Supporting Statement
Smokeless Tobacco Act Regulations
16 C.F.R. Part 307
OMB No. 3084-0082

(1) Circumstances Making the Collection of the Information Necessary[1]

The Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401-4411 ("Smokeless Tobacco Act" or the "Act"), requires, among other things, that manufacturers, packagers, and importers of smokeless tobacco products include one of three specified health warnings on product packaging and in advertisements. Section 3(d) of the Act, 15 U.S.C. § 4402(d), also requires smokeless tobacco companies to submit to the Federal Trade Commission for its review and approval plans specifying a method used to rotate, display, and distribute health warnings in their labeling and advertising. The Commission has issued regulations implementing these provisions.

To the best of the Commission's knowledge, all of the affected companies have previously filed plans. However, the plan submission requirement also applies to a company that amends its plan, or to a new company that enters the market.

(2) Use of the Information

The information contained in the plans will be reviewed by the Commission as required by the Smokeless Tobacco Act to determine whether the companies' plans for rotation, display, and distribution of warning statements satisfy the requirements of the regulations and will comply with the Smokeless Tobacco Act.

(3) Consideration of the Use of Information Technology to Reduce Burden

The reporting requirements of the Rule provide for the periodic filing of rotational plans. Firms subject to this requirement are permitted to use any technology at their disposal in preparing their filings, including, but not limited to, the use of electronic reproduction methods. The firms, however, must submit actual copies or exemplars of advertising and labeling that can be physically inspected to determine if they meet the Rule's "clear and conspicuous" standard. Accordingly, the Government Paperwork Elimination Act, Pub. L. No. 105-277, Title XVII, 112

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[1] OMB review is sought only for the parts of the regulations that require the submission of plans to the Commission, 16 C.F.R. § 307.11(b) and (c), and § 307.12(b) and (c). The Commission 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).

Stat. 2681-749 ("GPEA"), does not require the agency to provide electronic filing options, which would not be fully practicable for the reasons set forth.[2]

(4) Efforts to Identify Duplication

Staff knows of no other regulations addressing this subject area or requiring disclosure of similar information. Although the rotating health warning scheme of the regulations is similar to that applicable to cigarettes under the Comprehensive Smoking Education Act, Public Law 98-474, no other regulation provides for health warnings in the labeling or advertising of tobacco products. Further, the regulations incorporate the preemption standard of Section 7 of the Smokeless Tobacco Act. 16 C.F.R. § 307.2. Under Section 7, no statement relating to the use of smokeless tobacco products and health, other than the three 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 (unless the advertisement is a billboard) of a smokeless tobacco product. 15 U.S.C. § 4402.

(5) Efforts to Minimize the Burden on Small Organizations

The regulations contain some mandatory standards for meeting the requirements of the Smokeless Tobacco Act. However, any economic costs imposed on small entities are primarily imposed by the statute. The regulations impose few, if any, additional costs.

(6) Consequences of Collecting the Information Less Frequently

A submission is required only from a company that wishes to modify its existing plan, or from a new firm that enters the market to manufacture, package, or import smokeless tobacco products for sale in the U.S. Failing to collect this information would violate the Smokeless Tobacco Act and prevent the Commission from determining whether the plans are in compliance with the Act.

(7) Circumstances Requiring Collection Inconsistent With Guidelines

The reporting requirements in these regulations are consistent with all the applicable guidelines contained in 5 C.F.R. § 1320.5(d)(2).

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[2] The health warning disclosures separately mandated by the Rule do not constitute a collection of information. Nonetheless, the Commission notes that electronic disclosure pursuant to the Government Paperwork Elimination Act, P.L. No. 105-277, Title XVII, 112 Stat. 2681-749, would be impracticable because the mandated disclosures apply to product package labeling and print advertising, i.e., non-electronic media.

