

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.*

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**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

the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2019-D-2837 for "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2116, Silver Spring, MD 20993-0002, 301-796-2503.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The MR Environment presents unique safety hazards for patients and other persons with devices near or inside an MR system. Ensuring safety and effectiveness for a medical device intended to enter the MR Environment should be an integral part of the device

risk management. Appropriate testing and labeling, such as well supported MR Conditional labeling, should form the basis of adequate mitigations for the unique safety hazards in the MR Environment. This guidance document outlines FDA's current thinking on the testing needed for assessing the safety and compatibility of medical devices in the MR Environment and the recommended format for MRI Safety Information in device labeling.

##### II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment." 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.

##### III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1500059 to identify the guidance you are requesting.

##### IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. 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 the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E .....	Premarket notification .....	0910-0120
814, subparts A through E .....	Premarket approval .....	0910-0231
814, subpart H .....	Humanitarian Device Exemption .....	0910-0332
812 .....	Investigational Device Exemption .....	0910-0078
“De Novo Classification Process (Evaluation of Automatic Class III Designation)”.	De Novo classification process .....	0910-0844
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”.	Q-Submissions .....	0910-0756
801 and 809 .....	Medical Device Labeling Regulations .....	0910-0485

Dated: July 29, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2019-N-3560]

**Biosimilar 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 biosimilar user fees for fiscal year (FY) 2020. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2017 (BsUFA II), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application.

BsUFA II directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year. These fees apply to the period from October 1, 2019, through September 30, 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 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j-51, 379j-52, and 379j-53), as amended by BsUFA II (title IV of the FDA Reauthorization Act of 2017, Pub. L. 115-52), authorize the collection of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA’s BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing or the sponsor discontinues participation in FDA’s BPD program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA’s BPD program and wants to re-engage with FDA on development of the product, the sponsor must pay a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor’s request for a BPD meeting for that product or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA II also authorizes fees for certain biosimilar biological product applications and for each biosimilar

biological product identified in an approved biosimilar biological product application (section 744H(a)(2) and (3) of the FD&C Act). Under certain conditions, FDA will grant a small business a waiver from its first biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2018 through FY 2022, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA II. For FY 2020, the base revenue amount is the FY 2019 inflation adjusted fee revenue amount of \$40,947,463. The FY 2020 base revenue amount is to be adjusted for inflation and may be reduced, as appropriate, for long-term financial planning purposes.

This document provides fee rates for FY 2020 for the initial and annual BPD fee (\$117,987), for the reactivation fee (\$235,975), for an application requiring clinical data (\$1,746,745), for an application not requiring clinical data (\$873,373), and for the program fee (\$304,162). 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 \$40,947,463 prior to adjustments for inflation and operating reserves (see section 744H(c)(1) and (3) of the FD&C Act).

*A. FY 2020 Statutory Fee Revenue Adjustments for Inflation*

BsUFA II specifies that the \$40,947,463 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 744H(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 full-time equivalent (FTE) positions at FDA for the first 3 of the preceding 4 FYs,