



FDA U.S. FOOD & DRUG
ADMINISTRATION

FY 2024

Real Time Report

pursuant to the

Federal Food, Drug, and Cosmetic Act

*as amended by the Medical Device User Fee Amendments of
2022*

Acronyms

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

FDA – Food and Drug Administration

FUFRA 2022 – FDA User Fee Reauthorization Act of 2022

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 September 30, 2022, the FDA User Fee Reauthorization Act of 2022 (FUFRA) (Public Law 117-180) was signed into law. FUFRA 2022 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 2004 of FUFRA 2022, 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 2023, 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 guidance’s were issued as required by statute or pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022; 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 2022.”

Medical Devices

Guidance Documents

Pursuant to the MDUFA V 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 V 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 2024

#	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 Electronic Submission Template for Medical Device 510(k) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions	10/02/2023	Yes	No	N/A	No
2	Q1	⁴ Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-and-labeling-medical-devices-safety-magnetic-resonance-mr-environment	10/10/2023	Yes	No	N/A	No
3	Q1	⁴ Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices	10/10/2023	Yes	No	N/A	No

¹ www.fda.gov/media/158308/download.

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-2023-fy2023.

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
4	Q1	⁵ Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring	10/19/2023	Yes	No	N/A	No
5	Q1	Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses	10/24/2023	No	No	N/A	No
6	Q1	⁵ Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-certain-supplements-approved-premarket-approval-pma-or-humanitarian-device	11/02/2023	Yes	No	N/A	No
7	Q1	⁴ 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	11/3/2023	No	No	N/A	No
8	Q1	⁵ Enforcement Policy for Clinical Electronic Thermometers www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers	11/3/2023	Yes	No	N/A	No
9	Q1	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	11/17/2023	No	Yes	Section 2514 of the Prepare for and Respond to Existing Viruses, Emerging New 209 Threats, and Pandemics Act	A-List

⁵ This is a Level 1 guidance document that is immediately in effect 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
10	Q1	Select Updates for the 506J Guidance: 506J Device List and Additional Notifications www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-506j-guidance-506j-device-list-and-additional-notifications	11/17/2023	No	Yes	Section 2514 of the Prepare for and Respond to Existing Viruses, Emerging New 209 Threats, and Pandemics Act	A-List
11	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	11/17/2023	Yes	No	N/A	No
12	Q1	⁴ Data Standard Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	12/13/2023	Yes	No	N/A	No
13	Q1	Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-use-real-world-evidence-support-regulatory-decision-making-medical-devices	12/19/2023	Yes	Yes	Section 3629 of the Food and Drug Omnibus Reform Act (FDORA) & MDUFA V Commitment Letter V.F.	A-List
14	Q1	510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review	12/21/2023	Yes	Yes	Section 2502 of the Prepare for and Respond to Existing Viruses, Emerging New 209 Threats, and Pandemics Act	A-List
15	Q1	Digital Health Technologies for Remote Data Acquisition in Clinical Investigations www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations	12/22/2023	Yes	Yes	Section 3607(a) of the Food and Drug Omnibus Reform Act (FDORA)	No
16	Q2	⁴ Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled	01/08/2024	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
17	Q2	Characterization of Metallic Coatings and/or Calcium Phosphate Coatings on Orthopedic Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/characterization-metallic-coatings-andor-calcium-phosphate-coatings-orthopedic-devices	01/23/2024	Yes	No	N/A	No
18	Q2	Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials-and-clinical-studies-fda-regulated-medical	01/30/2024	Yes	No	N/A	No
19	Q2	Use of Data Monitoring Committees in Clinical Trials www.fda.gov/regulatory-information/search-fda-guidance-documents/use-data-monitoring-committees-clinical-trials	02/13/2024	Yes	No	N/A	No
20	Q2	Select Updates for the Medical Device User Fee Small Business Qualification and Certification Guidance www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-medical-device-user-fee-small-business-qualification-and-certification-guidance	02/22/2024	Yes	No	N/A	A-List
21	Q2	Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards www.fda.gov/regulatory-information/search-fda-guidance-documents/key-information-and-facilitating-understanding-informed-consent-guidance-sponsors-investigators-and	03/01/2024	No	No	N/A	No
22	Q2	Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-premarket-cybersecurity-guidance-section-524b-fdc-act	03/13/2024	Yes	No	N/A	A-List
23	Q2	Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-thermal-effects-medical-devices-produce-tissue-heating-andor-cooling	03/15/2024	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
24	Q2	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/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program-draft-guidance	03/15/2024	Yes	Yes	MDUFA V Commitment Letter II.A.	A-List
25	Q2	Animal Studies for Dental Bone Grafting Material Devices - Premarket Notification (510(k)) Submissions: Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/animal-studies-dental-bone-grafting-material-devices-premarket-notification-510k-submissions	03/29/2024	Yes	No	N/A	No
26	Q3	⁴ Data Standards Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	04/16/2024	Yes	No	N/A	No
27	Q3	Enforcement Policy for Certain In Vitro Diagnostic Devices for Immediate Public Health Response in the Absence of a Declaration under Section 564: Draft Guidance for Laboratory Manufacturers and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-certain-in-vitro-diagnostic-devices-immediate-public-health-response-absence	05/06/2024	No	No	N/A	A-List
28	Q3	Consideration of Enforcement Policies for Tests During a Section 564 Declared Emergency: Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-enforcement-policies-tests-during-section-564-declared-emergency	05/06/2024	No	No	N/A	A-List
29	Q3	Remanufacturing of Medical Devices: Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/remanufacturing-medical-devices	05/10/2024	Yes	No	N/A	A-List

