

OMB No. 0930-0106). However, a separate OMB approval will be requested for the OTP survey.

The OTP survey will use the same point prevalence date as the N-SSATS and will offer the same response options (paper questionnaire, online via the Internet, or by telephone with an interviewer). The information collected will include detailed information on

OTP client characteristics and OTP facility operations, information that is not currently obtained by the N-SSATS or other federally-sponsored surveys.

The findings will supplement information collected by the annual N-SSATS and will be published by SAMHSA in a separate report on Opioid Treatment Programs. Survey data will also be used to update SAMHSA's

"Medication-Assisted Treatment for Opioid Addiction State Profiles." These publications will be used by the Federal government, State and local governments, the U.S. Congress, researchers, and other health care professionals. The following Table summarizes the estimated response burden for the survey.

ESTIMATED TOTAL RESPONSE BURDEN FOR THE 2011 OTP SURVEY

	Number of respondents	Responses per respondent	Average hours per response	Total hour burden
Certified OTP Facilities—2011 Survey .....	1,200	1	.83	996

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8-1099, One Choke Cherry Road, Rockville, MD 20857 AND e-mail a copy to [summer.king@samhsa.hhs.gov](mailto:summer.king@samhsa.hhs.gov). Written comments should be received within 60 days of this notice.

Dated: September 23, 2010.

**Elaine Parry,**

Director, Office of Management, Technology, and Operations.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-367]

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506I(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:* Revision of a currently approval collection; *Title of Information Collection:* Medicaid Drug Program Monthly and Quarterly Drug Reporting Format; *Use:* In order for payment to be made under Medicaid, the drug labeler must complete and sign a drug rebate agreement and fill in the information on the related documents. The Patient Protection and Affordable Care Act of 2010 added two new data elements to potentially be reported by manufacturers. In addition, the Food and Drug Administration has informed us that "DESP" is now obsolete; therefore, we are replacing it with a more appropriate "rebate eligibility code" that will more accurately describe how a product is eligible for coverage under the drug rebate program. *Form Number:* CMS-367 (OMB#: 0938-0578); *Frequency:* Monthly and Quarterly; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 580; *Total Annual Responses:* 9,280; *Total Annual Hours:* 137,344 (For policy questions regarding this collection contact Gail Sexton at 410-786-4583. 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](mailto: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 November 1, 2010. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, E-mail: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: September 24, 2010.

**Michelle Shortt,**

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

[FR Doc. 2010-24477 Filed 9-30-10; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0488]

**Enforcement Action Plan for Promotion and Advertising Restrictions; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Enforcement Action Plan for Promotion and Advertising Restrictions" (Enforcement Action Plan), which describes FDA's plan to enforce the restrictions on promotion and advertising of menthol and other cigarettes to youth and other requirements relating to tobacco product promotion and advertising established by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). As described in the Enforcement Action Plan, FDA intends to use a multipronged approach that includes surveillance, inspections, enforcement actions, and education to enforce and facilitate compliance with these restrictions and requirements. The Enforcement Action Plan includes

provisions designed to ensure enforcement of the restrictions on promotion and advertising of menthol and other cigarettes to youth in minority communities. The Enforcement Action Plan will serve to satisfy FDA's obligation under the Tobacco Control Act. As described in this notice, FDA is publishing the Enforcement Action Plan on its Web site and providing copies upon request.

**ADDRESSES:** Submit written requests for single copies of the Enforcement Action Plan to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the document may be sent. Single copies may also be requested by calling 1-877-287-1373. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the Enforcement Action Plan.

