Supporting Statement
Requirements under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as amended by the Family Smoking Prevention and Tobacco Control Act

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 (Tobacco Control Act) (Public Law 111-31) into law. Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act) (15 USC §§ 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. Among the requirements in Section 3(b)(3) is that the rotation of label statements on packaging and advertising for each brand of smokeless tobacco must be "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" to, and approved by, FDA. At this time, as an exercise of enforcement discretion, FDA does not intend to commence or recommend enforcement of the requirement that a smokeless tobacco manufacturer, distributor, importer, or retailer must have an FDA-approved rotational warning plan so long as a rotational warning plan has been submitted to FDA by July 22, 2010. FDA believes that allowing additional time for the submission and review of rotational warning plans will permit an orderly transition of regulatory authority from the FTC to FDA to review and approve rotational warning plans.

   To the best of FDA's knowledge, all of the affected companies have previously submitted similar plans to the Federal Trade Commission (FTC), which had authority to implement the requirements of the Smokeless Tobacco Act prior to the Tobacco Control Act's amendments. However, since the requirements of the Smokeless Tobacco Act have been revised and since FDA will have authority to implement the Smokeless Tobacco Act on June 22, 2010, each affected company will be required to submit a new plan to FDA instead of FTC.

   This information is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

   This is a new, statutorily mandated collection of information for FDA. The information contained in the plans will be reviewed by FDA as required by the

[1] OMB review is sought only for the requirement to submit rotational plans to FDA. FDA does not seek clearance for the requirements regarding the display of health warnings for smokeless tobacco products because information originally 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 C.F.R. § 1320.3(c)(2).

Smokeless Tobacco Act to determine whether the companies' plans for rotation, display, and distribution of warning statements comply with Section 3 of the Smokeless Tobacco Act, as amended by the Tobacco Control Act.

3. Use of Improved Information Technology and Burden Reduction

   The Smokeless Tobacco Act does not specify the means for submission of rotational plans. FDA requests that rotational warning plans for smokeless tobacco products be submitted in writing. Based on the FTC's experience, most, if not all, submissions will be submitted by mail since companies like to provide actual copies of labels and advertisements.

4. Efforts to Identify Duplication and Use of Similar Information

   The FTC currently implements the requirements of section 3 of the Smokeless Tobacco Act until the amendments of the Tobacco Control Act become effective on June 22, 2010. Except for FTC regulations implementing the Smokeless Tobacco Act, FDA knows of no other regulations addressing this subject area or requiring disclosure of similar information. Although the rotating health warning scheme is similar to that applicable to cigarettes under the Federal Cigarette Labeling and Advertising Act (15 USC 1333), as amended by the Tobacco Control Act, no other statute provides for health warnings in the labeling 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 USC § 4406).

5. Impact on Small Businesses or Other Small Entities
   The rotational warning plan submission does not fall disproportionately upon small businesses. The Smokeless Tobacco Act requires the submission of this information from all manufacturers, distributors, and importers who manufacture, package, or import smokeless tobacco products for sale or distribution in the United States.

   FDA aids small businesses in dealing with the submission requirements of the Smokeless Tobacco Act by providing guidance, which will further describe the statutory requirements for submitting rotational warning plans.

6. Consequences of Collecting the Information Less Frequently
   Failing to collect this information would violate the Smokeless Tobacco Act and prevent the FDA from determining whether the plans are in compliance with 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
   FDA staff consulted FTC's information collection notice to estimate the burdens associated with this information collection. FTC originally implemented the rotational plan requirements in 1986 and thus has had twenty-four years of experience in this area.

   FDA also published on March 16, 2010, a Federal Register notice announcing an opportunity for public comment on this proposed collection of information (75 FR 12552). The comment period closed May 17, 2010. No comments were received.

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 rotational 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 rotational 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), FDA estimates that there are 14 companies affected by this information collection. To account for the entry of new smokeless tobacco companies who may be affected by this information collection, FDA is estimating the total number of respondents to be 20.

    When the FTC originally implemented the rotational plan requirements in 1986, the Smokeless Tobacco Council, Inc. indicated that the 6 companies it represented would require 700 to 800 hours in total (133 hours each) to complete an initial

rotational plan, involving multiple brands, multiple brand varieties, and multiple forms of both packaging and advertising. When the FTC requested an extension of their PRA clearance in 2007, the FTC decreased the estimate for submitting an initial plan from 143 hours to 60 hours, accounting for increased computerization and improvements in electronic communication over the subsequent 20 years since the Smokeless Tobacco Act was enacted. FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be reasonable. However, since the requirements of the new Smokeless Tobacco Act are unfamiliar to industry, FDA is increasing the time estimate for submitting initial plans to 100 hours.

12a. ***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 health warning label statements	20	1	20	100	**2000**

12b. ***Reporting Cost Burden Estimate***
The annual reporting cost to respondents for submitting rotational warning plans is $ 406,000. This is based on the assumption that management or attorneys will account for 80% of the estimated 2,000 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%) at an hourly rate of $15. [Management and attorneys' time (2,000 hours x 0.80 x $250 = $400,000) + clerical time (2,000 hours x 0.20 x $15 = $6,000) = **$406,000**]

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

The applicable requirements impose 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 in order to include the statutory health warnings or to prepare acetates for advertising, the warnings themselves disclose information completely 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 in any event. After FDA approves a plan for the rotation and display of the warnings required by the Smokeless Tobacco Act, the companies are required to make additional submissions to FDA only if they choose to change the way they display the warnings. Once companies have prepared the artwork for printing the required warnings on package labels, there are no additional start-up costs associated with the display of the warnings on packaging. Similarly, once companies have prepared artwork for the display of the warnings in advertising, there are 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 20 respondents mailing in their submission at a postage rate of $12 for a five pound parcel (business parcel post mail delivered from the furthest delivery zone). **Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to be $240.**

14. Annualized Cost to the Federal Government

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

Staff Costs

Full time Equivalents (FTE) = 30% of 1 full time equivalent
Annual Cost per FTE=$116,000
Total Annual Cost to the Federal Government = $34,800

Staff estimates that the current year's cost to FDA of implementing this requirement is approximately $34,800. This estimate is based on the assumption that approximately 30% 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 new collection for FDA.

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.