FY 2021

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 2021

#	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]Enforcement Policy for Modifications to FDA Cleared Molecular Influenza and RSV Tests During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-modifications-fda-cleared-molecular-influenza-and-rsv-tests-during-coronavirus	10/13/2020	Yes	No	N/A	No
2	Q1	Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-biocompatibility-certain-devices-contact-intact-skin	10/15/2020	Yes	No	N/A	No
3	Q1	Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-non-clinical-assessment-medical-devices-containing-nitinol	10/15/2020	Yes	No	N/A	No

[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-2020-fy-2020
[4] This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic 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
4	Q1	Testing for Biotin Interference in In Vitro Diagnostic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-biotin-interference-vitro-diagnostic-devices	10/16/2020	Yes	No	N/A	No
5	Q1	[4]Necessary Automated External Defibrillator Accessories: Policy Regarding Compliance Date www.fda.gov/regulatory-information/search-fda-guidance-documents/necessary-automated-external-defibrillator-accessories-policy-regarding-compliance-date	10/28/2020	No	No	N/A	No
6	Q1	[5]Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during	10/28/2020	Yes	No	N/A	No
7	Q1	[5]Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices	11/6/2020	No	No	N/A	No
8	Q1	Regulatory Considerations for Microneedling Products www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-microneedling-products	11/10/2020	Yes	No	N/A	No
9	Q1	Certificates of Confidentiality www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality	11/16/2020	No	No	N/A	No
10	Q1	Electromagnetic Compatibility (EMC) of Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices	11/17/2020	Yes	No	N/A	No

[5] 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
11	Q1	[4]Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-bioburden-reduction-systems-using-dry-heat-support-single-user-reuse-certain	11/25/2020	Yes	No	N/A	No
12	Q1	[4]Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc	11/25/2020	No	No	N/A	No
13	Q1	[4]Enforcement Policy for the Quality Standards of the Mammography Quality Standards Act During the COVID-19 Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-quality-standards-mammography-quality-standards-act-during-covid-19-public-health	12/4/2020	No	No	N/A	No
14	Q1	[4]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency	12/4/2020	Yes	No	N/A	No
15	Q1	Requesting FDA Feedback on Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products	12/4/2020	Yes	Yes	Section 3038 of the 21st Century Cures Act	No
16	Q1	Spinal Plating Systems - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/spinal-plating-systems-performance-criteria-safety-and-performance-based-pathway	12/11/2020	Yes	No	N/A	A-List

#	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
17	Q1	Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance	12/11/2020	Yes	No	N/A	A-List
18	Q1	Magnetic Resonance (MR) Receive-only Coil - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/magnetic-resonance-mr-receive-only-coil-performance-criteria-safety-and-performance-based-pathway	12/11/2020	Yes	No	N/A	A-List
19	Q1	[5]Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices	12/22/2020	Yes	No	N/A	No
20	Q1	Product Labeling for Laparoscopic Power Morcellators www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators	12/30/2020	Yes	No	N/A	A-List

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 2021

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter
1	Q1	Reauthorization of the Medical Device User Fee Amendments for fiscal years 2023 through 2027 (MDUFA V) www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-meeting-medical-device-user-fee-amendments-fiscal-years-2023-through-2027-10272020	10/27/2020	Yes