**FOR FURTHER INFORMATION CONTACT:** Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 877-287-1373, [ctpcpliance@fda.hhs.gov](mailto:ctpcpliance@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Tobacco Control Act (Public Law 111-31, 123 Stat. 1776) was enacted on June 22, 2009, providing FDA with the authority to regulate tobacco products in order to protect the public health generally, and to prevent and reduce tobacco use by minors. In enacting the Tobacco Control Act, Congress found, among other things, that the use of tobacco products by children is a pediatric disease and virtually all new users of tobacco products are under the minimum legal age to purchase such products (sections 2(1) and (4) of the Tobacco Control Act). Advertising, marketing, and promotion of tobacco products have been "especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth" (section 2(15) of the Tobacco Control Act). Additionally, the rates of tobacco use and tobacco-related mortality are higher among certain racial and ethnic groups, including American Indian and Alaska Natives, Asian men and African-American men. As the National Cancer Institute (NCI) noted in Monograph 19, "[t]argeting of various population groups—including \* \* \* specific racial and ethnic

populations \* \* \* has been strategically important to the tobacco industry."<sup>1</sup>

Section 105(a) of the Tobacco Control Act (21 U.S.C. 387f-1(a)) requires the Secretary of Health and Human Services (the Secretary) to develop and publish an action plan to enforce restrictions on promotion and advertising of menthol and other cigarettes to youth, including those provided in the final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" (75 FR 13225, March 19, 2010; 21 CFR part 1140). This action plan must also include provisions designed to ensure enforcement of the restrictions, including those provided in "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," on the promotion and advertising of menthol and other cigarettes to youth in minority communities.

Section 105(a) of the Tobacco Control Act also requires that the Secretary develop the Enforcement Action Plan in consultation with public health organizations and other stakeholders with demonstrated expertise and experience in serving minority communities. FDA created two dockets to solicit information, data, and views from all interested persons, including public health organizations and other stakeholders with demonstrated expertise and experience in serving minority communities, about the advertising and promotion of menthol and other cigarettes to youth in general, and to youth in minority communities. In the first docket, which was for the document entitled "Tobacco Product Advertising and Promotion to Youth and Racial and Ethnic Minority Populations; Request for Comments" (Docket No. FDA-2010-N-0207; 75 FR 29776, May 27, 2010), FDA requested information on ways in which the advertising and promotion of tobacco products may affect tobacco use among racial and ethnic minority populations; input on designing an action plan regarding enforcement of the regulations on advertising and promotion of menthol and other cigarettes to youth generally and to youth in minority communities; and information that will assist the Tobacco Products Scientific Advisory Committee to better

understand, report on, and make recommendations regarding the impact of the use of menthol in cigarettes among children, African-Americans, Hispanics, and other racial and ethnic minority communities.

FDA also established a docket and published an announcement for a meeting entitled "Web-Based Public Meeting to Discuss Issues Related to the Development of an Enforcement Action Plan; Request for Data, Information, and Views" (Docket No. FDA-2010-N-0295; 75 FR 34750, June 18, 2010). FDA held the Web-based public meeting on June 30, 2010, to seek participation, information, and views from all interested parties, including but not limited to, public health organizations, minority community groups and leaders, other stakeholders with demonstrated expertise and experience in serving minority communities, groups serving youth, patient groups, advertising agencies, and industry. In addition to general information, FDA sought information on specific topics relating to the restrictions on promotion and advertising of menthol and other cigarettes to youth, including youth in minority communities. FDA also encouraged stakeholders and other interested parties to submit data, information, and views on these topics as well as other pertinent information to the relevant docket.

In developing the Enforcement Action Plan, FDA considered the available information, including the data, information, and views presented at the Web-based public meeting and provided in electronic and written materials submitted to FDA by public health organizations, other stakeholders with demonstrated expertise and experience in serving minority communities, and other parties.

**II. Electronic Access**

An electronic version of the Enforcement Action Plan is available on the Internet at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: September 24, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-24685 Filed 9-30-10; 8:45 am]

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<sup>1</sup> National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use*, Tobacco Control Monograph No. 19, Bethesda, MD, U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, NIH Pub. No. 07-6242, June 2008, p. 11, available at <http://www.cancercontrol.cancer.gov/tcrb/monographs/19/index.html>.