As discussed in section V.A.2 of this document, some requests for removal from region- or country-wide import alerts will not lead to the assessment of a fee. Fees would only be assessed in situations where, in issuing the alert, FDA reviewed compliance information specific to a particular person or entity sufficiently related to the request for removal. An example of such a situation is where FDA analyzed samples of food from Processor A and found it to be contaminated, the food is then placed on a region- or country-wide import alert, and FDA receives a request to remove food from Processor A from the import alert.

4. Destruction of Food That Has Been Refused Admission

If a product is refused admission under section 801(a) of the FD&C Act, it must be exported within 90 days of the document of refusal or it is subject to destruction by CBP (section 801(a) of the FD&C Act). In practice, when a product is destroyed, destruction is often conducted by the owner or consignee under the supervision of FDA or CBP. Where FDA conducts a review and/or approves a destruction proposal and such supervision of destruction occurs, FDA considers this to be ''1 or more examinations conducted under section 801 * * * specifically to determine whether compliance has been achieved'' to FDA's satisfaction.

B. Who will be responsible for paying this fee?

The importer that is subject to the additional examinations that are described in section V.A of this document is responsible for paying the fee, according to section 743(a)(1)(D) of the FD&C Act.

1. Reconditioning of Imported Food

For reconditioning, the entity that is responsible for the reconditioning is responsible for paying the fee. The request for reconditioning can only be made by the owner or consignee of the food (21 CFR 1.95). If ownership changes, the new owner will be responsible for the reconditioning if that new owner executes a bond and obtains a new authorization (21 CFR 1.96(d)).

2. Importer Seeking Admission of an Article That Has Been Detained

The entity that introduces evidence regarding admissibility is responsible for paying this fee. This is the owner or consignee of the food that is being imported or offered for import. (Section 801(a) of the FD&C Act; 21 CFR 1.83(b) and 1.94(a).)

3. Entity Requesting Removal From an Import Alert for Detention Without Physical Examination.

FDA considers the entity that requests removal of the food from the import alert to be the importer subject to the examination and, thus, responsible for paying this fee.

4. Destruction of Food That Has Been Refused Admission

FDA considers the entity that destroys the product under FDA or CBP supervision to be the importer subject to the examination and, thus, responsible for paying this fee.

C. How much will this fee be?

The fee is to cover all expenses incurred in connection with arranging, conducting, and evaluating the results of the one or more additional examinations that are described in section V.A of this document.

For reconditioning, section 801(c) of the FD&C Act directs the owner or consignee to pay all expenses in connection with the supervision of reconditioning with respect to food and certain other FDA-regulated products. Those parties have been paying these expenses, but FDA did not have authority to retain those fees. FDA considers the enactment of section 743 of the FD&C Act to mean that, for food, FDA is now authorized to assess and retain these fees, but only with respect to the reconditioning of food and only if the other conditions of section 743 are met. If a fee is authorized under section 743 for a particular article of food, FDA considers this to mean it cannot collect a fee related to reconditioning that article under section 801(c).

For destruction, section 801(c) of the FD&C Act also directs the owner or consignee to pay all expenses in connection with the destruction of food and certain other FDA-regulated products under section 801(a). However, neither FDA nor CBP have had the authority to retain those fees. FDA considers the enactment of section 743 of the FD&C Act to mean that, for food, FDA is now authorized to assess and retain these fees, but only with respect to the destruction of food and only if the other conditions of section 743 are met. If a fee is authorized under section 743 for a particular article of food, FDA considers this to mean it cannot collect a fee related to destruction of that article under section 801(c) of the FD&C Act.

The direct hours spent on each such import reinspections will be billed at the appropriate hourly rate shown in table 3 of this document.

VI. 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 30 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.

VII. What are the consequences of not paying these user 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 United States Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: July 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–19331 Filed 7–29–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0556]

Center for Devices and Radiological Health 510(k) Clearance Process; Institute of Medicine Report: ''Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years;'' Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on the Institute of Medicine (IOM) report entitled: ''Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years.'' The establishment of this public docket does

not signify FDA endorsement or concurrence with any of the conclusions or recommendations contained within the report. FDA may, in the future, take additional measures to solicit public input in the report and specific recommendations contained therein. FDA will not adopt any of the recommendations contained in the report before the close of this comment period.

DATES: Submit either electronic or written comments on the report by September 30, 2011.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document. Submit electronic comments on the preliminary report 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5452, Silver Spring, MD 20993–0002, 301–796–5678.

SUPPLEMENTARY INFORMATION:

I. Background

In September 2009, CDRH convened an internal 510(k) Working Group as part of a two-pronged, comprehensive assessment of the 510(k) process. The first prong of this evaluation consisted of an internal evaluation of the 510(k) process, resulting in the publication of the CDRH preliminary internal evaluation entitled: ''510(k) Working Group Preliminary Report and Recommendations'' (*http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf*). This preliminary report was intended to communicate preliminary findings and recommendations regarding the 510(k) program and actions CDRH might take to address identified areas of concern. The report was issued on August 5, 2010 (75 FR 47307). After reviewing public comment, CDRH issued a plan of action for implementation of the previously announced recommendations on January 19, 2011 (*http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf*).

The second prong of the comprehensive assessment of the 510(k) process was an independent study by the IOM. At the request of FDA, IOM has evaluated the 510(k) clearance process and made recommendations aimed at protecting the health of the public and making available a mechanism to achieve timely access of medial devices to the market. On July 29, 2011, IOM released the report ''Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years.'' While FDA has not yet had the opportunity to fully evaluate this report, the agency does recognize the strong public interest in the comprehensive assessment of the 510(k) process and the IOM report. For this reason, FDA is opening a public docket and requesting public comment on the report. The establishment of this public docket does not signify agency endorsement or concurrence with any of the conclusions or recommendations contained within the report. FDA may, in the future, take additional measures to solicit public input in the report and specific recommendations contained therein. FDA will not adopt any of the recommendations contained in the report before the close of this comment period.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Electronic Access

The IOM report entitled: ''Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years'' can be obtained from the IOM Web site at *http://www.iom.edu/Activities/PublicHealth/510KProcess.aspx.*

Dated: July 26, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–19353 Filed 7–29–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0542]

Medical Device User Fee Rates for Fiscal Year 2012

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) 2012. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2007 (title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA)), authorizes FDA to collect user fees for certain medical device submissions, and annual fees for certain periodic reports and for certain establishments subject to registration. The FY 2012 fee rates are provided in this document. These fees apply from October 1, 2011, through September 30, 2012. 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 received. In order 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 be required to pay the higher standard fee. This document provides information on how the fees for FY 2012 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 the Medical Device User Fee and Modernization Act (MDUFMA):* visit FDA's Web site, *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm.*

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

SUPPLEMENTARY INFORMATION: