

FDA WEEKLY INTELLIGENCE

FDA Intelligence

Coverage: 2026-07-30 – 2026-08-05 (drug approval date basis)

Published: August 11, 2026

Plan: Individual Plan

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FDA Weekly Report — Week 32, 2026

Coverage: 2026-07-30 – 2026-08-05 (drug approval date basis)

Published: August 11, 2026

Note: the reporting period above is based on drug (NDA/BLA) approval dates. FDA typically publishes approvals 1–2 weeks after the decision date. Device data (510(k)/PMA) is published on an even longer lag, so the Medical Devices section covers 2026-07-20 to 2026-07-26.

Note: the issue number ("Week 32, 2026") is the ISO calendar week containing the END of the coverage period above, used only for stable issue numbering — it is not a claim that the coverage period spans that full Monday–Sunday week.

This Week at FDA

This week's FDA activity was defined by the approval of a single new molecular entity, OVEPOREXTON (ORZEYFUL), alongside one efficacy supplement for an unspecified product. The medical device sector saw significant developments with one novel De Novo authorization and a PMA approval, while continued regulatory scrutiny was evident in the issuance of four significant Warning Letters. A high volume of activity involving Asian firms further highlights their increasing engagement with the US regulatory landscape, a key trend for competitive intelligence.

1

NME Approvals

1

Total Drug Approvals

1

Efficacy Supplements

79

Device Clearances

1

PMA Originals

32

Asian Co. Events

Asian Company Watch — FDA Activity This Week

Coverage: drugs 2026-07-30–2026-08-05, devices 2026-07-20–2026-07-26 (device data is published on a longer lag).

Asian companies with FDA approvals or clearances this week. The highest-priority items below include strategic commentary on what it means for the competitive landscape; the remaining approvals are listed for completeness (full detail for every item is available in the accompanying Excel data set). Country classification is based on ultimate corporate group origin, not necessarily the filing legal entity's place of incorporation (e.g. a US-registered subsidiary of a Japanese parent group is classified as Japanese).

TAKEDA PHARMS USA Japan

OVEPOREXTON (ORZEYFUL)

The US entity of Japan's Takeda received FDA approval for Orzeyful (oveporexton), a tablet for treating narcolepsy type 1 in adult patients.

Intelligence: This new drug approval for a central nervous system disorder could strengthen the Takeda Group's growing neurology franchise in the competitive US market.

UMEDICA India

SACUBITRIL (SACUBITRIL AND VALSARTAN)

UMEDICA — Generic approval (ANDA) for SACUBITRIL (SACUBITRIL AND VALSARTAN).

ZYDUS LIFESCIENCES India

INDOCYANINE GREEN (INDOCYANINE GREEN)

India-based Zydus Lifesciences secured an ANDA approval for its generic Indocyanine Green for injection.

MACLEODS PHARMS LTD India

NINTEDANIB ESYLATE (NINTEDANIB ESYLATE)

MACLEODS PHARMS LTD — Generic approval (ANDA) for NINTEDANIB ESYLATE (NINTEDANIB ESYLATE).

MANKIND PHARMA India

THIAMINE HYDROCHLORIDE

MANKIND PHARMA — Generic approval (ANDA) for THIAMINE HYDROCHLORIDE (THIAMINE HYDROCHLORIDE).

GLAND India

ATROPINE SULFATE (ATROPINE)

Gland Pharma from India received an ANDA approval for its generic Atropine Sulfate injection.

KLM LABS PVT India

DOCOSANOL (DOCOSANOL)

India's KLM Labs Pvt received an ANDA approval for its generic docosanol cream.

DR REDDYS India

FEXOFENADINE HYDROCHLORIDE

DR REDDYS — Generic approval (ANDA) for FEXOFENADINE HYDROCHLORIDE (FEXOFENADINE HYDROCHLORIDE).

Samsung Electronics Co., Ltd. South Korea

Sleep Apnea Feature (v2.0)

2nd clearance in 2026 (42 total since 2013) — established filer

Predicate: K240929 (Apple, Inc., US)

South Korea's Samsung Electronics received 510(k) clearance for a software feature designed as an over-the-counter tool to assess the risk of sleep apnea.

Intelligence: This clearance for a software-as-a-medical-device (SaMD) feature on a consumer electronics platform positions Samsung to compete in the growing US digital health and wellness monitoring space.

MacroLux Medical Technology Co., Ltd. China

BubbleView Single-Use Digital Flexible Cystoscope (6 models)

2nd clearance in 2026 (7 total since 2024) — established filer

MacroLux Medical Technology Co., Ltd. received a 510(k) clearance for BubbleView Single-Use Digital Flexible Cystoscope (C38-CS, C38-CRS, C50-C, C50-CR, C50-CB, C50-CBR). FDA classifies this device as: Ureteroscope And Accessories, Flexible/Rigid.

