



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0125]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title "Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007--(OMB Control Number 0910-New)

This guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. Grandfathered tobacco products are not considered new tobacco products and thus are not subject to premarket review. A grandfathered tobacco product may also serve as the predicate tobacco product in a Section 905(j) Report: Demonstrating Substantial Equivalence for Tobacco Products (intended to be used toward demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e(j)(1)(A)(i))).

The guidance recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

FDA's estimate of the number of respondents is based on the fact that requesting an Agency determination of the grandfathered status of a tobacco product under the guidance is not required and also on indications of interest of making such request. The number of hours to gather the evidence is FDA's estimate of how long it might take one to review, gather, and

submit dated information if making a request for Agency determination. After further consideration of these estimates, FDA has reduced the number of hours to submit this information from 10 to 5 hours.

In the Federal Register of April 25, 2011 (76 FR 22903), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were submitted on FDA's estimates of the number of respondents or burden. FDA received three comments that generally addressed topics related to the recommendations of the guidance, including questions about the status of tobacco products that were in test markets in the United States as of February 15, 2007, and how much evidence should be submitted.

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

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	150	1	150	5	750

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based the estimates on information it received from interactions with the industry that 3 large manufacturers might submit as many as 25 packages of evidence annually, and other manufacturers might submit as many as 125 packages of evidence indicating that their tobacco product was commercially marketed in the United States as of February 15, 2007, for a total of 150 responses annually. FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. This is a reduction from FDA's original estimate of 10 hours per response. FDA estimates that it should take approximately 750 hours annually (150 responses times 5 hours for each response) to respond to this collection of information.

Dated: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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