information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Program/Home Health Prospective Payment System Rate Update for Calendar Year 2010: Physician Narrative Requirement and Supporting Regulation; *Use:* Section (o) of the Act (42 U.S.C. 1395 x) specifies certain requirements that a home health agency must meet to participate in the Medicare program. To qualify for Medicare coverage of home health services a Medicare beneficiary must meet each of the following requirements as stipulated in § 409.42: Be confined to the home or an institution that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1) or 1919 of Act; be under the care of a physician as described in § 409.42(b); be under a plan of care that meets the requirements specified in § 409.43; the care must be furnished by or under arrangements made by a participating HHA, and the beneficiary must be in need of skilled services as described in § 409.42(c). Subsection 409.42(c) of our regulations requires that the beneficiary need at least one of the following services as certified by a physician in accordance with § 424.22: Intermittent skilled nursing services and the need for skilled services which meet the criteria in § 409.32; Physical therapy which meets the requirements of § 409.44(c), Speech-language pathology which meets the requirements of § 409.44(c); or have a continuing need for occupational therapy that meets the requirements of § 409.44(c), subject to the limitations described in § 409.42(c)(4). On March 23, 2010, the Affordable Care Act of 2010 (Pub. L., 111–148) was enacted. Section 6407(a) (amended by section 10605) of the Affordable Care Act amends the requirements for physician certification of home health services contained in Sections 1814(a)(2)(C) and 1835(a)(2)(A) by requiring that, prior to certifying a patient as eligible for Medicare's home health benefit, the physician must document that the physician himself or herself or a permitted non-physician practitioner has had a face-to-face encounter (including through the use of tele-health services, subject to the requirements in section 1834(m) of the Act)'', with the patient. The Affordable Care Act provision does not amend the statutory requirement that a physician must certify a patient's eligibility for Medicare's home health benefit, (see Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act. *Form Number:* CMS–10311 (OMB control number: 0938–1083); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits); *Number of Respondents:* 345,600; *Total Annual Responses:* 345,600; *Total Annual Hours:* 28,800. (For policy questions regarding this collection contact Hillary Loeffler at 410–786–0456.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Documentation Requirements Concerning Emergency and Nonemergency Ambulance Transports Described in the Beneficiary Signature Regulations in 42 CFR 424.36(b); *Use:* The statutory authority requiring a beneficiary's signature on a claim submitted by a provider is located in section 1835(a) and in 1814(a) of the Social Security Act (the Act), for Part B and Part A services, respectively. The authority requiring a beneficiary's signature for supplier claims is implicit in sections 1842(b)(3)(B)(ii) and in 1848(g)(4) of the Act. Federal regulations at 42 CFR 424.32(a)(3) state that all claims must be signed by the beneficiary or on behalf of the beneficiary (in accordance with 424.36). Section 424.36(a) states that the beneficiary's signature is required on a claim unless the beneficiary has died or the provisions of 424.36(b), (c), or (d) apply. We believe that for emergency and nonemergency ambulance transport services, where the beneficiary is physically or mentally incapable of signing the claim (and the beneficiary's authorized representative is unavailable or unwilling to sign the claim), that it is impractical and infeasible to require an ambulance provider or supplier to later locate the beneficiary or the person authorized to sign on behalf of the beneficiary, before submitting the claim to Medicare for payment. Therefore, we created an exception to the beneficiary signature requirement with respect to emergency and nonemergency ambulance transport services, where the beneficiary is physically or mentally incapable of signing the claim, and if certain documentation requirements are met. Thus, we added subsection (6) to paragraph (b) of 42 CFR 424.36. The information required in this ICR is needed to help ensure that services were in fact rendered and were rendered as billed. *Form Number:* CMS–10242 (OMB control number: 0938–1049); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits, Not-For-Profit Institutions); *Number of Respondents:* 10,402; *Total Annual Responses:* 14,155,617; *Total Annual Hours:* 1,180,578. (For policy questions regarding this collection contact Martha Kuespert at 410–786–4605.)

Dated: July 26, 2016.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016–17987 Filed 7–28–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1773]

Change of Address for the Food and Drug Administration Center for Food Safety and Applied Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is providing notice that the street address for the Center for Food Safety and Applied Nutrition's (CFSAN's) Harvey W. Wiley Federal Building in College Park, MD has changed. The new street address is 5001 Campus Drive.

FOR FURTHER INFORMATION CONTACT: John Reilly, Center for Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

SUPPLEMENTARY INFORMATION: The purpose of this notice is to inform the public that the street address for CFSAN's Harvey W. Wiley Federal Building in College Park, MD has changed. The street, formerly known as Paint Branch Parkway, has been renamed ''Campus Drive'' and the street number has been changed to ''5001.'' Thus, the building's street address has changed from 5100 Paint Branch Parkway to 5001 Campus Drive, and our full address is: Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

Consequently, any mailed correspondence addressed to CFSAN's Harvey W. Wiley Federal Building should use the new street address beginning immediately.

Dated: July 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17659 Filed 7–28–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Medical Device User Fee Rates for Fiscal Year 2017

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) 2017. 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 2017, which apply from October 1, 2016, through September 30, 2017. 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 2017, you should not submit a FY 2017 Small Business Qualification and Certification request. This document provides information on how the fees for FY 2017 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/ForIndustry/UserFees/MedicalDeviceUserFee/ucm20081521.htm.*

For questions relating to this notice: Maurille Beheton, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202C), Silver Spring, MD 20993–0002, 301–796–4689.

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 2017 is $268,443. From this starting point, this document establishes FY 2017 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 2017 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 2017

The total revenue amount for FY 2017 is $130,184,348, as set forth in the statute prior to the inflation adjustment and offset of excess collections (see 21 U.S.C. 379j(b)(3)). MDUFA 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 2017 are described in this document.

A. Inflation Adjustment

MDUFA specifies that the $130,184,348 is to be adjusted for inflation increases for FY 2017 using two separate adjustments—one for payroll costs and one for non-pay cost (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2017 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 2017. The 3-year average is 1.8759 percent (rounded).

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

Fiscal Year	2013	2014	2015	3-Year average
Total PC&B	$1,927,703,000	$2,054,937,000	$2,232,304,000	.....
Total FTE	13,974	14,555	15,484	.....
PC&B per FTE	$137,949	$141,184	$144,168	.....
Percent change from previous year	1.1690%	2.3451%	2.1136%	1.8759%