FY 2019

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. 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).[2]

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2019

#	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	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM623529	10/18/2018	Yes	No	N/A	A-List
2	Q1	Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking - Immediately in Effect Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592340	11/05/2018	No	No	N/A	A-List
3	Q1	Recommendations for Dual 510(k) and CLIA Waiver by Application Studies - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586502	11/29/2018	No[3]	No	N/A	A-List

[1] www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf; see section VI (Performance Reports)
[2] www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm580172.htm
[3] CDRH policy is to say 'no' unless the guidance document is 100% (or almost 100%) related to the process for the review of device applications. The CLIA aspects of this guidance are not related, whereas the 510(k) aspects are.

#	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	Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586506	11/29/2018	No	Yes	Sec. 3057 of the 21st Century Cures Act	A-List
5	Q1	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626742	11/30/2018	Yes	No	N/A	A-List
6	Q1	Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626743	11/30/2018	Yes	No	N/A	A-List
7	Q1	User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345633	12/12/2018	Yes	No	N/A	A-List
8	Q1	Manufacturing Site Change Supplements: Content and Submission - Final Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM467414	12/17/2018	Yes	No	N/A	A-List
9	Q1	Breakthrough Devices Program - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664	12/18/2018	Yes	Yes	Sec. 3051 of the 21st Century Cures Act (Sec. 515B(f) of the FD&C Act)	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 2019

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter
1	Q1	Remanufacturing and Servicing Devices Public Workshop	12/10/2018 to 12/11/2018	No