Officer, Fax Number: (202) 395–6974, E-mail: *OIRA_submission@omb.eop.gov.*

Dated: March 8, 2010.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Proposed Project: Substance Abuse Prevention and Treatment Block Grant Synar Report Format, FFY 2011–2013—(OMB No. 0930–0222)—Revision

Section 1926 of the Public Health Service Act [42 U.S.C. 300x–26] stipulates that funding Substance Abuse Prevention and Treatment (SAPT) Block Grant agreements for alcohol and drug abuse programs for fiscal year 1994 and subsequent fiscal years require States to have in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18. This section further requires that States conduct annual, random, unannounced inspections to ensure compliance with the law; that the State submit annually a report describing the results of the inspections, describing the activities carried out by the State to enforce the required law, describing the success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18, and describing the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

Before making an award to a State under the SAPT Block Grant, the Secretary must make a determination that the State has maintained compliance with these requirements. If a determination is made that the State is not in compliance, penalties shall be applied. Penalties ranged from 10 percent of the Block Grant in applicable year 1 (FFY 1997 SAPT Block Grant Applications) to 40 percent in applicable year 4 (FFY 2000 SAPT Block Grant Applications) and subsequent years. Respondents include the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, Palau, Micronesia, and the Marshall Islands.

Regulations that implement this legislation are at 45 CFR 96.130, are approved by OMB under control number 0930–0163, and require that each State submit an annual Synar report to the Secretary describing their progress in complying with section 1926 of the PHS Act. The Synar report, due December 31 following the fiscal year for which the State is reporting, describes the results of the inspections and the activities carried out by the State to enforce the required law; the success the State has achieved in reducing the availability of tobacco products to individuals under the age of 18; and the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

SAMHSA's Center for Substance Abuse Prevention will request OMB approval of revisions to the current report format associated with Section 1926 (42 U.S.C. 300x–26). The report format is minimally changing. Any changes in either formatting or content are being made to simplify the reporting process for the States and to clarify the information as the States report it; both outcomes will facilitate consistent, credible, and efficient monitoring of Synar compliance across the States and will reduce the reporting burden by the States. All of the information required in the new report format is already being collected by the States. Most of the specific revisions appear in Section I (Compliance Progress) of the report format and include clarifications to Questions 4a, 5b, 5e and 5f. Additionally, three new questions (5c, 5d and 5g) have been added and two items have been added to Question 7b. Information on these additions appears below:

Question 5c: Level of Enforcement—This question, which asks the State to select whether enforcement is conducted only at those outlets randomly selected for the Synar survey, only at a subset of outlets not randomly selected for the Synar survey, or a combination of the two, has been newly added to the ASR format. It has been added to provide additional information about State enforcement programs, which is frequently requested by partner agencies and can also be used to target technical assistance.

Question 5d: Frequency of Enforcement—This question, which asks the State to select whether every tobacco outlet in the State did or did not receive at least one enforcement compliance check in the last year, has been newly added to the ASR format. It has been added to provide additional information about State enforcement programs, which is frequently requested by partner agencies and can also be used to target technical assistance.

Question 5g. Relationship of State Synar Program to FDA-Funded Enforcement Program—This question, which asks the State to describe the relationship between the State's Synar program and the Food and Drug Administration (FDA)-funded enforcement program, has been added to the ASR format. The Family Smoking Prevention and Tobacco Control Act, recently signed into law by President Obama, requires the FDA to reissue the 1996 regulation aimed at reducing young people's access to tobacco products and curbing the appeal of tobacco to the young. This regulation must be reissued by April 2010. As part of the implementation of this regulation, FDA will be contracting with States to enforce new Federal youth access provisions. This question asks the State to describe the relationship and coordination between its Synar program and the enforcement program funded by FDA.

Question 7b. Synar Survey Results for States that Do Not Use the Synar Survey Estimation System (SSES)—Two items have been added to this question (accuracy rate and completion rate). These items were added to ensure that the same statistical parameters are asked of both States that do and do not use the SSES to analyze their Synar survey results.

