Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR.'' The draft guidance describes the circumstances under which certain applications for FDC and copackaged versions of previously approved antiretroviral therapies for the treatment of HIV under PEPFAR will not be assessed user fees. The draft guidance also describes circumstances under which some of the applications that will be assessed fees may be eligible for a public health or a barrier-to-innovation waiver.

As part of PEPFAR, FDA issued in May 2004 a draft guidance entitled ''Fixed Dose Combination and Co-Packaged Drug Products for the Treatment of HIV'' (Fixed Dose Guidance) (69 FR 28931, May 19, 2004). The Fixed Dose Guidance described some scenarios for approval of FDC or copackaged products for the treatment of HIV, provided examples of drug combinations considered acceptable for FDC/copackaging, and examples of those not considered acceptable for FDC/copackaging. The draft guidance also explained that the Federal Food, Drug, and Cosmetic Act provides for certain circumstances in which FDA can grant sponsors a waiver or reduction in fees. The draft guidance also stated that the agency was evaluating the circumstances under which it may grant user fee waivers or reductions for sponsors developing FDC and copackaged versions of previously approved antiretroviral therapies for the treatment of HIV. Since issuance of the Fixed Dose Guidance, several potential applicants have asked that we clarify whether sponsors submitting drug applications under the Fixed Dose Guidance and under the PEPFAR program will be required to pay user fees under the Prescription Drug User Fee Act (PDUFA) and if so, whether they would be eligible for a waiver of those fees. As explained in this draft guidance, in some of the scenarios described in the Fixed Dose Guidance, a sponsor could qualify for fee exemptions or would only be assessed a half-fee either because the sponsor is using an active ingredient that has already been approved or the application does not require clinical data for approval. A sponsor of an application that would be assessed either a full- or a half-fee may also qualify for a waiver of the application fee under several provisions of PDUFA.

We expect that most of the applications, products, and establishments for FDC and copackaged HIV therapies proposed for use in the PEPFAR program will either not be assessed fees in the first instance or will qualify for a waiver under the special circumstances part of the barrier-to-innovation user fee waiver.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on waivers of user fees for FDC and copackaged products for the treatment of HIV under PEPFAR. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7729 Filed 4–15–05; 8:45 am]

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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 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, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (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: Application for Certification and Recertification as a Federally Qualified Health Center (FQHC) Look-Alike (OMB No. 0915–0142): Revision

The Health Resources and Services Administration (HRSA) proposes to revise the application guide used by organizations applying for certification or recertificaion as a Federally Qualified Health Center (FQHC) Look-Alike for purposes of cost-based reimbursement under the Medicaid and Medicare programs. The guide will be revised to reflect legislative, policy, and technical changes since August 2003, the issuance date of the last guidance. The estimated burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Application	40	1	100	4,000

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Recertification	100	1	15	1,500
Total	140			5,500

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 12, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–7725 Filed 4–15–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part A (Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS) to reflect a realignment of functions and responsibilities within the Office of Inspector General (OIG). The statement of organization, functions, and delegations of authority conforms to and carries out the statutory requirements for operating OIG. Chapter AF was last published in its entirety on July 2, 2004.

The realignment of functions and responsibilities within OIG has been done to allow greater staff flexibility and to better reflect the current work environment and priorities within the organization. In addition, this notice sets forth a number of technical changes in Chapter AF that serve to update references to office titles and statutory authorities.

As amended, Chapter AF now reads as follows:

Section AF.00, Office of Inspector General—Mission

The Office of Inspector General (OIG) was established by law as an independent and objective oversight unit of the Department to carry out the mission of promoting economy, efficiency and effectiveness through the elimination of waste, abuse and fraud. In furtherance of this mission, the organization:

A. Conducts and supervises audits, investigations, inspections and evaluations relating to HHS programs and operations.

B. Identifies systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and makes recommendations to prevent their recurrence.

C. Leads and coordinates activities to prevent and detect fraud and abuse in HHS programs and operations.

D. Detects wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to bear.

E. Keeps the Secretary and the Congress fully and currently informed about problems and deficiencies in the administration of HHS programs and operations and about the need for and progress of corrective action, including imposing sanctions against providers of health care under Medicare and Medicaid who commit certain prohibited acts.

In support of its mission, OIG carries out and maintains an internal quality assurance system and a peer review system with other Offices of Inspectors General, including periodic quality assessment studies and quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards, and other requirements are followed, are effective, and are functioning as intended in OIG operations.

Section AF.10, Office of Inspector General—Organization

There is at the head of OIG a statutory Inspector General, appointed by the President and confirmed by the Senate. This office consists of six organizational units:

A. Immediate Office of the Inspector General (AFA)

B. Office of Management and Policy (AFC)

C. Office of Evaluation and Inspections (AFE)

D. Office of Counsel to the Inspector General (AFG)

E. Office of Audit Services (AFH)

F. Office of Investigations (AFJ)

Section AF.20, Office of Inspector General—Functions

The component sections that follow describe the specific functions of the organization.

Section AFA.00, Immediate Office of the Inspector General—Mission

The Immediate Office of the Inspector General (IOIG) is directly responsible for meeting the statutory mission of OIG as a whole and for promoting effective OIG internal quality assurance systems, including quality assessment studies and quality control reviews of OIG processes and products. The office also plans, conducts and participates in a variety of interagency cooperative projects and undertakings relating to fraud and abuse with the Department of Justice (DOJ), the Centers for Medicare & Medicaid Services (CMS) and other governmental agencies, and is responsible for the reporting and legislative and regulatory review functions required by the Inspector General Act.

Section AFA.10, Immediate Office of the Inspector General—Organization

IOIG is comprised of the Inspector General, the Principal Deputy Inspector General and an immediate office staff, including the Office of External Affairs.

Section AFA.20, Immediate Office of the Inspector General—Functions

As the senior official of the organization, the Inspector General supervises the Chief Counsel to the Inspector General and the Deputy Inspectors General, who head the major OIG components. The Inspector General is appointed by the President, with the advice and consent of the Senate, and reports to and is under the general supervision of the Secretary or, to the extent such authority is delegated, the Deputy Secretary, but does not report to and is not subject to supervision by any other officer in the Department. In keeping with the independence conferred by the Inspector General Act, the Inspector General assumes and exercises, through line management, all functional authorities related to the administration and management of OIG and all mission-related authorities stated or implied in the law or delegated directly from the Secretary.