# 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*

## Summary

This section provides a summary of the total numbers for each category contained in this report, for certain activities as they relate to the process for the review of devices, within the current fiscal year (FY) as of September 30, 2026.

| Category | Total |
|---|---|
| Guidance Documents | 29 |
| Public Meetings | 6 |

## 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 |

[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 |
|---|---|---|---|---|---|---|---|
| 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 |
| 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 |

[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 |
|---|---|---|---|---|---|---|---|
| 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 www.fda.gov/regulatory-information/search-fda-guidance-documents/cuffless-non-invasive-blood-pressure-measuring-devices-clinical-performance-testing-and-evaluation | 01/23/2026 | Yes | No | N/A | No |
| 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 | 03/30/2026 | Yes | Yes | MDUFA V Commitment Letter V.E. | 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 |
|---|---|---|---|---|---|---|---|
| | | www.fda.gov/regulatory-information/search-fda-guidance-documents/incorporating-voluntary-patient-preference-information-over-total-product-life-cycle-0 | | | | | |
| 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 |
| 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 |
| 24 | Q4 | [4]Hemodialysis Blood Tubing Sets - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/hemodialysis-blood-tubing-sets-premarket-notification-510k-submissions | 07/23/2026 | Yes | No | N/A | No |
| 25 | Q4 | [4]Applying Human Factors and Usability Engineering to Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices | 08/03/2026 | 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 |
|---|---|---|---|---|---|---|---|
| 26 | 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 | 09/02/2026 | Yes | No | N/A | No |
| 27 | 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 | 09/02/2026 | Yes | No | N/A | No |
| 28 | Q4 | Electronic Submission Template for Premarket Approval Applications (PMA) www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-premarket-approval-applications-pma | 09/18/2026 | Yes | Yes | 745A(b)(3) of the FD&C Act | No |
| 29 | Q4 | Robotically-Assisted Surgical Devices - Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/robotically-assisted-surgical-devices-premarket-submissions | 09/25/2026 | 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 of the Medical Devices Advisory Committee Meeting | 12/03/2025 | No |
| 3 | Q1 | General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee Meeting | 12/10/2025 | Yes |
| 4 | Q4 | Public Meeting on the Reauthorization of the Medical Device User Fee Amendments (MDUFA) | 8/05/2026 | Yes |
| 5 | Q4 | Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee Meeting | 9/23/2026 | No |
| 6 | Q4 | Regulatory Science Innovations Catalyzing Medical Device Development Meeting | 9/25/2026 | No |