

C. How much will this fee be?

The fee is based on the number of direct hours spent on taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

V. How must the fees be paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 90 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

VI. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-18622 Filed 8-1-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA-2013-N-0473]

Human Immunodeficiency Virus Patient-Focused Drug Development and Human Immunodeficiency Virus Cure Research; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of public meeting entitled "Human Immunodeficiency Virus (HIV) Patient-Focused Drug Development and HIV Cure Research," published in the

Federal Register of May 21, 2013 (78 FR 29755). In that notice, FDA requested public comment regarding patients' perspective on current approaches to managing HIV, symptoms experienced because of HIV or its treatment, and issues related to HIV cure research. FDA is reopening the comment period to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments to the docket by September 3, 2013.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1170, Silver Spring, MD 20993-0002, 301-796-0684, FAX: 301-847-8443, email: Pujita.Vaidya@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of May 21, 2013 (78 FR 29755), FDA announced the notice of public meeting entitled "HIV Patient-Focused Drug Development and HIV Cure Research." In that notice, FDA requested public comment on specific questions regarding patients' perspective on current approaches to managing HIV, symptoms experienced because of HIV or its treatment, and issues related to HIV cure research. Interested persons were given until July 14, 2013, to comment on the questions. The Agency is reopening the comment period until September 3, 2013 to allow interested persons additional time to submit comments.

II. Specific Questions for Public Comment

As part of Patient-Focused Drug Development, FDA is gathering input from HIV patients and patient advocates on current approaches to managing HIV, symptoms experienced because of HIV or its treatment, and issues related to HIV cure research. FDA is interested in receiving patient input that addresses the following questions.

Topic 1: Patients' Perspective on Current Approaches to Managing HIV and on Symptoms Experienced Because of HIV or Its Treatment

1. What are you currently doing to help manage your HIV and any symptoms you experience because of your condition or other therapies? (Examples may include prescription medicines, over-the-counter products, and nondrug therapies such as diet modification.)

a. What specific symptoms do your therapies or treatments address?
b. How long have you been on treatment and how has your treatment regimen changed over time?

2. How well does your current treatment regimen treat any significant symptoms of your condition?

a. How well have these treatments worked for you as your condition has changed over time?

b. Are there symptoms that your current regimen does not address at all or does not treat as well as you would like?

3. What are the most significant downsides to your current therapies or treatments, and how do they affect your daily life? (Examples of downsides could include bothersome side effects, physical change to your body because of treatment, going to the hospital for treatment.)

4. Of all the symptoms that you experience because of your condition or because of your therapy or treatment, which one to three symptoms have the most significant impact on your life? (Examples could include diarrhea, insomnia, difficulty concentrating, etc.)

- Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, daily hygiene, driving, etc.)

5. Assuming there is currently no complete cure for your condition, what specific things would you look for in an ideal therapy or treatment to manage your condition?

Topic 2: Patients' Perspectives on HIV Cure Research

1. What do you believe are the benefits of participating in an HIV cure research study?

2. What would motivate you to participate or to not participate in an HIV cure research study?

3. What risks would you find unacceptable for participating in an HIV cure research study and why? (Examples of risks that may be associated with participation in an HIV cure research study include common

side effects such as nausea and fatigue, and less common but serious adverse events such as blood clots, infection, seizures, and cancer.)

4. In certain HIV cure research studies, you would be asked to stop any other HIV medications that you are currently taking. How would this affect your decision whether to participate in an HIV cure research study?

5. The process of informed consent is an important way for the researchers to communicate the purpose of an HIV research study, as well as its expected benefits and potential risks, so that people can make an informed decision whether to participate in the study.

a. How should the informed consent clearly communicate to you the purpose of an HIV cure research study, particularly when a study is designed only to provide scientific information that could guide future research and development of treatments?

b. How should the informed consent clearly communicate to you the potential benefits of an HIV cure research study? In particular, how should the informed consent describe benefit when we do not think that participants in the study may gain any direct health benefits?

c. How should informed consent communicate clearly to you the potential risks of participating in an HIV cure research study? In particular, how should the informed consent describe a study if there is very limited understanding about how the medications or interventions may affect participants or what are the potential risks of those interventions or medications?

d. Is there any other information that you would find helpful when deciding whether to enter an HIV cure research study?

6. What else do you want FDA to know about HIV Cure Research from your perspective?

III. How To Submit Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0007]

Medical Device User Fee Rates for Fiscal Year 2014

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2014. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2012, which was signed by the President on July 9, 2012 (MDUFA III), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. The FY 2014 fee rates are provided in this document. These fees apply from October 1, 2013, through September 30, 2014. To avoid delay in the review of your application, you should pay the fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is recognized by the U.S. Treasury. If you want to pay a reduced small business fee, you must qualify as a small business before you make your submission to FDA; if you do not qualify as a small business before you make your submission to FDA, you will have to pay the higher standard fee. This document provides information on how the fees for FY 2014 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT: For information on Medical Device User Fees: Visit FDA's Web site at <http://www.fda.gov/mdufa>.

For questions relating to this notice: David Miller, Office of Financial Management (HFA-100), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-796-7103.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, and notices (for simplicity, this document refers to these collectively as "submissions" or "applications"); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee. (See 21 U.S.C. 379j(d) and (e).) Additionally, the Secretary of Health and Human Services (the Secretary) may, at the Secretary's sole discretion, grant a fee waiver or reduction if the Secretary finds that such waiver or reduction is in the interest of public health. (See 21 U.S.C. 379j(f).)

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2013 through FY 2017; the base fee for a premarket application received by FDA during FY 2014 is \$252,960. From this starting point, this document establishes FY 2014 fee rates for other types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2013 through FY 2017; the base fee for an establishment registration in FY 2014 is \$3,200. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.

II. Revenue Amount for FY 2014

The base revenue amount for FY 2014 is \$112,580,497, as set forth in the statute prior to the inflation adjustment. MDUFA directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. The fee calculations for FY 2014 are described in this document.