

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 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 this guidance document.

FOR FURTHER INFORMATION CONTACT: Michael Jones, Center for Drug Evaluation and Research (HFD-5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR." The guidance describes the circumstances under which user fees will not be assessed for certain applications for FDC and co-packaged versions of previously approved antiretroviral therapies for the treatment of HIV under PEPFAR. The guidance also describes some 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.

In May 2004, as part of PEPFAR, FDA issued a draft guidance entitled "Fixed Dose Combination and Co-Packaged Drug Products for the Treatment of HIV" (Fixed Dose Guidance) (69 FR 28931, May 19, 2004).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 draft Fixed Dose Guidance described some scenarios for approval of FDC or co-packaged products for the treatment of HIV and provided examples of drug combinations considered acceptable for FDC/co-packaging and examples of those not considered acceptable for FDC/co-packaging. The 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 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 co-packaged versions of previously approved antiretroviral therapies for the treatment of HIV. Since issuance of the draft Fixed Dose Guidance, several potential applicants have asked that we clarify whether sponsors submitting

drug applications covered by the draft Fixed Dose Guidance and proposed for use in 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.

In the **Federal Register** of April 18, 2005 (70 FR 20145), FDA announced the availability of a draft version of this guidance. FDA did not receive any comments in response to that draft guidance, and the agency has made only minor editorial changes to the guidance.

This guidance describes some of the scenarios under which 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 co-packaged 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 "other circumstances" part of the barrier-to-innovation user fee waiver.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on waivers for FDC and co-packaged HIV PEPFAR products. 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 regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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 may be seen 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 guidance document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 1, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-2124 Filed 2-7-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given that the following committee will convene its fifty-fifth meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: February 28, 2007, 9 a.m.-4:15 p.m., March 1, 2007, 9 a.m.-4:15 p.m., March 2, 2007, 9 a.m.-10:30 a.m.

Place: The Sofitel Lafayette Square, 806 15th Street NW., Washington, DC 20005, *Phone:* 202-730-8800.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health and human services in rural areas.

Agenda: Wednesday morning, February 28, at 9 a.m., the meeting will be called to order by the Chairperson of the Committee, the Honorable David Beasley, Elizabeth M. Duke, Administrator of the Health Resources and Services Administration, has been invited to give opening remarks. The first presentation is titled Rural America: Then, Now and in the Future. The speakers will be John Cromartie and Carol Jones, Economic Research Service, U.S. Department of Agriculture. Following this session will be three panels on rural health and human services issues. The first will be a rural health panel with Becky Slifkin of the North Carolina Rural Health Research and Policy Analysis Center at the University of North Carolina at Chapel Hill; Gary Hart of the WWAMI Rural Health Research Center at the University of Washington; and Andy Coburn of the Maine Rural Health Research Center at the University of Southern Maine. The second will be a rural health panel with the following speakers: Julie Schoenman of the National Opinion Research Center at the University of Chicago; Michelle Casey of the

Upper Midwest Rural Health Research Center at the University of Minnesota; and Keith Mueller of the Rural Policy Research Institute. The final panel of the day will be a rural human services panel with Robert Gibbs of the Economic Research Service at the U.S. Department of Agriculture; Dennis Dudley with the U. S. Administration on Aging; and Brian Dabson of the Poverty Center at the Rural Policy Research Institute. The Wednesday meeting will close at 4:15 p.m.

Thursday morning, March 1, at 9 a.m., the Committee will open with a discussion on Wednesday's sessions. Immediately following, the Committee Chair will lead a discussion of the topics for the 2008 Report to the Secretary and assign Subcommittees. The first presentation of the day will be on Rural Policy Moving Forward by Mike O'Grady, Senior Fellow with the National Opinion Research Center. This will be followed by a presentation on the Commonwealth Fund Activity by Mary Wakefield, Director of the Center for Rural Health at the University of North Dakota. After lunch the Committee will have discussion on the day's presentations. The formal Committee meeting for Thursday will close at 2:30 p.m. The Subcommittees will meet from 2:30 p.m. to 4 p.m.

The final session will be convened Friday morning, March 2, at 9 a.m. The Committee will receive reports from the Subcommittee discussions on Thursday, draft the letter to the Secretary, and discuss the June meeting. The meeting will be adjourned at 10:30 a.m.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Tom Morris, M.P.A., Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A-55, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), Telephone (301) 443-0835. The Committee meeting agenda will be posted on ORHP's Web site <http://www.ruralhealth.hrsa.gov>.

Dated: February 2, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: Correction

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions; correction.

SUMMARY: The HHS Office of Inspector General Published a document in the **Federal Register** of October 18, 2006, imposed exclusions. The document contained the incorrect monthly exclusions.

FOR FURTHER INFORMATION CONTACT: Jacqueline Freeman, (410) 786-5197.

Correction

In the **Federal Register** of October 18, 2006, in FR Doc. 71 FR 61485, on page 61492, The list was for the September 2006 exclusions. The correct exclusions for September 2006 should read:

Subject name, address	Effective date
PROGRAM-RELATED CONVICTION	
ABAD, NILDA	10/19/2006
ALPINE, CA	
ALLISON, KEITH	10/19/2006
LOS ANGELES, CA	
ANDERSON, THEODORE	10/19/2006
KINGSTON, WA	
BOUCHARD, JOHN	10/19/2006
PHILLIPSBURG, KS	
BOUGHTON, LLOYD	10/19/2006
LOS ANGELES, CA	
BRAZIL, MICHAEL	10/19/2006
ARLINGTON, VA	
CACAL, ROQUE	10/19/2006
LOS ANGELES, CA	
CACAL, ROSA	10/19/2006
LOS ANGELES, CA	
CARDILLO, JOHN	10/19/2006
BERKELEY HEIGHTS, NJ	
DELATOUR, GREGORY	10/19/2006
MIAMI, FL	
DELGADO, JOSUE	10/19/2006
BALDWIN PARK, CA	
DODDS, KYLE	10/19/2006
INDEPENDENCE, OR	
EASON, KIM	10/19/2006
FRESNO, CA	
EDWARDS, PHYLLIS	10/19/2006
HAMILTON, OH	
EVANS, AMY	10/19/2006
PATASKALA, OH	
FINLEY, SANDRA	10/19/2006
OKLAHOMA CITY, OK	
FLORES, VERGIL	10/19/2006
MESQUITE, TX	
FRANK, PAUL	10/19/2006
FORT DIX, NJ	
GALLEGOS, JODY	10/19/2006
THORNTON, CO	
GORDON, RICHARD	10/19/2006
SURPRISE, AZ	
GOTTSCHALL, ZAY	10/19/2006
BUTTE, MT	
HABEEB, GREGORY	10/19/2006
CLARK SUMMIT, PA	
HARRIS, KATRINA	10/19/2006
NILES, OH	
HARRIS, TAMMY	10/19/2006
AUSTIN, TX	
HARTSFIELD, ARCHIE	10/19/2006
EL PASO, TX	
HERIC, THOMAS	10/19/2006
HAWTHORNE, CA	
HERNANDEZ, JOSE	10/19/2006

Subject name, address	Effective date
MIAMI, FL	
HOLSAN, JASON	10/19/2006
GRAND JUNCTION, CO	
HOVATTER, KATHY	10/19/2006
PARMA, OH	
ISHAK, MAHER	10/19/2006
HARRIMAN, NY	
JOHNSON, SHELIA	10/19/2006
SARDINIA, OH	
JONES, WANDA	10/19/2006
YOUNGSTOWN, OH	
LAZARO, JUAN	10/19/2006
WESTBROOK, ME	
LUETTGEN, TAMMIE	10/19/2006
ALLENTOWN, PA	
MALAHIMOV, BORIS	10/19/2006
BRADFORD, PA	
MALCOLM-FORBES, SONIA ...	10/19/2006
COLUMBUS, OH	
MAYHUGH, JEFFREY	10/19/2006
THORNVILLE, OH	
MORTON, GEORGE	10/19/2006
PHENIX, VA	
PARKER, ROGER	10/19/2006
HAMPTON, VA	
PETERSON, RENE	10/19/2006
DES MOINES, IA	
REISBORD, DAVID	10/19/2006
LOS ANGELES, CA	
RUMMELT, HERMAN	10/19/2006
DULUTH, MN	
SERRANO, SUSAN	10/19/2006
DUBLIN, CA	
SHUMAKER, MARY	10/19/2006
SARDINIA, OH	
SISNEY, DEBRA	10/19/2006
BULL SHOALS, AR	
SOLIS, MARY	10/19/2006
WEST COVINA, CA	
SPEARS, RAMESHIA	10/19/2006
GRANDVIEW, MO	
SPEIGHT, DIANNA	10/19/2006
LAS VEGAS, NV	
STATLER, JOHN	10/19/2006
DAYTON, OH	
STIMPSON, RIETA	10/19/2006
HELENA, MT	
WALLED, RAFAEL	7/5/2006
MIAMI, FL	
WALLERICK, MELANIE	10/19/2006
YOUNGSTOWN, OH	
WILLIAMS, DRANETTA	10/19/2006
GATESVILLE, TX	
WILLIAMS, HENRY	10/19/2006
HUNTSVILLE, TX	
WOODBURY PHARMACY, INC	10/19/2006
HARRIMAN, NY	

FELONY CONVICTION FOR HEALTH CARE FRAUD

BAILEY, LLEWELLYN	10/19/2006
ROSEDALE, NY	
BALL, HEIDI	10/19/2006
SPRINGFIELD, OR	
BATTERTON, CAROL	10/19/2006
CHEYENNE, OK	
BENTLEY, WILLIAM	10/19/2006
MONROE, WA	
BLEVINS, CHARLES	10/19/2006
MONTGOMERY, AL	
BOUGHTON, DARLA	10/19/2006