FY 2023

Real Time Report

pursuant to the

Federal Food, Drug, and Cosmetic Act

as amended by the Medical Device User Fee Amendments of 2022

Acronyms

FD&C Act – Federal Food, Drug, and Cosmetic Act

FDA – Food and Drug Administration

FDAUFRA 2022 – FDA User Fee Reauthorization Act of 2022

FY – Fiscal Year (October 1 to September 30)

MDUFA – Medical Device User Fee Amendments

Q1 – Quarter 1 (October 1 to December 31)

Q2 – Quarter 2 (January 1 to March 31)

Q3 – Quarter 3 (April 1 to June 30)

Q4 – Quarter 4 (July 1 to September 30)

Background

On September 30, 2022, the FDA User Fee Reauthorization Act of 2022 (FDAUFRA) (Public Law 117-180) was signed into law. FDAUFRA 2022 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by revising and extending the user fee programs for human drugs, biologics, generic drugs, medical devices, and biosimilar biological products.

Section 738A(a)(1)(A)(iii) of the FD&C Act, as amended by section 2004 of FDAUFRA 2022, requires the Food and Drug Administration (FDA) to provide "Real Time" reporting, posted on a quarterly basis, of guidance documents and public meetings related to the process for the review of devices.

Real Time Reporting Under Section 738A(a)(1)(A)(iii) of the FD&C Act

This report is being issued pursuant to the requirement of section 738A(a)(1)(A)(iii) of the FD&C Act, which states:

> "Not later than 30 calendar days after the end of the second quarter of fiscal year 2023, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary [of Health and Human Services] shall post…on the internet website of the Food and Drug Administration…
>
> - "The number and titles of draft and final guidance on topics related to the process for the review of devices, and whether such guidances were issued as required by statute or pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022; and
> - "The number and titles of public meetings held on topics related to the process for the review of devices, and if such meetings were required by statute or pursuant to a commitment under the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022."

Medical Devices

Guidance Documents

Pursuant to the MDUFA V Commitment Letter,[1] the table below includes all FDA guidance documents issued in the specified quarter related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA V Commitment Letter are indicated as such.[2] The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List). [3]

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2023

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	[4]FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals	10/3/2022	Yes	No	N/A	No
2	Q1	[4]FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals	10/3/2022	Yes	No	N/A	No
3	Q1	[4]FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals	10/3/2022	Yes	No	N/A	No
4	Q1	[4]User Fees for 513(g) Requests for Information www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information	10/5/2022	Yes	No	N/A	No

[1] www.fda.gov/media/158308/download.
[2] CDRH provides the annotation of "yes" for guidances that are substantially related to the process. CDRH provides the annotation of "no" for guidances that contain a minimal amount of guidance related to the process.
[3] www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2023-fy2023.
[4] This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2).

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
5	Q1	[4]User Fees and Refunds for Premarket Notification Submissions (510(k)s) www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-premarket-notification-submissions-510ks	10/5/2022	Yes	No	N/A	No
6	Q1	[4]User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-premarket-approval-applications-and-device-biologics-license-applications	10/5/2022	Yes	No	N/A	No
7	Q1	[4]User Fees and Refunds for De Novo Classification Requests www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-de-novo-classification-requests	10/5/2022	Yes	No	N/A	No
8	Q1	Procedures for Handling Post-Approval Studies Imposed by PMA Order www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-handling-post-approval-studies-imposed-pma-order	10/7/2022	Yes	No	N/A	A-List
9	Q1	Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act	10/7/2022	Yes	No	N/A	A-List
10	Q1	Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Health Care www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-breakthrough-devices-program-guidance-reducing-disparities-health-and-health-care	10/21/2022	Yes	No	N/A	A-List
11	Q1	[4]Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions	10/26/2022	Yes	Yes	MDUFA V Commitment Letter V.B.	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
12	Q1	Referencing the Definition of "Device" in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents www.fda.gov/regulatory-information/search-fda-guidance-documents/referencing-definition-device-federal-food-drug-and-cosmetic-act-guidance-regulatory-documents	11/14/2022	No	No	N/A	No
13	Q1	Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-malfunction-summary-reporting-vmsr-program-manufacturers	12/9/2022	Yes	No	N/A	A-List
14	Q1	Content of Human Factors Information in Medical Device Marketing Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions	12/9/2022	Yes	No	N/A	B-List
15	Q1	Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection (December 2022) www.fda.gov/regulatory-information/search-fda-guidance-documents/circumstances-constitute-delaying-denying-limiting-or-refusing-drug-or-device-inspection-december	12/16/2022	No	No	N/A	No

Public Meetings

Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, public meetings that are related to the process for the review of devices are listed in the table below.

Table 2: Public Meetings Held on Topics Related to the Process for the Review of Devices for FY 2023

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter
1	Q1			
2				