FY 2022

Real Time Report

pursuant to the

Medical Device User Fee Amendments

as amended by the FDA Reauthorization Act of 2017

Acronyms

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

FDA – Food and Drug Administration

FDARA – FDA Reauthorization Act of 2017

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 August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52) was signed into law. FDARA 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 903 of FDARA, 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 2018, 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 2017; 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 2017."

Medical Devices

Guidance Documents

Pursuant to the MDUFA IV 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 IV 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 2022

#	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]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	10/5/2021	Yes	No	N/A	No
2	Q1	[4]De Novo Classification Process (Evaluation of Automatic Class III Designation) http://www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation	10/5/2021	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	10/5/2021	Yes	No	N/A	No
4	Q1	[4]Acceptance Review for De Novo Classification Requests www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests	10/5/2021	Yes	No	N/A	No
5	Q1	Surgical Staplers and Staples for Internal Use - Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-	10/8/2021	Yes	No	N/A	A-List

[1] www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.
[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-2022-fy2022.
[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
		documents/surgical-staplers-and-staples-internal-use-labeling-recommendations					
6	Q1	Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-unique-device-identification-policy-regarding-global-unique-device-identification	10/14/21	No	No	N/A	A-List
7	Q1	Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products	10/20/21	No	Yes	Section 709(c) of the FDA Reauthorization Act	No
8	Q1	Content of Premarket Submissions for Device Software Functions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions	11/4/21	Yes	Yes	MDUFA IV Commitment Letter Section IV.I.3.c.	A-List
9	Q1	[5]Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised	11/15/21	No	No	N/A	No
10	Q1	[5]Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health	11/15/21	Yes	No	N/A	No
11	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	12/16/21	No	No	N/A	No
12	Q1	Digital Health Technologies for Remote Data Acquisition in Clinical Investigations	12/23/21	Yes	No	N/A	No

[5] This is a Level 1 guidance document that is immediately implemented as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(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
		www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations					
13	Q1	Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease	12/23/21	Yes	No	N/A	A-List
14	Q1	Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-during-coronavirus-disease	12/23/21	Yes	No	N/A	A-List
15	Q1	Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-medical-devices-physiologic-closed-loop-control-technology	12/23/21	Yes	No	N/A	No
16	Q1	Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions	12/23/21	Yes	No	N/A	No
17	Q1	Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/arthroscopy-pump-tubing-sets-intended-multiple-patient-use-premarket-notification-510k-submissions	12/23/21	Yes	No	N/A	No
18	Q1	Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/pathology-peer-review-nonclinical-toxicology-studies-questions-and-answers	12/27/21	Yes	No	N/A	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
19	Q1	Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) www.fda.gov/regulatory-information/search-fda-guidance-documents/non-clinical-and-clinical-investigation-devices-used-treatment-benign-prostatic-hyperplasia-bph	12/27/21	Yes	No	N/A	No
20	Q2	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc	1/11/22	No	No	N/A	A-List
21	Q2	Patient Engagement in the Design and Conduct of Medical Device Clinical Studies www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies	1/26/22	Yes	No	N/A	B-List
22	Q2	Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use	1/26/22	Yes	Yes	MDUFA Commitment Letter IV.F.3.a	No
23	Q2	Principles of Premarket Pathways for Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-premarket-pathways-combination-products	1/31/22	Yes	No	N/A	No
24	Q2	Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Notification Orders www.fda.gov/regulatory-information/search-fda-guidance-documents/appeal-options-available-mammography-facilities-concerning-adverse-accreditation-decisions	3/2/22	No	No	N/A	No
25	Q2	[4]Center for Devices and Radiological Health (CDRH) Appeals Processes www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes	3/2/22	No	No	N/A	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
26	Q2	Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C www.fda.gov/regulatory-information/search-fda-guidance-documents/initiation-voluntary-recalls-under-21-cfr-part-7-subpart-c	3/4/22	No	No	N/A	No
27	Q2	Certain Ophthalmic Products: Policy Regarding Compliance With 21 CFR Part 4 Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/certain-ophthalmic-products-policy-regarding-compliance-21-cfr-part-4-guidance-industry	3/23/22	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 2022

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter
1	Q1	Regenerative Medicine 101 Webinar: Information for Patients, Caregivers & Advocates	11/16/21	No