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30	Q3	Processes and Practices Applicable to Bioresearch Monitoring Inspections: Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicable-bioresearch-monitoring-inspections	06/05/2024	Yes	No	N/A	No
31	Q3	Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection: Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/circumstances-constitute-delaying-denying-limiting-or-refusing-drug-or-device-inspection	06/20/2024	No	No	N/A	No
32	Q3	⁴ Laboratory Developed Tests: Small Entity Compliance Guide: Guidance for Laboratory Manufacturers and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/laboratory-developed-tests-small-entity-compliance-guide	06/25/2024	No	No	N/A	No
33	Q3	Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies: Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies	06/26/2024	Yes	Yes	Section 3602 of the Food and Drug Omnibus Reform Act (FDORA)	No
34	Q3	Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products: Draft Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/essential-drug-delivery-outputs-devices-intended-deliver-drugs-and-biological-products	06/28/2024	Yes	No	N/A	No
35	Q4	Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/purpose-and-content-use-related-risk-analyses-drugs-biological-products-and-combination-products	07/09/2024	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
36	Q4	Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/addressing-misinformation-about-medical-devices-and-prescription-drugs-questions-and-answers	07/09/2024	No	No	N/A	No
37	Q4	Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-considerations-studies-devices-intended-treat-opioid-use-disorder	07/11/2024	Yes	No	N/A	No
38	Q4	Dental Curing Lights - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-curing-lights-premarket-notification-510k-submissions	07/12/2024	Yes	No	N/A	No
39	Q4	Dental Composite Resin Devices - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-composite-resin-devices-premarket-notification-510k-submissions	07/12/2024	Yes	No	N/A	No
40	Q4	⁴ Acceptable Media for Electronic Product User Manuals www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptable-media-electronic-product-user-manuals	08/19/2024	No	No	N/A	No
41	Q4	Predetermined Change Control Plans for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/predetermined-change-control-plans-medical-devices	08/22/2024	Yes	Yes	Section 3308 of the Food and Drug Omnibus Reform Act (FDORA)	A-List
42	Q4	⁴ 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	08/23/2024	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
43	Q4	Electronic Submission Template for Medical Device De Novo Requests: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-de-novo-requests	08/23/2024	Yes	No	N/A	No
44	Q4	⁴ Mammography Quality Standards Act and Regulation Amendments: Small Entity Compliance Guide www.fda.gov/regulatory-information/search-fda-guidance-documents/mammography-quality-standards-act-and-regulation-amendments-small-entity-compliance-guide	08/26/2024	No	No	N/A	No
45	Q4	Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-malfunction-summary-reporting-vmsr-program-manufacturers	08/29/2024	Yes	No	N/A	B-List
46	Q4	Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle www.fda.gov/regulatory-information/search-fda-guidance-documents/incorporating-voluntary-patient-preference-information-over-total-product-life-cycle	09/06/2024	Yes	Yes	MDUFA V Commitment Letter V.E.	A-List
47	Q4	⁴ Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Referring Provider Notification Orders www.fda.gov/regulatory-information/search-fda-guidance-documents/appeal-options-available-mammography-facilities-concerning-adverse-accreditation-decisions	09/10/2024	No	No	N/A	No
48	Q4	⁴ Data Standards Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	09/16/2024	Yes	No	N/A	No
49	Q4	Conducting Clinical Trials With Decentralized Elements www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements	09/18/2024	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
50	Q4	Chemical Analysis for Biocompatibility Assessment of Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/chemical-analysis-biocompatibility-assessment-medical-devices	09/20/2024	Yes	No	N/A	A-List
51	Q4	The Accreditation Scheme for Conformity Assessment (ASCA) Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-program	09/23/2024	Yes	No	N/A	A-List
52	Q4	Biocompatibility Testing of Medical Devices - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program : Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme-0	09/23/2024	Yes	No	N/A	A-List
53	Q4	Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and-0	09/23/2024	Yes	No	N/A	A-List
54	Q4	Clarification of Radiation Control Regulations For Manufacturers of Diagnostic X-Ray Equipment: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/clarification-radiation-control-regulations-manufacturers-diagnostic-x-ray-equipment	09/30/2024	No	No	N/A	No

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55	Q4	Dental Impression Materials - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-impression-materials-performance-criteria-safety-and-performance-based-pathway	09/30/2024	Yes	No	N/A	No
56	Q4	Dental Ceramics - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-ceramics-performance-criteria-safety-and-performance-based-pathway	09/30/2024	Yes	No	N/A	No
57	Q4	Dental Cements - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-cements-performance-criteria-safety-and-performance-based-pathway	09/30/2024	Yes	No	N/A	No
58	Q4	Air Powered Dental Handpieces and Air Motors - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff www.fda.gov/regulatory-information/search-fda-guidance-documents/air-powered-dental-handpieces-and-air-motors-performance-criteria-safety-and-performance-based	09/30/2024	Yes	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 2024

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter