DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service
Food and Drug Administration

Memorandum

Date December 21, 2010

From Team Leader, Paperwork Reduction Act Team
Office of Information Management

Subject Request for Emergency Processing of "Reports Intended to Demonstrate the Substantial Equivalence of a New Tobacco Product"

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB
Through: HHS Reports Clearance Officer

FDA's Center for Tobacco Products would like to request OMB's permission to use the emergency clearance procedures for the information collection required for the guidance document which contains recommendations related to the submission of a section 905(j) report intended to demonstrate substantial equivalence for a tobacco product under the Family Smoking Prevention and Tobacco Control Act (FSPTCA).

Background

The Family Smoking Prevention and Tobacco Control Act (FSPTCA) amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) by creating a new category of regulated products, tobacco products. The FSPTCA creates many new requirements for the tobacco industry. Section 101 of FSPTCA amends the FD&C Act by adding, among other things, new sections 905 and 910.

Section 910 requires that FDA must review a premarket application and issue an order before a new tobacco product may be commercially marketed. An order under section 910 is not required, however, if a manufacturer submits a report under section 905(j) for the new tobacco product and FDA issues an order finding the tobacco product to be substantially equivalent to a predicate tobacco product. The FSPTCA contains a special provision for products placed on the market between February 15, 2007 and March 22, 2011. Section 905 requires that, for those products, a section 905(j) report must be submitted to FDA by March 22, 2011 in order for the product remain on the market. To ensure that this guidance is issued in enough time for manufacturers to use it to prepare their submissions and to satisfy the PRA requirements, FDA is requesting permission to use the emergency clearance procedures for the information collection requirements of the guidance. The Secretary of Health and Human Services has delegated to the Commissioner of the Food and Drug Administration the responsibility for administering the FD&C Act, including sections 905 and 910.

Section 905(j) requires manufacturers who wish to demonstrate substantial equivalence for tobacco products commercially marketed after February 15, 2007 to include in their section 905(j) reports recommendations for providing information comparing the characteristics of the new and predicate tobacco product, including:

1) materials,
2) ingredients,
3) design,

4) composition,
5) heating source, or
6) other features.

FDA also intends to include in the guidance recommendations on how to submit a section 905(j) report, and intends to issue the guidance as immediately in effect to ensure that manufacturers have the benefit of FDA's recommendations in time to prepare their 905(j) reports.

The information collected in a 905(j) report will be used by the medical, scientific, and engineering staffs of FDA in making determinations as to whether or not a new tobacco product is substantially equivalent to a predicate tobacco product and whether the new tobacco product can enter the U.S. market. The 905(j) report will also allow scientific and medical review of tobacco products to determine whether the new tobacco product does not raise different questions of public health from a predicate product.

Information Collection

FDA requests permission to use the emergency clearance process to obtain OMB approval of the issuance of this guidance, which contains recommendations related to the submission of a section 905(j) report intended to demonstrate the substantial equivalence for a tobacco product under the FSPTCA. In order to provide respondents with adequate time to prepare information for submission to FDA, we will need to issue this guidance as soon as possible, preferably no later than January 15, 2011. If FDA were to use the normal clearance procedures, the information needed by manufacturers to submit 905(j) reports would be unavailable and the submission of information to obtain substantial equivalence review may be delayed.

Description of Respondents

Respondents to this collection of information are manufacturers of tobacco products, or agents thereof, who wish to market and sell their products in the United States.

FDA estimates that it will receive 150 section 905(j) reports of substantial equivalence for a new tobacco product annually, as required by sections 905 and 910 of the FD&C Act, and each report will take a manufacturer 360 hours to complete. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 54,000 hours. The agency bases its estimate on its experience with the submission of other premarket information applicable to other FDA regulated products.

Estimated Annual Reporting Burden

FD&C Act Sections	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
905(j) and 910(a)	150	1	150	360	54,000
Total					54,000