Application fees can also be paid online with an electronic check (ACH). FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after the user fee ID number is generated.

The tax identification number of FDA is 53–0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2016 under the new fee schedule in August 2015. Payment will be due on October 1, 2015. FDA will issue invoices in November 2016 for any products and establishments subject to fees for FY 2016 that qualify for fee assessments after the August 2015 billing.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18914 Filed 7–31–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1358]

Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation; Guidance for Industry.'' The guidance document provides recommendations to submitters and FDA reviewers in preparing and reviewing premarket notification submissions (hereafter referred to as ''510(k) submission'' or ''510(k)'') for HLA in vitro diagnostic (IVD) device test kits. The guidance applies specifically to nucleic acid-based HLA test kits used for the matching of donors and recipients in transfusion and transplantation, whether testing is for a single locus or for multiple loci simultaneously, for which the premarket submission to FDA will be a 510(k). The guidance announced in this notice finalizes the draft guidance of the same title dated November 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation; Guidance for Industry.'' The guidance provides recommendations to submitters and FDA reviewers in preparing and reviewing 510(k) submissions for IVD device test kits, specifically for nucleic acid-based HLA test kits used for the matching of donors and recipients in transfusion and transplantation, whether testing is for a single locus or for multiple loci simultaneously. The guidance includes detailed information on the types of studies FDA recommends for validation of HLA test kits submitted as 510(k)s. More specifically, the guidance document addresses the types of studies and other information that FDA recommends to be used in designing and conducting studies for validation of nucleic acid-based HLA test kits and preparing a 510(k) submission.

In the **Federal Register** of November 20, 2013 (78 FR 69693), FDA announced the availability of the draft guidance of the same title dated November 2013. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made for purposes of clarity and accuracy. The guidance announced in this notice finalizes the draft guidance dated November 2013.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on premarket notification (510(k)) submissions for nucleic acid-based HLA test kits used for matching of donors and recipients in transfusion and transplantation. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 812 have been approved under OMB control numbers 0910–0078 and 0910–0582; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 56 have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0586.

III. 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18956 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Medical Device User Fee Rates for Fiscal Year 2016

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) 2016. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 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. This notice establishes the fee rates for FY 2016, which apply from October 1, 2015, through September 30, 2016. To avoid delay in the review of your application, you should pay the application 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 making your submission to FDA; if you do not qualify as a small business before making your submission to FDA, you will have to pay the higher standard fee. Please note that the establishment registration fee is not eligible for a reduced small business fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2016, you should not submit a FY 2016 Small Business Qualification and Certification request. This document provides information on how the fees for FY 2016 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, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202E), Silver Spring, MD 20993–0002, 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 2016 is $263,180. From this starting point, this document establishes FY 2016 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 2016 is $3,872. 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 2016

The total revenue amount for FY 2016 is $129,339,949, as set forth in the statute prior to the inflation adjustment. (See 21 U.S.C. 379j(b)(3)(D)). MDUFA III (Pub. L. 112–144) directs FDA to use the yearly total revenue amount as a starting point to set the standard fee rates for each fee type. The fee calculations for FY 2016 are described in this document.

Inflation Adjustment

MDUFA III specifies that the $129,339,949 is to be adjusted for inflation increases for FY 2016 using two separate adjustments—one for payroll costs and one for non-pay costs (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2016 is the sum of one plus these two separate adjustments, and is compounded as specified (see 21 U.S.C. 379j(c)(2)(C)(1) and 379j(c)(2)(B)(ii)).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see 21 U.S.C. 379j(c)(2)(C)).

Table 1 summarizes the actual cost and FTE data for the specified FYs, and provides the percent change from the previous FY and the average percent change over the first 3 of the 4 FYs preceding FY 2016. The 3-year average is 2.2328 percent (rounded).

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

Fiscal year	2012	2013	2014	3-Year average
Total PC&B	$1,824,703,000	$1,927,703,000	$2,054,937,000	
Total FTE	13,382	13,974	14,555	