

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0091]

DDM

Display Date 2-7-07  
Publication Date 2-8-07  
Certifier A. Corbin

**Guidance for Industry on User Fee Waivers for Fixed Dose Combination 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.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR." This guidance describes the circumstances under which user fees will not be assessed for certain applications for fixed dose combination (FDC) and co-packaged 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). The guidance also describes some circumstances under which most 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 agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the 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 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: 2/1/07  
February 1, 2007.

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

**BILLING CODE 4160-01-S**

**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

A handwritten signature in black ink, appearing to be "M. Shuren", written over a horizontal line.