Taiwan Surgical Corporation Taiwan**Inno-Hook™ Disposable Clip Appliers**

 2nd clearance in 2026 (8 total since 2015) — established filer

 Predicate: K133202 (Teleflex Medical, US)

Taiwan Surgical Corporation received 510(k) clearance for its disposable ligating clip appliers and implantable clips used in surgery.

Intelligence: This clearance for a fundamental surgical tool may support the Taiwanese company's efforts to supply US hospitals and surgical centers with cost-effective disposable instruments.

Rhein Laser Technologies Co., Ltd. China**Medical Thulium Fiber Laser Systems**

 1st clearance in 2026 (4 total since 2024) — established filer

 Predicate: K133891 (Asclepion Laser Technologies GmbH, DE)

China's Rhein Laser Technologies secured 510(k) clearance for its UroFiber 150Q, a medical thulium fiber laser system for surgical applications.

Intelligence: With this clearance for a high-power surgical laser, Rhein Laser Technologies could become a new capital equipment supplier for US hospitals, particularly in urology and other surgical specialties.

Xuzhou Kernel Medical Equipment Co., Ltd. China**Uv Phototherapy (3 models)**

 1st clearance in 2026 (9 total since 2014) — established filer

 Predicate: K230382 (Daavlin Distributing Co., US)

Xuzhou Kernel Medical Equipment Co., Ltd. from China received 510(k) clearance for its UV phototherapy device.

Intelligence: This clearance provides a US market pathway for the Chinese manufacturer's phototherapy equipment, potentially targeting dermatological applications.

Beijing Honghugaoxiang Science and Technology Development CO China**Raney Clips Kit**

 First FDA clearance — new US market entrant

 Predicate: K012219 (Aesculap, Inc., US)

The Chinese company Beijing Honghugaoxiang Science and Technology Development received 510(k) clearance for its Raney Clips Kit, a type of scalp clip used in neurosurgery.

Intelligence: This clearance for a specialized neurosurgical disposable product could allow the company to supply a niche segment within the US surgical device market.

Mediclus Co., Ltd. South Korea

One-Fil LC

 5th clearance in 2026 (14 total since 2023) — established filer

 Predicate: K230270 (3M Espe Dental Products, US)

Mediclus Co., Ltd. received a 510(k) clearance for One-Fil LC. FDA classifies this device as: Liner, Cavity, Calcium Hydroxide.

Hamamatsu Photonics K.K. Japan

NanoZoomer S540MD Slide Scanner System

 2nd clearance in 2026 (10 total since 1989) — established filer

 Predicate: K203364 (Barco N.V., BE)

Hamamatsu Photonics K.K. received a 510(k) clearance for NanoZoomer S540MD Slide Scanner System. FDA classifies this device as: Whole Slide Imaging System.

Tianjin Huahong Technology Co., Ltd. China

Lancet

 3rd clearance in 2026 (13 total since 2021) — established filer

 Predicate: K243306 (Tianjin Huahong Technology Co., Ltd., CN)

This is a multiple-use blood lancet for single patient use.

Esonic Technology (Wuhan) Co., Ltd. China

ePascal S/ ePascal SOR/ ePascal S5/...

 1st clearance in 2026 (2 total since 2025) — established filer

 Predicate: K191007 (Supersonic Imagine, FR)

Esonic Technology (Wuhan) Co., Ltd. received a 510(k) clearance for ePascal S/ ePascal SOR/ ePascal S5/ ePascal SA/ ePascal SE/ ePascal 80Elite/ ePascal 80/ MOZI-X1/ MOZI-X12/ DF-41E Diagnostic ultrasound system. FDA classifies this device as: System, Imaging, Pulsed Doppler, Ultrasonic.

Resvent Medical Technology Co., Ltd. China

RXiBreeze PAP System (RXiBreeze 20C)

 First FDA clearance — new US market entrant

 Predicate: K153387 (3B Medical, Inc., US)

Resvent Medical Technology Co., Ltd. received a 510(k) clearance for RXiBreeze PAP System (RXiBreeze 20C). FDA classifies this device as: Ventilator, Non-Continuous (Respirator).

Shenzhen Kaiyan Medical Equipment Co., Ltd. China

FACEGYM Pro Device (HD-109)

 7th clearance in 2026 (24 total since 2023) — established filer

 Predicate: K221443 (Xtreem Pulse, LLC, US)

This transcutaneous electrical stimulator is intended for aesthetic purposes.