(8) Consultation Outside the Agency

In drafting the original regulations, the staff used as guidance the legislative history of the Smokeless Tobacco Act, the statutory scheme governing rotational health warnings for cigarettes, and other pertinent information, including the Fair Packaging and Labeling Act. To gain an understanding of the industry and the problems that might arise, the Bureau of Consumer Protection staff had discussions with the Smokeless Tobacco Council, Inc., the trade association for most of the major domestic manufacturers of snuff and chewing tobacco. The rulemaking process provided additional opportunity for public input concerning these regulations. No comments were received about the reporting requirements.

Commission staff has also discussed the regulations with affected firms on an on-going basis in connection with addressing their questions concerning the regulations' requirements and the firms' compliance obligations. In these discussions, affected businesses generally have not expressed any particular concerns regarding the cost or time burdens associated with information collection under the regulations.

More recently, as part of a regulatory review of the regulations, the agency sought public comment for, among other things, the burdens imposed by the regulations, including those associated with information collection under the regulations. 65 Fed. Reg. 11,944 (Mar. 7, 2000). The agency received no comments on the reporting requirements.

Finally, as required by 5 C.F.R. § 1320.8(d)(1), the FTC sought public comments on its proposal to extend its current OMB clearance for the Rule's information collection requirements. See 72 Fed. Reg. 27,311 (May 15, 2007). No comments were received. Pursuant to the OMB's implementing regulations, the FTC is providing a second opportunity for public comment while seeking OMB approval to extend the existing PRA clearance for the Rule.

(9) Payments and Gifts to Respondents

There is no provision for payments or gifts to respondents.

(10) & (11) Confidentiality/Matters of a Sensitive Nature

No information of a personal or sensitive nature will be involved in the submission of these plans. To the extent that information covered by the regulations is collected by the Commission for law enforcement purposes, trade secrets and confidential commercial information submitted to the agency are protected under the Federal Trade Commission Act, the Freedom of Information Act, and other applicable law. See Sections 6(f) and 21 of the Federal Trade Commission Act, 15 U.S.C. §§ 46(f) and 57b-2; 16 C.F.R. §§ 4.10-4.11 (2001).

(12) Estimated Annual Hours and Labor Cost Burden

Staff estimates that the average annual paperwork burden for the three-year clearance period sought is no more than 1,000 hours, with associated annual labor cost of no more than $203,000.[3]

The five smokeless tobacco manufacturers that comprise the dominant share of the domestic smokeless tobacco market filed their plans with the Commission long ago. Additional annual reporting burden would occur only if a company introduces a new brand or otherwise opts to display the health warnings in a manner not previously approved. Under those circumstances, a company would need to file an amendment to its plan. Although it is not possible to predict whether any of these companies will seek to amend an existing approved plan (and possibly none will), staff conservatively assumes that each of these five smokeless tobacco companies will file one amendment per year, for a total burden of not more than 200 hours. This estimate is conservative because over the past five years, none of these companies filed amendments to their existing plans, and the Commission has not changed the relevant regulations. Commission staff believes it reasonable to assume that each of these five smokeless tobacco companies would spend no more than 40 hours to prepare an amended plan, and possibly considerably less time if the amendment was minor or applied only to one brand or brand variety.

Commission staff also estimates that over the requested three-year clearance period up to four smokeless tobacco manufacturers, packagers, or importers will file an initial plan that includes rotational schemes for both packaging and advertising, for an additional burden of no more than 240 hours. This estimate is conservative because over the past five years, only four initial plans with both packaging and advertising schemes have been filed with the FTC. When the regulations were first proposed in 1986, representatives of the Smokeless Tobacco Council, Inc. indicated that the six companies it represented would require approximately 700 to 800 hours in total (133 hours each) to complete the initial required plans, involving multiple brands, multiple brand varieties, and multiple forms of both packaging and advertising. The four initial plans submitted over the past five years are considerably less complex. Each of these plans involves only one or two brands or brand varieties, with more limited types of advertising and packaging. In addition, three of the four companies submitting plans had prior familiarity with the preparation of rotational warning plans. Further, increased computerization and

