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

Terms of Clearance: None.

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. 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.

This collection of information is for the submission of warning plans to FDA for smokeless tobacco products.

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.

This collection of information is being collected from private sector for-profit businesses.

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 of the expected respondents to this collection of information will submit their warning plans electronically.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of information being requested by this collection of information. FDA knows of no other regulations addressing this subject area or requiring disclosure of similar information. Although the warning statement requirements 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 3(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 draft 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. The consequence of collecting this collection of information less frequently could result in a product being labeled as misbranded or adulterated.

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

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

In the Federal Register of February, 19, 2016 (81 FR 8505), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA related comment was received.

(Comment) The comment believes that warning plans should not be renewed every year, but should remain in force as long as necessary after their approval.

(Response) FDA does not require that a previously FDA-approved warning plan be resubmitted. FDA reviews and approves warning plans only once, unless a submitter seeks to change the distribution or display of warnings on packages or rotation of warnings in advertisements, in which case the submission would be considered a supplement. The purpose of FDA's proposed extension is to account for the entry of new smokeless tobacco product brands and advertising onto the market place.

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 52 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 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.

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden[1]					
Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of rotational plans for health warning label statements	100	1	100	60	6,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

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 billing rate of $250 per hour, and that clerical support will account for the remaining time (20 percent) at an hourly billing 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. As a normal business practice, the companies may keep copies of their plans to document that packaging and advertising complies with the requirements of the Smokeless Tobacco Act. This 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.

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

There are no changes to this collection.

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.