Guangzhou Daxin Health Technology Co., Ltd. China

Blood Pressure Monitor (6 models)

 1st clearance in 2026 (2 total since 2025) — established filer

 Predicate: K222125 (Shenzhen AOJ Medical Technology Co., Ltd., CN)

Guangzhou Daxin Health Technology Co., Ltd. received a 510(k) clearance for Blood Pressure Monitor (M501, M501A, M502, M502A, M502C, M502D). FDA classifies this device as: System, Measurement, Blood-Pressure, Non-Invasive.

Fims Co., Ltd. South Korea

3d Cage Cervical

 1st clearance in 2026 (2 total since 2019) — established filer

Fims Co., Ltd. received a 510(k) clearance for 3d Cage Cervical. FDA classifies this device as: Intervertebral Fusion Device With Bone Graft, Cervical.

Microlife Corporation Taiwan

Microlife Wrist Blood Pressure Monitor,

 2nd clearance in 2026 (3 total since 2025) — established filer

 Predicate: K211288 (Microlife Intellectual Property GmbH, CH)

Microlife Corporation received a 510(k) clearance for Microlife Wrist Blood Pressure Monitor, (Model BPHJG5-G). FDA classifies this device as: System, Measurement, Blood-Pressure, Non-Invasive.

Beijing Konted Medical Technology Co., Ltd. China

Pocket Ultrasound System (5 models)

 1st clearance in 2026 (3 total since 2023) — established filer

 Predicate: K241979 (Beijing Konted Medical Technology Co.,Ltd, CN)

Beijing Konted Medical Technology Co., Ltd. received a 510(k) clearance for Pocket Ultrasound System (C10MTpro, C10MXpro, C10MSpro, C10MBpro, C10MRpro). FDA classifies this device as: System, Imaging, Pulsed Doppler, Ultrasonic.

Hefei Meyer Optoelectronic Technology, Inc. China

Dental Cone-beam Computed Tomography

 First FDA clearance — new US market entrant

 Predicate: K230985 (Planmeca Oy, FI)

Hefei Meyer Optoelectronic Technology, Inc. received a 510(k) clearance for Dental Cone-beam Computed Tomography (mDX-15P Series). FDA classifies this device as: X-Ray, Tomography, Computed, Dental.

MANTIZ Co., Ltd. South Korea

QUATTRO Spinal system

 First FDA clearance — new US market entrant

MANTIZ Co., Ltd. received a 510(k) clearance for QUATTRO Spinal system (Open Configuration); QUATTRO-GADGET Spinal system (MIS Configuration). FDA classifies this device as: Thoracolumbosacral Pedicle Screw System.

Airs Medical, Inc. South Korea

SwiftMR

 2nd clearance in 2026 (6 total since 2021) — established filer

 Predicate: K253775 (Airs Medical, Inc., KR)

Airs Medical, Inc. received a 510(k) clearance for SwiftMR. FDA classifies this device as: Automated Radiological Image Processing Software.

VISION MEDICAL Co., Ltd. South Korea

VS-370CF, VS-370CT

 First FDA clearance — new US market entrant

 Predicate: K230474 (Palliare, Ltd., IE)

VISION MEDICAL Co., Ltd. received a 510(k) clearance for VS-370CF, VS-370CT. FDA classifies this device as: Insufflator, Automatic Carbon-Dioxide For Endoscope.

Medical Impact South Korea

EZ-Close™ (3 models)

 First FDA clearance — new US market entrant

 Predicate: K132362 (Teleflexmedical, Inc., US)

Medical Impact received a 510(k) clearance for EZ-Close™ (EZ Close Port Site Closing Device, EZ Close MAX Port Site Closing Device, EZ Close II Port Site Closing Device). FDA classifies this device as: Laparoscope, General & Plastic Surgery.

Shenzhen TPH Technology Co., Ltd. China

DiscreetDuo™ Flow Wearable Breast Pump

 7th clearance in 2026 (23 total since 2022) — established filer

 Predicate: K240536 (Shenzhen TPH Technology Co., Ltd., CN)

Shenzhen TPH Technology Co., Ltd. received a 510(k) clearance for DiscreetDuo™ Flow Wearable Breast Pump (Model S3). FDA classifies this device as: Pump, Breast, Powered.

Olympus Surgical Technologies America Japan

SOLTIVE™ Laser System (4 models)

 1st clearance in 2026 (13 total since 2012) — established filer

 Predicate: K242191 (Olympus Surgical Technologies America, US)

Olympus Surgical Technologies America received a 510(k) clearance for SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories). FDA classifies this device as: Powered Laser Surgical Instrument.

Wavepulse (Xiamen) Healthcare Technology Co., Ltd. China

Air Compression Massager (EP30B001 I)

 First FDA clearance — new US market entrant

 Predicate: K230500 (Jiangsu Maxf Electric Appliance Co., Ltd., CN)

Wavepulse (Xiamen) Healthcare Technology Co., Ltd. received a 510(k) clearance for Air Compression Massager (EP30B001 I). FDA classifies this device as: Massager, Powered Inflatable Tube.

