and financial reports are due 90 days after the close of the project period.

VII. Agency Contacts

Program Office Contact: Catherine Beck, Administration for Children and Families, Office of Community Services' Operations Center, 1515 Wilson Boulevard, Suite 100, Arlington, VA 22209, Phone: 1–800–281–9519, Fax: 703–528–0716, E-mail: *OCS@lcgnet.com.*

Grants Management Office Contact: Barbara Ziegler-Johnson, Administration for Children and Families, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Aerospace Building, Washington, DC 20447–0002, Phone: 1–800–281–9519, Fax: 703–528–0716, E-mail: *OCS@lcgnet.com.*

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *www.Grants.gov.* Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html.*

The FY 2006 President's budget does not include or propose funding for the Community Food and Nutrition Program. Future funding is based on the availability of Federal funds.

Direct federal grants, subaward funds, or contracts under this community Food and Nutrition Program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this Program. Regulations pertaining to the prohibition of Federal funds for inherently religious activities can be found on the HHS Web site at *http://www.os.HHS.gov/fbci/waisgate21.pdf.*

Additional Information about this program and its purpose can be located on the following Web site: *http://www.acf.hhs.gov/programs/ocs.*

Please reference Section IV.3 for details about acknowledgement of received applications.

Dated: April 7, 2005.

Josephine B. Robinson,

Director, Office of Community Services.

[FR Doc. 05–7461 Filed 4–15–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005F–0138]

Kareem I. Batarseh; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Kareem I. Batarseh has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a mixture of hydrogen peroxide, silver nitrate, phosphoric acid, tartaric acid, glutamic acid, and sodium tripolyphosphate as an antimicrobial agent in bottled drinking water.

FOR FURTHER INFORMATION CONTACT: Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1278.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409 (b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 5A4759) has been filed by Kareem I. Batarseh, P.O. Box 8, College Park, MD 20741–0008. The petition proposes to amend the food additive regulations in part 172 *Food Additives Permitted For Direct Addition To Food For Human Consumption* (21 CFR part 172) to provide for the safe use of a mixture of hydrogen peroxide, silver nitrate, phosphoric acid, tartaric acid, glutamic acid, and sodium tripolyphosphate as an antimicrobial agent in bottled drinking water.

The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: April 1, 2005.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 05–7727 Filed 4–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0091]

Draft Guidance for Industry on User Fee Waivers for Fixed Dose Combination Products and Co-Packaged Human Immunodeficiency Virus Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR.'' This draft guidance describes the circumstances under which certain applications for fixed dose combination (FDC) and copackaged versions of previously approved antiretroviral therapies for the treatment of human immunodeficiency virus (HIV) under the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief (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.

DATES: Submit written or electronic comments on the draft guidance by June 17, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Michael Jones, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers

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]

BILLING CODE 4160–01–S

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