Important Information on Medical Device User Fees for Fiscal Year 2022 (October 1, 2021 through September 30, 2022)

Dear Medical Device Stakeholder:

This letter provides information about the annual establishment registration fees, the small business program, and medical device user fees for Fiscal Year 2022 (FY2022), which are effective October 1, 2021, through September 30, 2022.

Federal law authorizes the U.S. Food and Drug Administration (FDA) to collect user fees for certain medical device submissions and establishment registration. On August 2, 2021, the FDA announced the FY2022 user fees in a Federal Register notice titled **Medical Device User Fee Rates for Fiscal Year 2022.** User fees are required for the following types of medical device submissions: titled User fees are required for the following types of medical device submissions:

- premarket notifications (510(k)s)
- premarket approval applications (PMAs)
- product development protocols (PDPs)
- De Novo classification requests
- some PMA and PDP supplements (for example, panel-track, 180-day, real-time, 30-day notice)
- premarket reports (PMRs)
- annual fee for periodic reporting on a class III device (PMAs, PDPs, and PMRs)
- requests for device classification information (513(g)s)
- original biologics license applications (BLAs) for certain medical devices reviewed by the FDA's Center for Biologics Evaluation and Research (CBER)
- BLA efficacy supplements

In addition, all medical device establishments are required to pay an annual establishment registration fee.

FY2022 User Fee for Establishment Registration

For FY2022, the registration fee for each establishment is $5,672 (in United States dollars). There are no waivers or reductions for small establishments, businesses, or groups.

The annual establishment registration fee must be paid between October 1, 2021, and December 31, 2021.

The following educational resources on Device Advice Device Advice and CDRH Learn provide more information on the process for initial and annual registration of your medical device establishment:

Device Advice (text-based education)

Device Registration and Listing

CDRH Learn (video-based education)

1. Device Establishment Registration and Listing: Overview
2. Paying the Annual Registration User Fee via the Device Facility User Fee (DFUF) Website
3. FURLS Device Registration and Listing: Annual Registration
4. FURLS Device Registration and Listing: Initial Registration

FY2022 Small Businesses: Fee Reduction and Fee Waiver for Certain Medical Device Submissions

To reduce the financial burden on small businesses, the Center for Devices and Radiological Health (CDRH) provides reduced medical device user fee for some types of submissions for a certified small business. “Small business” is defined as a business with $100 million or less in gross receipts or sales, including receipts or sales from its affiliates. In addition, if a small business has gross receipts or sales of $30 million or less, it is eligible to have the fee waived for its first PMA, PDP, PMR or BLA.

The business must apply and be certified by CDRH before they can apply the small business fee reduction or waiver to a submission with a user fee. Any business, regardless of location, may apply to be certified as a small business. For more information, please review the Medical Device User Fee Small Business Qualification and Certification Guidance.

As of August 1, 2021, CDRH is accepting Small Business Determination requests for FY2022. The FY2022 Small Business status will be from time of certification through September 30, 2022.

FY2022 User Fees for Medical Device Submissions

The following table identifies the FY2022 User Fees for Medical Device Submissions (in U.S. dollars).

Application Type	Standard Fee	Small Business Fee†
510(k) ‡	$12,745	$3,186
513(g)	$5,061	$2,530
PMA, PDP, PMR, BLA	$374,858	$93,714
De Novo Classification Request	$112,457	$28,114
Panel-track Supplement	$281,143	$70,286
180-Day Supplement	$56,229	$14,057
Real-Time Supplement	$26,240	$6,560
BLA Efficacy Supplement	$374,858	$93,714
30-Day Notice	$5,998	$2,999
Annual Fee for Periodic reporting on a Class device (PMAs, PDPs, and PMRs)	$13,120	$3,280

Small Business Fee: For businesses certified by CDRH as a small business.

‡ Note: all types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the user fee. There is no user fee for a 510(k) submitted to the FDA by an FDA-accredited third-party reviewer.

The FY2022 user fees apply to medical device submissions received by the FDA between October 1, 2021 and September 30, 2022. If you wish to pay the FY2022 user fee for a submission, both your submission **and** your user fee payment must be received by September 30, 2022.

If you plan to submit a submission, the user fee payment must be received **on or before** the date you send the submission. The review of the submission will begin only after we receive your full payment.

Do not send your user fee payment to the FDA with your application. For additional information or instructions about how to submit the fee, please visit the Medical Device User Fees webpage.

For More Information
If you have questions about medical device user fees, regulatory requirements, or other related information, please contact the Division of Industry and Consumer Education (DICE) **at the Center for Devices and Radiological Health (CDRH). Contact DICE at (800) 638-2041 or 301-796-7100 between 9:00 a.m. - 12:30 p.m. and 1:00 p.m. - 4:30 p.m. Eastern Time or by email at** DICE@fda.hhs.gov.

Questions regarding products regulated by the Center for Biologics Evaluation and Research (CBER) should be directed to the Office of Communication, Outreach and Development (OCOD), Manufacturers Assistance and Technical Training (MATT) Branch. Contact CBER MATT at (800) 835-4709 or (240) 402-8010 or by email at industry.biologics@fda.hhs.gov.

Additional information about medical device user fees and the implementation of MDUFA IV is available on the FDA Medical Device User Fee Amendments (MDUFA) webpage. On this site, you may also sign up to receive updates each time the FDA updates information about MDUFA and other information relevant to the device industry.

Caveats

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