Written comments and recommendations concerning the proposed information collection should be sent by June 7, 2010 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays inOMB’s receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.


Elaine Parry,
Director, Office of Program Services.

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Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on June 7, 2010.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: OIRA_submission@omb.eop.gov.

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, Jonnalynn.Capezzuto@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.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products—(OMB Control Number 0910–0650)—Extension

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. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 et seq.) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 905(b) of the act (21 U.S.C. 395(b)), as amended by the Tobacco Control Act, requires that “every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products † † † register with FDA the name, places of business, and all establishments owned or operated by that person. Every person must register by December 31 of each year. Section 905(i)(1) of the act, as amended by the Tobacco Control Act, requires that all registrants “shall, at the time of registration under any such subsection, file with [FDA] a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution,” along with certain accompanying consumer information, such as all labeling and a representative sampling of advertisements. Section 904(a)(1) of the act, as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit “a listing of all ingredients, including tobacco, substances, compounds, and additives that are † † † added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.” Since the Tobacco Control Act was enacted on June 22, 2009, and includes the ingredients added as of the date of submission. Section 904(c) of the act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both (1) Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (November 12, 2009, 74 FR 58298) and (2) Listing of Ingredients in Tobacco Products (December 1, 2009, 74 FR 62795) to assist persons making such submissions to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed the eSubmitter application to streamline the data entry process for registration and product listing and for ingredient listing. This tool allows for importation of large quantities of structured data, attachments of files (e.g., in portable document format (PDFs) and certain media files), and automatic acknowledgement of FDA’s receipt of submissions. FDA also developed paper forms (FDA Form 3742—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments and FDA Form 3743—Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the eSubmitter application and the paper forms can be accessed at http://www.fda.gov/tobacco.

In the Federal Register of September 1, 2009 (74 FR 45219), FDA published a notice announcing that a proposed collection of information had been submitted to OMB for emergency processing under the PRA. In the Federal Register of September 15, 2009 (74 FR 47257), FDA published a notice correcting the length of the comment period, keeping it open until October 1, 2009. In the Federal Register of October 13, 2009 (74 FR 52420), FDA published a notice reopening the comment period until October 26, 2009. Based on comments indicating that the burden estimates were too low, FDA has adjusted its original burden estimates. FDA has adjusted its burden estimate for registration and product listing for owners and operators of domestic establishments under section 905 of the act from 0.75 hours per response to 3.75 hours per response. FDA has adjusted its burden estimate for listing of ingredients under section 904 of the act from 0.75 hours per response to 3.0 hours per response. FDA also decreased...