FY 2020

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 2020

#	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	Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/intravascular-catheters-wires-and-delivery-systems-lubricious-coatings-labeling-considerations	10/10/2019	Yes	N/A	N/A	N/A
2	Q1	Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling www.fda.gov/regulatory-information/search-fda-guidance-documents/coronary-peripheral-and-neurovascular-guidewires-performance-tests-and-recommended-labeling	10/10/2019	Yes	N/A	N/A	N/A
3	Q1	Breast Implants - Certain Labeling Recommendations to Improve Patient Communication www.fda.gov/regulatory-information/search-fda-guidance-documents/breast-implants-certain-labeling-recommendations-improve-patient-communication	10/24/2019	Yes	N/A	N/A	A-List
4	Q1	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	11/14/2019	No	Yes	Sec. 704 of the FDA Reauthorization Act of 2017	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

#	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	Certificates of Confidentiality www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality	11/25/2019	No	N/A	N/A	N/A
6	Q1	Magnetic Resonance (MR) Coil - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/magnetic-resonance-mr-coil-performance-criteria-safety-and-performance-based-pathway	12/9/2019	Yes	N/A	N/A	A-List
7	Q1	[3]Real-Time Premarket Approval Application (PMA) Supplements www.fda.gov/regulatory-information/search-fda-guidance-documents/real-time-premarket-approval-application-pma-supplements	12/16/2019	Yes	N/A	N/A	N/A
8	Q1	[3]FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic	12/16/2019	Yes	N/A	N/A	N/A
9	Q1	[3]eCopy Program for Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions	12/16/2019	Yes	N/A	N/A	N/A
10	Q1	[3]Annual Reports for Approved Premarket Approval Applications (PMA) www.fda.gov/regulatory-information/search-fda-guidance-documents/annual-reports-approved-premarket-approval-applications-pma	12/16/2019	Yes	N/A	N/A	N/A
11	Q1	[3]Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-and-filing-reviews-premarket-approval-applications-pmas	12/16/2019	Yes	N/A	N/A	N/A
12	Q1	[3]30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes www.fda.gov/regulatory-information/search-fda-guidance-documents/30-day-notices-135-day-premarket-approval-pma-supplements-and-75-day-humanitarian-device-exemption	12/16/2019	Yes	N/A	N/A	N/A

[3] 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
13	Q1	Bridging for Drug-Device and Biologic-Device Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/bridging-drug-device-and-biologic-device-combination-products	12/19/2019	No	N/A	N/A	N/A
14	Q1	[3]Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket	12/20/2019	Yes	N/A	N/A	N/A
15	Q1	Requesting FDA Feedback on Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products	12/26/2019	Yes	Yes	Sec. 3038 of the 21st Century Cures Act	N/A
16	Q2	Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/peripheral-percutaneous-transluminal-angioplasty-pta-and-specialty-catheters-premarket-notification	1/13/2020	Yes	N/A	N/A	N/A
17	Q2	[3]Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-performance-assessment-considerations-computer-assisted-detection-devices-applied-radiology	1/22/2020	Yes	N/A	N/A	N/A
18	Q2	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	1/28/2020	Yes	N/A	N/A	N/A
19	Q2	Peripheral Vascular Atherectomy Devices - Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/peripheral-vascular-atherectomy-devices-premarket-notification-510k-submissions	2/13/2020	Yes	N/A	N/A	N/A

#	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
20	Q2	Recommendations for Dual 510(k) and CLIA Waiver by Application Studies www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-dual-510k-and-clia-waiver-application-studies	2/26/2020	Yes	N/A	N/A	A-List
21	Q2	Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-clinical-laboratory-improvement-amendments-1988-clia-waiver-applications	2/26/2020	Yes	Yes	Sec. 3057 of the 21st Century Cures Act	A-List
22	Q2	Product Labeling for Laparoscopic Power Morcellators www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators	2/26/2020	Yes	N/A	N/A	N/A
23	Q2	[4]Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency	2/29/2020	Yes	N/A	N/A	N/A
24	Q2	Bone Anchors - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/bone-anchors-premarket-notification-510k-submissions	3/3/2020	Yes	N/A	N/A	N/A
25	Q2	Soft (Hydrophilic) Daily Wear Contact Lenses - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/soft-hydrophilic-daily-wear-contact-lenses-performance-criteria-safety-and-performance-based-pathway	3/4/2020	Yes	N/A	N/A	A-List
26	Q2	[3]Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-510k-submissions-electrosurgical-devices-general-surgery	3/9/2020	Yes	N/A	N/A	N/A

[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
27	Q2	510(k) Third Party Review Program www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program	3/12/2020	Yes	N/A	Sec. 523 of the FDA Reauthorization Act of 2017	A-List
28	Q2	[4]Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency	3/16/2020	Yes	N/A	N/A	N/A
29	Q2	Restricted Delivery Systems: Flow Restrictors for Oral Liquid Drug Products Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/restricted-delivery-systems-flow-restrictors-oral-liquid-drug-products-guidance-industry	3/17/2020	No	N/A	N/A	N/A
30	Q2	[4]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic	3/18/2020	Yes	N/A	N/A	N/A
31	Q2	[4]Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic	3/19/2020	No	N/A	N/A	N/A
32	Q2	[4]Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during	3/20/2020	Yes	N/A	N/A	N/A

#	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
33	Q2	[4]Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-ventilators-and-accessories-and-other-respiratory-devices-during-coronavirus	3/22/2020	Yes	N/A	N/A	N/A
34	Q2	[4]Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health	3/25/2020	Yes	N/A	N/A	N/A
35	Q2	[4]FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic	3/27/2020	Yes	N/A	N/A	N/A
36	Q2	[3]Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a	3/27/2020	No	N/A	N/A	N/A
37	Q2	[4]Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease	3/29/2020	Yes	N/A	N/A	N/A
38	Q2	[4]Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health	3/30/2020	Yes	N/A	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 2020

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter
1	Q2	Artificial Intelligence for Radiological Imaging Public Workshop	2/25-26/2020	No
2	Q2	Medical Extended-Reality Public Workshop - Towards Best Evaluation Practices in Virtual and Augmented Reality in Medicine	3/5/2020	No
3	Q2	DNA for Cancer Screening	3/9/2020	No