (21 U.S.C. 387s)), FDA estimates that there are 36 companies affected by this information collection. To account for the entry of new smokeless tobacco companies that may be affected by this information collection, FDA is now estimating the total number of respondents to be 100.

When the FTC requested an extension of their approved information collection in 2007, based on over 20 years implementing the warning plan requirements and taking into account increased computerization and improvements in electronic communication, the FTC estimated submitting an initial plan would take 60 hours. Based on FDA's experience over the past several years, FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable.

12a. Annualized Hour Burden Estimate

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

Estimated Annual Reporting Burden

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Submission of rotational plans for	100	1	100	60	6,000

health warning label statements					

12b. Annualized Cost Burden Estimate

The estimated annual reporting cost to respondents for submitting rotational warning plans is $1,218,000. This estimate is based on the assumption that management or attorneys will account for 80 percent of the estimated 6,000 hours required to draft initial plans, at an hourly rate of $250 per hour, and that clerical support will account for the remaining time (20 percent) at an hourly rate of $15. [Management and attorneys' time (6,000 hours x 0.80 x $250 = $1,200,000) + clerical time (6,000 hours x 0.20 x $15 = $18,000) = $1,218,000.]

Respondent	Total Burden Hours	Hourly Wage Grade	Total Costs
Tobacco industry: management and attorneys	4,800	$250	$1,200,000
Tobacco industry: clerical	1,200	$15	$18,000
Total			$1,218,000

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

The requirement to submit a warning plan for smokeless tobacco products imposes minimal start-up costs. The companies may keep copies of their plans to ensure that packaging and advertising complies with the requirements of the Smokeless Tobacco Act. Such recordkeeping would require the use of office supplies, e.g., file folders and paper, all of which the companies should have on hand in the ordinary course of their business. While companies submitting initial plans may incur one-time capital expenditures for equipment used to print package labels, or to prepare acetates for advertising, in order to include the statutory health warnings, the warnings themselves disclose information supplied by the Federal Government. As such, the disclosure does not constitute a "collection of information" as it is defined in the regulations implementing the PRA, nor, by extension, do the financial resources expended in relation to it constitute paperwork "burden." See 5 CFR 1320.3(c)(2). Moreover, any expenditures relating to the statutory health warning requirements would likely be minimal. After FDA approves a plan for the equal distribution and display of warning statements on packaging, and the quarterly rotation of warning statements in advertising for each brand of

smokeless tobacco product, as required by the Smokeless Tobacco Act, the companies are required to make additional submissions to FDA only if they change their warning plan. Once companies have prepared the artwork for printing the required warnings on packages, there is no additional start-up costs associated with the display of the warnings on packaging. Similarly, once companies have prepared artwork for including warnings in advertising, there is no additional start-up costs associated with printing the warnings in those materials.

There will likely be small capital costs associated with this collection that pertain to the postage for mailing submissions. Estimating this cost is problematic because the costs would vary depending on the size/weight of the mailed submission. FDA's estimate is based upon all 100 respondents mailing in their submission at a postage rate of $12 for a 5-pound parcel (business parcel post mail delivered from the furthest delivery zone). Therefore due to the increase in respondents, FDA estimates that the total postage cost for mailing the rotational warning plans will be $1,200, an increase of $960.

14. Annualized Cost to the Federal Government

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

Staff Costs:
Full-time Equivalents (FTE) = 50 percent of 1 full time equivalent
Annual Cost per FTE=$116,000
Total Annual Cost to the Federal Government = $58,000

FDA estimates that the current year's cost of implementing this requirement is approximately $58,000. This estimate is based on the assumption that approximately 50 percent of an FTE's work year is devoted to administering the requirements. The salary rate of $116,000 includes salary, benefits, overhead, technical staff, support staff, etc. This annual rate was determined by the Agency's current estimates of staff expenses.

15. Explanation for Program Changes or Adjustments

This is a request for an extension with an adjustment in burden due to new estimates. The number of respondents is expected to increase from 20 to 100 for an increase of 80, and the number of burden hours is expected to increase from 2,000 to 6,000 hours. This is due to FDA's estimates that new smokeless tobacco companies will submit warning plans under this collection of information. The total increase in burden is 4,000 hours, due to an expected increase in industry education and more importers and retailers realizing that they will need to submit warning plans. Additionally due to the increase in respondents, FDA estimates that the total postage cost for mailing the rotational warning plans will be $1,200, an increase of $960.

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.