Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Haleh Saber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2117, Silver Spring, MD 20993–0002, 301–796–7550; or John Leighton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2204, Silver Spring, MD 20993–0002, 301–796–7550.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.'' This guidance represents FDA's current thinking on nonclinical studies needed in support of FIH studies and for approval for therapeutic radiopharmaceuticals. *Therapeutic radiopharmaceutical* refers to a pharmaceutical that contains a radionuclide and is used in patients with cancer to treat the disease or palliate tumor-related symptoms (*e.g.,* pain). This guidance discusses the following concepts: Evaluation of toxicities from the ligand; evaluation of radiation toxicities; and information for product labeling as related to reproductive toxicity, genotoxicity, carcinogenicity, contraception, and use in lactating women.

Currently, no FDA or International Council for Harmonisation guidance addresses nonclinical studies in support of FIH trials and approval for radiopharmaceuticals for treatment of cancer. The guidance for industry ''Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals'' (available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079242.pdf*) describes nonclinical studies to address late radiation toxicity only. This guidance, however, provides further clarification of recommendations made in that guidance for the timing and design of late radiation toxicity studies. This guidance is intended to bring consistency in nonclinical safety assessment and in product labeling for therapeutic radiopharmaceuticals and to reduce the number of nonclinical studies that are not informative for product use.

This 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 ''Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations.'' 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. This guidance is not subject to Executive Order 12866.

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 collection of information in 21 CFR 312.23(a)(8) for submitting pharmacological and toxicology information has been approved under OMB control number 0910–0014; the collection of information in 21 CFR 201.56 and 201.57 for preparing human prescription drug labeling has been approved under OMB control number 0910–0572; the collection of information in the ''Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling'' final rule has been approved under OMB control number 0910–0624.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: July 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16504 Filed 8–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2020. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products, and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2020.

FOR FURTHER INFORMATION CONTACT: Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively) establish two different kinds of user fees. Fees are assessed as follows: (1) Application fees are assessed on certain types of applications for the review of human drug and biological products; and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). When specific conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act) or exempt certain prescription drug products from fee (section 736(k) of the FD&C Act).

For FY 2018 through FY 2022, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VI. The base revenue amount for FY 2020 is $1,001,479,592. The FY 2020 base revenue amount is adjusted for inflation and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment). An additional dollar amount specified in the statute (see section 736(b)(1)(F) of the FD&C Act) is then added to provide for additional full-time equivalent (FTE) positions to support PDUFA VI initiatives. The FY 2020 revenue amount may be adjusted further, if necessary, to provide for

sufficient operating reserves of carryover user fees. Finally, the amount is adjusted to provide for additional direct costs to fund PDUFA VI initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees provide 80 percent of the total revenue.

This document provides fee rates for FY 2020 for an application requiring clinical data ($2,942,965), for an application not requiring clinical data ($1,471,483), and for the prescription drug program fee ($325,424). These fees are effective on October 1, 2019, and will remain in effect through September 30, 2020. For applications that are submitted on or after October 1, 2019, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2020

The base revenue amount for FY 2020 is $1,001,479,592 prior to adjustments for inflation, capacity planning, additional FTE, operating reserve, and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2020 Statutory Fee Revenue Adjustments for Inflation

PDUFA VI specifies that the $1,001,479,592 is to be adjusted for inflation increases for FY 2020 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per FTE positions at FDA for the first 3 of the preceding 4 FYs, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications for the first 3 of the preceding 4 FYs (see section 736(c)(1)(A) and (B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs and provides the percent changes from the previous FYs and the average percent changes over the first 3 of the 4 FYs preceding FY 2020. The 3-year average is 3.1175 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

Fiscal year	2016	2017	2018	3-Year Average
Total PC&B	$2,414,728,159	$2,581,551,000	$2,690,678,000	
Total FTE	16,381	17,022	17,023	
PC&B per FTE	$147,408	$151,660	$158,061	
Percent Change From Previous Year	2.2474	2.8845	4.2206	3.1175

The statute specifies that this 3.1175 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of human drug applications. Table 2 shows the PC&B and the total obligations for the process for the review of human drug applications for the first 3 of the preceding 4 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

Fiscal year	2016	2017	2018	3-Year average
Total PC&B	$652,508,273	$711,016,627	$792,900,647	
Total Costs	$1,157,817,695	$1,206,657,269	$1,374,508,527	
PC&B Percent	56.3567	58.9245	57.6861	57.6558

