

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 in OMB'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.

Dated: April 28, 2010.

Elaine Parry,

Director, Office of Program Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-901A and 901D]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Federal Qualification Application (42 CFR 417.140) and Medicare Health Care Prepayment Plan Application (42 CFR 417.800); *Use:* The application is the collection form used to obtain information to determine if an applicant meets the regulatory requirements to enter into a contract with CMS as a

Federal Qualified health maintenance organization (HMO) or to provide health benefits to Medicare beneficiaries as a Medicare Health Care Prepayment Plan contractor. *Form Number:* CMS-901A & 901D (OMB#: 0938-0470); *Frequency:* Once; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 800 (For policy questions regarding this collection contact Heidi Arndt at 410-786-1607. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by July 6, 2010:

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-10623 Filed 5-6-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: CMS-10293]

Centers for Medicare & Medicaid Services; Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Tribal Consultation State Plan Amendment Template; *Use:* Effective July 1, 2009, section 5006 of the American Recovery and Reinvestment Act of 2009 (Recovery Act) amended section 1902(a)(73) of the Act to require that certain States utilize a process for the State to seek advice on a regular, ongoing basis from designees of the Indian Health Service (IHS) and Urban Indian Organizations concerning Medicaid and Children's Health Insurance Program (CHIP) matters having a direct effect on them. The consultation process is required for the 37 States in which 1 or more Indian Health Programs or Urban Indian Organizations furnish health care services. The State Medicaid agency for each of these States will complete the template page and submit it for approval as part of a State plan amendment, to document how it meets the requirements for tribal consultation. *Form Number:* CMS-10293 (OMB#: 0938-NEW); *Frequency:* Reporting—Once and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 37; *Total Annual Responses:* 37; *Total Annual Hours:* 37. (For policy questions regarding this collection contact Lane Terwilliger at 410-786-2059. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to

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, E-mail: OIRA_submission@omb.eop.gov.

Michelle Shortt,

Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-10622 Filed 5-6-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0074]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

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 (the PRA).

DATES: Fax written comments on the collection of information by June 7, 2010.

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 e-mailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0650. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: 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, the information required under section 904(a)(1) of the act must be submitted to FDA by December 22,

2009, and include 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 52495), 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