FOR FURTHER INFORMATION CONTACT: Carol Drew, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 301–796–3505.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 10, 2010 (75 FR 32952), FDA announced the availability of a draft guidance entitled "'Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act." The Agency considered received comments as it finalized this guidance. The guidance document discusses the meaning of the term "harmful and potentially harmful constituent" in the context of implementing the listing requirements of section 904(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387d(e)).

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111–310) into law. The Tobacco Control Act amended the FD&C Act 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 904(e) of the FD&C Act, as added by the Tobacco Control Act, requires FDA to establish, and periodically revise as appropriate, "a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand." The guidance discusses the meaning of the term "harmful and potentially harmful constituent" in the context of implementing the listing requirements of section 904(e).

II. Significance of Guidance

This guidance is being issued as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the meaning of the term "harmful and potentially harmful constituents" in the context of section 904(e) of the FD&C Act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: January 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1990 Filed 1–28–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Ryan White HIV/AIDS Program Part F Dental Services Report (OMB No. 0915–0151)—[Extension]

The Dental Reimbursement Program (DRP) and the Community Based Dental Partnership Program under Part F of the Ryan White HIV/AIDS Program, offer funding to accredited dental education programs to support the provision of oral health services for HIV-positive individuals. Institutions eligible for these Ryan White HIV/AIDS Programs are accredited schools of dentistry, post-doctoral dental education programs, and dental hygiene programs.

The DRP Application is the Dental Services Report that schools and programs use to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV, or to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C. 300ff–111(b). The Dental Services Report collects data in four different areas: Program information, patient demographics and services, funding, and training. It also requests applicants to provide narrative descriptions of their services and facilities, as well as their links and collaboration with community-based providers of oral health services.

The primary purpose of collecting this information annually is to verify eligibility and determine reimbursement amounts for DRP applicants, as well as to document the program accomplishments of Community-Based Dental Partnership Program grant recipients. This information also allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating patients with HIV, (2) the number and characteristics of clients who receive HIV/AIDS program-supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to patients with HIV, and (5) the scope of grant recipients' community-based collaborations and training of providers. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected in the Dental Services Report is critical for HRSA, state and local grantees, and individual providers, to help assess the status of existing HIV-related health service delivery systems.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Dental Services Report	70	1	70	20	1,400
Total	70	1	70	20	1,400

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: January 25, 2011.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2011–2009 Filed 1–28–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Data System for Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184)—[Extension]

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry of Transplant Recipients (SRTR) and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, to ensure that all qualified entities are accepted for membership in the OPTN, and to ensure patient safety.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
121.3(b)(2)—OPTN membership and application requirements	40	3	120	15	1,800
121.3(b)(4)—Appeal for OPTN membership	2	1	2	3	6
121.6(c) (Reporting)—Submitting criteria for organ acceptance	900	1	900	0.5	450
121.6(c) (Disclosure)—Sending criteria to OPOs	900	1	900	0.5	450
121.7(b)(4)—Reasons for Refusal	900	38	34,200	0.5	17,100
121.7(f)—Transplant to prevent organ wastage	260	1.5	390	0.5	195
121.9(b)—Designated Transplant Program Requirements	10	1	10	5.0	50
121.9(d)—Appeal for designation	2	1	2	6	12
Total	954		36,524		20,063

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: January 25, 2011.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2011–1997 Filed 1–26–11; 11:15 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections