FY 2018

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

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 Food and Drug Administration Reauthorization Act (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 2018

#	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	User Fees and Refunds for De Novo Classification Requests - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM576306	10/02/2017	Yes	No	N/A	A-List
2	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	10/02/2017	Yes	No	N/A	A-List
3	Q1	FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089734	10/02/2017	Yes	No	N/A	A-List
4	Q1	FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM576305	10/02/2017	Yes	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

5	Q1	User Fees for 513(g) Requests for Information - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209858	10/02/2017	Yes	No	N/A	A-List
6	Q1	User Fees and Refunds for Premarket Notification Submissions (510(k)s) - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345931	10/02/2017	Yes	No	N/A	A-List
7	Q1	FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738	10/02/2017	Yes	No	N/A	A-List
8	Q1	Administrative Procedures for CLIA Categorization - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070889	10/02/2017	No	No	N/A	A-List
9	Q1	Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176	10/02/2017	Yes	No	N/A	A-List
10	Q1	Display Devices for Diagnostic Radiology - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM484914	10/02/2017	No	No	N/A	N/A
11	Q1	Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57) - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM578044	10/02/2017	No	No	N/A	N/A
12	Q1	Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM578118	10/02/2017	Yes	No	N/A	N/A

13	Q1	Breakthrough Devices Program - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664	10/25/2017	Yes	Statute	Sec. 515B(f) of the FD&C Act	N/A
14	Q1	Deciding When to Submit a 510(k) for a Software Change to an Existing Device - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514737	10/25/2017	Yes	Commitment Letter	Section I.2	N/A
15	Q1	Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514771	10/25/2017	Yes	Statute	Sec. 3059(b) of the 21st Century Cures Act	N/A
16	Q1	Acceptance Review for De Novo Classification Requests - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM582251	10/30/2017	Yes	Commitment Letter	Section E	N/A
17	Q1	Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM505756	10/30/2017	No	No	N/A	N/A
18	Q1	De Novo Classification Process (Evaluation of Automatic Class III Designation) - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080197	10/30/2017	Yes	No	N/A	N/A
19	Q1	Product Labeling for Certain Ultrasonic Surgical Aspirator Devices - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM528182	10/30/2017	Yes	No	N/A	N/A
20	Q1	Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585417.pdf	11/17/2017	Yes	Statute	Section 3034 of 21st Century Cures Act	N/A

21	Q1	Unique Device Identification: Direct Marking of Devices - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM452262	11/17/2017	No	No	N/A	N/A
22	Q1	Pediatric Information for X-ray Imaging Device Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM302938	11/28/2017	Yes	No	N/A	N/A
23	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	11/29/2017	No	No	N/A	N/A
24	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	11/29/2017	No	Statute	Sec. 3057 of the 21st Century Cures Act	N/A
25	Q1	Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM499809	12/05/2017	Yes	No	N/A	N/A
26	Q1	FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions - Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM504091	12/05/2017	Yes	No	N/A	N/A
27	Q1	Software as a Medical Device (SAMD): Clinical Evaluation - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904	12/08/2017	Yes	No	N/A	N/A

28	Q1	Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820	12/08/2017	Yes	No	N/A	N/A
29	Q1	Clinical and Patient Decision Support Software - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587819	12/08/2017	Yes	No	N/A	N/A
30	Q1	The Least Burdensome Provisions: Concept and Principles - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914	12/15/2017	Yes	No	N/A	A-List
31	Q1	Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071465	12/18/2017	Yes	No	N/A	B-List
32	Q1	Investigational IVDs Used in Clinical Investigations of Therapeutic Products - Draft Guidance for Industry, Food and Drug Administration Staff, Sponsors, and Institutional Review Boards www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM589083	12/18/2017	Yes	No	N/A	N/A
33	Q1	Medical Device Accessories - Describing Accessories and Classification Pathways - Guidance for Industry and FDA Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672	12/20/2017	Yes	No	N/A	A-List
34	Q2	Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices - Immediately in Effect Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592340	1/16/2018	No	No	N/A	A-List
35	Q2	Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56) - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592775	1/19/2018	No	No	N/A	N/A

36	Q2	Refuse to Accept Policy for 510(k)s - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014	1/30/2018	Yes	No	N/A	N/A
37	Q2	Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313368	1/30/2018	Yes	No	N/A	N/A
38	Q2	Acceptance of Clinical Data to Support Medical Device Applications and Submissions: Frequently Asked Questions - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM597273	2/21/2018	Yes	No	N/A	N/A
39	Q3	Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence through Performance Criteria - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM604195	4/12/2018	Yes	No	N/A	A-List
40	Q3	Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics - Guidance for Stakeholders and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM509837	4/13/2018	Yes	No	N/A	A-List
41	Q3	Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS) - Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases - Guidance for Stakeholders and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM509838	4/13/2018	Yes	No	N/A	A-List
42	Q3	Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM573663	4/16/2018	Yes	No	N/A	N/A
43	Q3	Multiple Function Device Products: Policy and Considerations - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM605683	4/27/2018	Yes	No	N/A	A-List

44	Q3	Recommended Content and Format of Complete Test Reports for Non-Clinical Bench Performance Testing in Premarket Submissions - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM606051	5/31/2018	Yes	No	N/A	N/A
45	Q3	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM609753	6/7/2018	Yes	Yes	Commitment Letter Sec. II.A	A-List
46	Q3	Humanitarian Device Exemption (HDE) Program - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM389275	6/13/2018	Yes	Yes	Sec. 3052(b) of The 21st Century Cures Act	A-List
47	Q3	Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM610631	6/15/2018	Yes	No	N/A	N/A
48	Q3	Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM610630	6/15/2018	Yes	No	N/A	N/A
49	Q3	Logical Observation Identifiers Names and Codes for In Vitro Diagnostic Tests - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM610636	6/15/2018	No	No	N/A	N/A

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 2018

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter
1	Q1	Ophthalmic Digital Health Workshop	10/23/2017	No
2	Q1	Cardiac Troponin Assays Workshop	11/28/2017	No
3	Q2	Self-Collection Devices for Pap Test Workshop	1/11/2018	No
4	Q2	NGS Workshop - Weighing the Evidence: Variant Classification & Interpretation in Precision Oncology	1/29/2018	No
5	Q2	Fostering Digital Health Innovation: Developing the Software Precertification Program	1/30/2018 to 1/31/2018	Commitment Letter
6	Q3	Study Design Considerations for Devices including Digital Health Technologies for Sleep Disordered Breathing (SDB) Workshop	4/16/2018	No
7	Q3	Orthopedic SMART Devices Workshop	4/30/2018	No
8	Q3	Accreditation Scheme for Conformity Assessment (ASCA) of Medical Devices to FDA-Recognized Standards	5/22/2018 to 5/23/2018	Commitment Letter