The payroll adjustment is 3.1175 percent from table 1 multiplied by 57.6558 percent (or 1.7974 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of human drug applications for the first 3 years of the preceding 4 FYs (see section 736(c)(1)(B) of the FD&C Act). As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018,[1] the ''Washington-Baltimore, DC-MD-VA-WV'' index was discontinued and replaced with two separate indices (*i.e.,* ''Washington-Arlington-Alexandria, DC-VA-MD-WV'' and ''Baltimore-Columbia-Towson, MD''). In order to continue applying a CPI that best reflects the geographic region in which FDA is headquartered and that provides the most current data available, the Washington-Arlington-Alexandria index will be used in calculating the relevant adjustment factors for FY 2020 and subsequent years. Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area. The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0, CUUSS35ASA0.*

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Year	2016	2017	2018	3-Year average
Annual CPI	253.422	256.221	261.445	
Annual Percent Change	1.1003	1.1045	2.0389	1.4146

[1] The Bureau of Labor Statistics' announcement of the geographical revision can be viewed at *https://www.bls.gov/cpi/additional-resources/geographic-revision-2018.htm.*

The statute specifies that this 1.4146 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of human drug applications obligated. Because 57.6558 percent was obligated for PC&B (as shown in table 2), 42.3442 percent is the portion of costs other than PC&B (100 percent minus 57.6558 percent equals 42.3442 percent). The non-payroll adjustment is 1.4146 percent times 42.3442 percent, or 0.5990 percent.

Next, we add the payroll adjustment (1.7974 percent) to the non-payroll adjustment (0.5990 percent), for a total inflation adjustment of 2.3964 percent (rounded) for FY 2020.

We then multiply the base revenue amount for FY 2020 ($1,001,479,592) by 1.023964, yielding an inflation-adjusted amount of $1,025,479,049.

B. FY 2020 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after $1,001,479,592 has been adjusted for inflation, the inflation-adjusted amount shall be further adjusted to reflect changes in the resource capacity needs for the process of human drug application reviews (see section 736(c)(2) of the FD&C Act). The statute prescribes an interim capacity planning adjustment be utilized until a new methodology can be developed through a process involving an independent evaluation as well as obtaining public comment. The interim capacity planning adjustment is applied to FY 2020 fee setting.

To determine the FY 2020 capacity planning adjustment, FDA calculated the average number of each of the five elements specified in the capacity planning adjustment provision: (1) Human drug applications (new drug applications (NDAs)/biologics license applications (BLAs)); (2) active commercial investigational new drug applications (INDs) (IND applications that have at least one submission during the previous 12 months); (3) efficacy supplements; (4) manufacturing supplements; and (5) formal meetings, type A, B, B(EoP), C, and written responses only (WRO) issued in lieu of such formal meetings, over the 3-year period that ended on June 30, 2018, and the average number of each of these elements over the most recent 3-year period that ended June 30, 2019.

The calculations are summarized in table 4. The 3-year averages for each element are provided in column 1 (''3-Year Average Ending 2018'') and column 2 (''3-Year Average Ending 2019''). Column 3 reflects the percent change from column 1 to column 2. Column 4 shows the weighting factor for each element. The weighting factor methodology has been updated for PDUFA VI. The previous methodology relied on the relative value of the standard costs for the elements included in the adjuster, and summed to 100 percent. The weighting factor now is the time invested in activities related to the element expressed as a percentage of total time invested in PDUFA activities, and will adjust only the costs attributed to the elements included in the model (hence the weighting factor does not now sum to 100 percent). Column 5 is the weighted percent change in each element. This is calculated by multiplying the weighting factor in each line in column 4 by the percent change in column 3. The values in column 5 are summed, reflecting an adjustment of 2.2697 percent (rounded).