[3] Commission staff estimates of paperwork burden are based on its knowledge of the smokeless tobacco industry and the time companies require to prepare rotational warning plans for submission to and review by the Commission. Staff's estimates are further informed by discussions it has had with companies filing rotational plans or their representatives during the Commission's review of submitted plans. In estimating total annual burden hours and associated labor costs, staff considered its experience gained from the plans submitted over the past five years.

improvements in electronic communication over the past 20 years have decreased the time needed for the preparation and drafting of rotational warning plans. Staff estimates that it would require no more than 60 hours to prepare such an initial plan, and that four initial plans will be submitted.

Staff anticipates that over the next three years, up to four smokeless tobacco manufacturers, packagers, or importers may submit initial plans covering packaging alone, for an additional burden of no more than 160 hours. Over the past five years, the Commission has received four such plans. Because each of the plans involved only a single brand, a single form of packaging, and no advertising, the estimated time to prepare the plans is very modest. Staff anticipates that the companies that submit initial plans covering packaging alone will spend no more than 40 hours each to prepare the plans, and possibly considerably less. This estimate is conservative. Like other estimates stated herein, this is based on the total number of plans submitted to the FTC over the past five years, rather than annually.

Finally, staff estimates that over the next three years, up to four amendments will be filed by companies other than the five largest smokeless tobacco manufacturers. Over the past five years, the Commission has received four such plans. Each of the amendments involved very modest changes to the existing plans. Staff estimates that four companies submitting similar amended plans will spend no more than 20 to 40 hours each to prepare the amendments, for an additional burden estimate of no more than 160 hours. As above, this is conservatively based on the total number of plans submitted to the FTC over the past five years, rather than annually.

Based on these assumptions, the total annual hours should not exceed 1,000 hours. [(5 companies x 40 hours each) + (4 companies x 60 hours each) + (4 companies x 40 hours each) + (4 companies x 40 hours each) = 760 total hours, rounded to one thousand hours]

The total annualized labor cost to these companies should not exceed $203,000. This is based on the assumption that management or attorneys will account for 80% of the estimated 1,000 hours required to draft initial or amended 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 (1,000 hours x 0.80 x $250 = $200,000) + clerical time (1,000 hours x 0.20 x $15 = $3,000) = $203,000]

(13) Estimated Annual Capital or Other Non-labor Costs

The applicable requirements impose minimal start-up costs. The companies may keep copies of their plans to ensure that labeling 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. For companies that have already submitted approved plans, there are no capital expenditures. After the Commission 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 the Commission 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 and possibly acetates for the display of the warnings in advertising, there are no additional start-up costs associated with printing the warnings in those materials.

(14) Estimate of Cost to the Federal Government

Staff estimates that the current year's cost to the FTC Bureau of Consumer Protection of implementing this requirement is approximately $9,800. This estimate is based on the assumption that no more than 5 percent of an attorney work year is devoted to administering the regulations. The cost in attorney time will not exceed $5,000. In addition, approximately 10 percent of a paralegal's work year will be devoted to administering the regulations. The cost in paralegal time will be $4,800.

(15) Program Changes or Adjustments

There are no program changes, and staff has retained its prior burden hour estimate. However, it has revised upward estimated labor cost based on an increased hourly labor rate for managerial and attorney time to draft initial or amended plans. See #12 for further discussion.

(16) Publication of Information

While the Commission is required by Section 8(b) of the Smokeless Tobacco Act, 15 U.S.C. § 4407(b), to report to Congress concerning current sales, advertising, and marketing

practices associated with smokeless tobacco products, there are no plans to publish any information contained in these plans for statistical use.

(17) & (18) Failure to Display the OMB Expiration Date/Exceptions to Certification

Not applicable.