

FY 2026

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

FDAUFRA 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 (FDAUFRA)) (Public Law 117-180) was signed into law. FDAUFRA 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 FDAUFRA 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 FY 2026 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] Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for FY 2026.

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2026

#	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	Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-selecting-developing-or-modifying-fit-purpose-clinical-outcome	10/22/2025	Yes	Yes	Section 3002 of the 21st Century Cures Act	No
2	Q1	Quality Management System Information for Certain Premarket Submission Reviews www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-management-system-information-certain-premarket-submission-reviews	10/27/2025	Yes	No	N/A	A-List
3	Q1	Menstrual Products - Performance Testing and Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/menstrual-products-performance-testing-and-labeling-recommendations	10/28/2025	Yes	No	No	A-List
4	Q1	Cross-Center Master Files: Where to Submit www.fda.gov/regulatory-information/search-fda-guidance-documents/cross-center-master-files-where-submit	11/25/2025	Yes	No	N/A	No

[1] www.fda.gov/media/158308/download.
[2] CDRH provides the annotation of "yes" for guidance's that are substantially related to the process. CDRH provides the annotation of "no" for guidance's that contain a minimal amount of guidance related to the process.
[3] CDRH Proposed Guidance Development | FDA

#	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	[4]eCopy Program for Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions	12/03/2025	Yes	No	N/A	No
6	Q1	Study of Sex Differences in the Clinical Evaluation of Medical Products www.fda.gov/regulatory-information/search-fda-guidance-documents/study-sex-differences-clinical-evaluation-medical-products	12/15/2025	Yes	No	N/A	No
7	Q1	Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-safety-reporting-investigational-drugs-and-devices	12/15/2025	Yes	No	N/A	No
8	Q1	Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices	12/18/2025	Yes	Yes	Section 3629 of the Food and Drug Omnibus Reform Act (FDORA) & MDUFA V Commitment Letter V.F.	A-List
9	Q1	Processes and Practices Applicable to Bioresearch Monitoring Inspections www.fda.gov/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicable-bioresearch-monitoring-inspections	12/19/2025	Yes	Yes	Section 3612 of the Food and Drug Omnibus Reform Act (FDORA)	No
10	Q2	[4]General Wellness: Policy for Low Risk Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices	01/06/2026	Yes	No	N/A	No
11	Q2	Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval www.fda.gov/regulatory-information/search-fda-guidance-documents/minimal-residual-disease-and-complete-response-multiple-myeloma-use-endpoints-support-accelerated	01/21/2026	Yes	No	N/A	No
12	Q2	Cuffless Non-invasive Blood Pressure Measuring Devices – Clinical Performance Testing and Evaluation	01/23/2026	Yes	No	N/A	No

[4] This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2)

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		www.fda.gov/regulatory-information/search-fda-guidance-documents/cuffless-non-invasive-blood-pressure-measuring-devices-clinical-performance-testing-and-evaluation					
13	Q2	[4]Clinical Decision Support Software www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software	01/29/2026	Yes	No	N/A	No
14	Q2	[4]Computer Software Assurance for Production and Quality Management System Software www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software	02/03/2026	No	No	N/A	No
15	Q2	[4]Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket	02/03/2026	Yes	No	N/A	No
16	Q2	Medical Devices with Indications Associated with Weight Loss - Premarket Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-indications-associated-weight-loss-premarket-considerations	03/13/2026	Yes	No	N/A	B-List
17	Q2	[4]Pyrogen and Endotoxins Testing: Questions and Answers[4] www.fda.gov/regulatory-information/search-fda-guidance-documents/pyrogen-and-endotoxins-testing-questions-and-answers	03/18/2026	Yes	No	N/A	No
18	Q2	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-0	03/30/2026	Yes	Yes	MDUFA V Commitment Letter V.E.	A-List
19	Q3	Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-regarding-premarket-and-other-requirements-certain-niosh-approved-air-purifying	04/20/2026	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
20	Q3	Patient-Matched Guides for Orthopedic Implants www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-matched-guides-orthopedic-implants	05/07/2026	Yes	No	N/A	No
21	Q3	Content of Human Factors Information in Medical Device Marketing Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions	05/29/2026	Yes	No	N/A	B-List
22	Q3	Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-and-device-manufacturer-communications-payors-formulary-committees-and-similar-entities	06/03/2026	No	No	N/A	No
23	Q3	Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements www.fda.gov/regulatory-information/search-fda-guidance-documents/intent-exempt-certain-unclassified-medical-devices-premarket-notification-requirements	06/05/2026	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 2026

#	Quarter Held	Title	Date Held	Required by Statute or Commitment Letter
1	Q1	Digital Health Advisory Committee Meeting	11/06/2025	No
2	Q1	Circulatory System Devices Panel Advisory Committee Meeting	12/03/2025	No
3	Q1	General Hospital and Personal Use Devices	12/10/2025	Yes