TABLE 4—CAPACITY PLANNING ADJUSTER (INTERIM METHODOLOGY) CALCULATION FOR FY 2020

Element	Column 1 3-Year average ending 2018	Column 2 3-Year average ending 2019	Column 3 Percent change (column 1 to column 2)	Column 4 Weighting factor (percent)	Column 5 Weighted percent Lchange
NDAs/BLAs	162.00	168.67	4.1152	16.5464	0.6809
Active Commercial INDs	8,057.00	8,335.67	3.4587	22.2644	0.7701
Efficacy Supplements	234.33	262.33	11.9488	4.1340	0.4940
Manufacturing Supplements	2,561.67	2,578.67	0.6636	5.2980	0.0352
Meetings Scheduled and WROs	3,136.33	3,295.33	5.0696	5.7119	0.2896
FY 2020 Capacity Planning Adjuster	2.2697				

Table 5 shows the calculation of the inflation and capacity planning adjusted amount for FY 2020. The FY 2020 base revenue amount, $1,001,479,592, shown on line 1 is multiplied by the inflation adjustment factor of 1.023964, resulting in the inflation-adjusted amount of $1,025,479,049 shown on line 3. That amount is then multiplied by one, plus the capacity planning adjustment of 2.2697 percent, resulting in the inflation and capacity planning adjusted amount of $1,048,754,347 shown on line 5.

TABLE 5—PDUFA INFLATION AND CAPACITY PLANNING ADJUSTED AMOUNT FOR FY 2020, SUMMARY CALCULATION

FY 2020 Revenue Amount	$1,001,479,592	Line 1.
Inflation Adjustment Factor for FY 2020 (1 plus 2.3964 percent)	1.023964	Line 2.
Inflation-Adjusted Amount	$1,025,479,049	Line 3.
Capacity Planning Adjustment Factor for FY 2020 (1 plus 2.2697 percent)	1.022697	Line 4.
Inflation and Capacity Planning Adjusted Amount	$1,048,754,347	Line 5.

The capacity planning adjustment adds $23,275,298 to the fee revenue amount for FY 2020. This increase is driven by the fact that the counts of elements for 2019 (year ending June 30) are at or near the highest levels since the first incorporation of the workload adjuster in 2003. The NDA/BLA count in 2019 is the second highest annual number recorded since the advent of the workload adjuster methodology in 2003. Active commercial INDs, efficacy supplements, and meetings/WROs are higher in 2019 than in any previous year recorded in the workload adjuster (note: meetings/WROs have been recorded only since 2014, while the other elements have been recorded since 2003). The manufacturing supplement count is approximately 6 percent below the highest number recorded in the

history of the workload adjuster. Comparing 2019 to 2016, the first year included in the average in column 1 in the adjustment, NDA/BLAs are 14 percent higher, active commercial INDs are 11 percent higher, efficacy supplements are 39 percent higher, manufacturing supplements are 2 percent higher, and meetings scheduled and WROs are 16 percent higher. This significant and across the board increase in submission activity is the driver of the $23,275,298 upward adjustment to the fee revenue amount.

Per the commitments made in PDUFA VI, this increase in the revenue amount will be allocated to and used by organizational review components engaged in direct review work to enhance resources and expand staff capacity and capability (see II.A.4 on p.37 of the PDUFA VI commitment letter).[2]

C. FY 2020 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VI provides an additional dollar amount for each of the 5 fiscal years covered by PDUFA VI for additional FTE to support PDUFA VI enhancements outlined in the PDUFA VI commitment letter. The amount for FY 2020 is $16,953,329 (see section 736(b)(1)(F) of the FD&C Act). Adding this amount to the inflation and capacity planning adjusted revenue amount, $1,048,754,347, equals $1,065,707,676.

D. FY 2020 Statutory Fee Revenue Adjustments for Operating Reserve

PDUFA VI provides for an operating reserve adjustment to allow FDA to increase the fee revenue and fees for any given fiscal year during PDUFA VI to maintain up to 14 weeks of operating reserve of carryover user fees. If the carryover balance exceeds 14 weeks of operating reserves, FDA is required to decrease fees to provide for not more than 14 weeks of operating reserves of carryover user fees.

To determine the 14-week operating reserve amount, the FY 2020 annual base revenue adjusted for inflation, capacity planning, and additional dollar amounts, $1,065,707,676, is divided by 52, and then multiplied by 14. The 14-week operating reserve amount for FY 2020 is $286,921,297.

To determine the end of year operating reserve amount, the Agency must assess actual operating reserve at the end of the third quarter of FY 2019, and forecast collections and obligations in the fourth quarter of FY 2019. The estimated end of year FY 2019 operating reserve is $186,273,705.

Because the estimated end of year FY 2020 PDUFA operating reserve does not exceed the 14-week operating reserve for FY 2020, FDA will not reduce the FY 2020 PDUFA fee revenue in FY 2020.

E. FY 2020 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VI specifies that $8,730,000, adjusted for inflation, be added in addition to the operating reserve adjustment to account for additional direct costs in FY 2020. This additional direct cost adjustment is adjusted for inflation by multiplying $8,730,000 by the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such index for 2016 (see section 736(c)(4)(B) of the FD&C Act). Because of the geographical revision made by the Bureau of Labor and Statistics, the Washington-Arlington-Alexandria index will be used in calculating the direct cost adjustment inflation factor for FY 2020 and subsequent years. The annual index for 2018, 261.445, divided by such index for 2016, 253.422, results in an adjustment factor of 1.031659, making the additional direct cost adjustment equal to $9,006,383.

The final FY 2020 PDUFA target revenue is $1,074,714,000 (rounded to the nearest thousand dollars).

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate 20 percent of the total target revenue amount, or $214,942,800 in FY 2020.

B. Estimate of the Number of Fee-Paying Applications and Setting the Application Fees

FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive during the next FY by averaging the number of fee-paying FAEs received in the 3 most recently completed FYs. Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the FY.

In estimating the number of fee-paying FAEs, a full application requiring clinical data counts as one FAE. An application not requiring clinical data counts as one-half of an FAE. An application that is withdrawn before filing, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount. Prior to PDUFA VI, the FAE amount also included supplements; supplements have been removed from the FAE calculation as the supplement fee has been discontinued in PDUFA VI.

As table 6 shows, the average number of fee-paying FAEs received annually in the most recent 3-year period is 73.036145 FAEs. FDA will set fees for FY 2020 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 6—FEE-PAYING FAES

FY	2016	2017	2018	3-Year average
Fee-Paying FAEs	70.483437	79.750000	68.874999	73.036145

Note: Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the FY.

The FY 2020 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 73.036145, into the fee revenue amount to be derived from application fees in FY 2020, $214,942,800. The result is a fee of $2,942,965 per full application requiring clinical data, and $1,471,483 per application not requiring clinical data.

IV. Fee Calculations for Prescription Drug Program Fees

PDUFA VI assesses prescription drug program fees for certain prescription drug products; in addition, an applicant will not be assessed more than five

[2] The PDUFA VI commitment letter can be viewed at *https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.*

program fees for a fiscal year for prescription drug products identified in a single approved NDA or BLA (see section 736(a)(2)(C)). Applicants are assessed a program fee for a fiscal year only for user fee eligible prescription drug products identified in a human drug application approved as of October 1 of such fiscal year.

FDA estimates 2,740 program fees will be invoiced in FY 2020 before factoring in waivers, refunds, and exemptions. FDA approximates that there will be 54 waivers and refunds granted. In addition, FDA approximates that another 44 program fees will be exempted in FY 2020 based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates 2,642 program fees in FY 2020, after allowing for an estimated 98 waivers and reductions, including the orphan drug exemptions. The FY 2020 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($859,771,200) by the estimated 2,642 program fees, for a FY 2020 program fee of $325,424.

V. Fee Schedule for FY 2020

The fee rates for FY 2020 are displayed in table 7:

TABLE 7—FEE SCHEDULE FOR FY 2020

Fee category	Fee rates for FY 2020
Application:	
Requiring clinical data	$2,942,965
Not requiring clinical data ..	1,471,483
Program	325,424

VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application subject to fees under PDUFA that is submitted on or after October 1, 2019. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express).

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 website after completing the Prescription Drug User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online). Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an application and other penalties. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2020 program fees under the new fee schedule in August 2019. Payment will be due on October 1, 2019. FDA will issue invoices in December 2019 for FY 2020 program fees that qualify for fee assessments after the August 2019 billing.

Dated: July 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16435 Filed 8–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2837]

Testing and Labeling Medical Devices for Safety in the Magnetic Resonance Environment; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.'' FDA developed this draft guidance to provide FDA's recommendations on the testing needed for assessing the safety and compatibility of medical devices in the Magnetic Resonance (MR) Environment and the recommended format for Magnetic Resonance Imaging (MRI) Safety Information in medical device labeling. This draft guidance document is anticipated to aid in consistency of reviews, testing, and MRI safety labeling across a variety of medical devices. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by October 1, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to