Additionally, in Appendix B (Synar Survey Sampling Methodology), the following changes are being made with respect to the Annual Synar Report:

Question 10. Provide the following information about sample size calculation for the current FFY Synar survey. This question has been added to Appendix B and asks the State to provide information about the specific input values used to calculate the effective, target and original sample sizes for the current FFY Synar survey. This question will reduce the need for SAMHSA/CSAP to request additional clarifying information from the State when SAMHSA/CSAP is unable to

match the sample sizes reported by the State.

In Appendix D (List Sampling Frame Coverage Study), the following changes are being made with respect to the Annual Synar Report:

Question 2. Percent Coverage Found. This question has been split into 4 sub-parts, asking the State to report the unweighted percent coverage found, the weighted percent coverage found, the number of outlets found through canvassing, and the number of outlets matched on the list frame. The question has been split into these sub-parts to avoid SAMHSA/CSAP having to request additional clarifying information from the State during the review process.

Question 3. Description of the Coverage Study Methods and Results. This question has been expanded from one question to ten questions, which ask the State to provide specific information about the coverage study methods and results. Specifically, instead of one general question asking the State to "provide a description of the coverage study methods and results," the ten new questions query the State about specific aspects of the coverage study design, methodology and results. These specific questions will reduce the need for SAMHSA/CSAP to request additional clarifying information from the State during the review process.

There are no changes to Section II (Intended Use), or to Forms 1–5 or Appendix C.

ANNUAL REPORTING BURDEN

45 CFR citation	Number of respondents [1]	Responses per respondents	Hours per response	Total hour burden
Annual Report (Section 1—States and Territories) 96.130(e)(1–3)	59	1	15	885
State Plan (Section II–States and Territories) 96.130(e)(4,5)96.130(g)	59	1	3	177
Total	59			1,062

[1] Red Lake Indian Tribe is not subject to tobacco requirements.

Written comments and recommendations concerning the proposed information collection should be sent by April 12, 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: 202–395–5806.

Dated: March 5, 2010.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. 2010–5400 Filed 3–11–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0247]

Food and Drug Administration Transparency Task Force; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is soliciting comments from interested persons on ways in which FDA can increase transparency between FDA and regulated industry.

DATES: Submit electronic or written comments by April 12, 2010.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Afia Asamoah, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 2220, Silver Spring, MD 20993–0002, 301–796–4625, FAX: 301–847–3531, e-mail: *Afia.Asamoah@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Transparency promotes accountability and provides information to the public about government activities and initiatives. For FDA, providing information to the public in a timely, user-friendly manner is important to enhance the work of the agency.

Government transparency and accountability is a priority for the Obama Administration. On January 21, 2009, President Obama instructed executive departments and agencies to take appropriate action, consistent with law and policy, to disclose information to the public rapidly, and in a form that is easily accessible and user friendly. Executive departments and agencies have been charged with harnessing new technologies to make information about agency operations and decisions available online and readily available to the public. Executive departments and agencies have been asked to solicit public input to identify information of greatest use to the public.

The Open Government Directive, issued by the Director of the Office of Management and Budget on December 8, 2009, further instructed executive departments and agencies to take specific actions to implement a transparent, collaborative, and participatory government.

FDA has formed an internal Transparency Task Force to develop recommendations for making useful and understandable information about FDA activities and decisionmaking more readily available to the public. The recommendations will focus on disclosing relevant information in a timely manner and in a user-friendly format, and in a manner compatible with the agency's goal of protecting confidential information, as appropriate. As a part of this transparency initiative, the Task Force has held two public meetings, on June 24, 2009, and November 3, 2009, and established a public docket to seek public input on these issues. As a result of the input the Task Force has received thus far, it has decided to separate the Transparency Initiative into three phases: (1) Creating a Web-based resource called "FDA Basics," that provides information about commonly misunderstood agency activities and frequently asked questions; (2) improving FDA's disclosure of information to the public; and (3) improving FDA's transparency to regulated industry.

The first two phases are complete or well underway. "FDA Basics" was launched on FDA's Web site on January