Drug Approvals

1 new drug approval this week (1 NME). 1 efficacy supplement. 9 generics (ANDA).

New Drug Approvals (NDA / BLA)

OVEPOREXTON

ORZEYFUL

NME

Priority Review

TAKEDA PHARMS USA

WHAT IT IS

Novel molecular entity; oral tablets; FDA Priority Review.

APPROVED INDICATION

New indication for the treatment of narcolepsy type 1 (narcolepsy with cataplexy) in adult patients.

[\[approval letter\]](#)

MARKETING STATUS

Per the approval letter, DEA controlled-substance scheduling was not yet complete as of this letter; the legal date of approval is deferred to the date DEA publishes its Federal Register scheduling notice, and the product may not be marketed before then (see the approval letter in the Letter Collection for the full text).

Efficacy Supplements

LUTETIUM LU 177 VIPIVOTIDE TETRAXETAN

PLUVICTO

Efficacy Supplement (Classification Unavailable)

NOVARTIS

WHAT IT IS

Mechanism and formulation not specified in available source text.

APPROVED INDICATION

(The original FDA approval letter text was obtained, but it did not contain a sentence clearly stating this week's indication, so a confirmed description is not provided. Please see the accompanying Letter Collection or the official FDA document for the full text.) [\[approval letter\]](#)

Medical Devices

Coverage period for this section: **2026-07-20 to 2026-07-26** — FDA publishes device decisions later than drug approvals, so this differs from the report period (2026-07-30 to 2026-08-05) and is anchored to the latest available device data.

510(k) clearances: **78** (plus 1 separate De Novo authorization). PMA (premarket approval) totals **55**, broken down below — Original/Panel-Track represent new or significant changes.

PMA Original: **1** | Panel-Track: **1** | 30-Day Notice: **34** | Other: **19**

PMA Approvals

SimpleScreen™ CRC

Freemome, LLC

FDA classifies this device as: System, colorectal neoplasia, DNA methylation and hemoglobin detection.

HiResolution™ Bionic Ear System

Advanced Bionics

FDA classifies this device as: Implant, cochlear.

510(k) / De Novo Clearances (most recent 10)

Device	Applicant	Date
Sleep Apnea Feature (v2.0) An over-the-counter device to assess the risk of sleep apnea.	Samsung Electronics Co., Ltd.	2026-07-20
BubbleView Single-Use Digital Flexible Cystoscope (6 models) FDA classifies this device as: Ureteroscope And Accessories, Flexible/Rigid.	MacroLux Medical Technology Co., Ltd.	2026-07-20
Inno-Hook™ Disposable Clip Appliers FDA classifies this device as: Clip, Implantable.	Taiwan Surgical Corporation	2026-07-20
OTTAVA™ Robotic Surgical System De Novo FDA classifies this device as: System, Surgical, Computer Controlled Instrument.	Auris Health, Inc., part of Johnson & Johnson MedTech	2026-07-21
Medical Thulium Fiber Laser Systems FDA classifies this device as: Powered Laser Surgical Instrument.	Rhein Laser Technologies Co., Ltd.	2026-07-21
Uv Phototherapy (3 models) Xuzhou Kernel Medical Equipment Co., Ltd. received FDA clearance for this device.	Xuzhou Kernel Medical Equipment Co., Ltd.	2026-07-21
Raney Clips Kit FDA classifies this device as: Clip, Scalp.	Beijing Honghugaoxiang Science and Technology Development CO	2026-07-21
One-Fil LC FDA classifies this device as: Liner, Cavity, Calcium Hydroxide.	Mediclus Co., Ltd.	2026-07-21

NanoZoomer S540MD Slide Scanner System

Hamamatsu Photonics K.K.

2026-

FDA classifies this device as: Whole Slide Imaging System.

07-22

Lancet

Tianjin Huahong Technology Co., Ltd.

2026-

A blood lancet used for glucose testing and similar purposes (intended for repeated use on a single patient only; not to be shared between patients).

07-22

* Full 79-item 510(k)/De Novo dataset available in the Excel file attached to this issue.

 Warning Letters

Total this week: **4** | Significant (manufacturing/GMP, or not classifiable as unapproved/labeling-only): **4** | Unapproved/labeling ONLY (no manufacturing-quality finding; mostly supplement/personal-import cases): **0**

United States **2** | Germany **1** | India **1**

 YTD 2026: only 8 of 40 letters (20%) could be assigned a country this year — too small a classified sample for a meaningful country breakdown (omitted).

Thomas Brunner Hygiene GmbH (CDER) **Germany**

Marketing of an unapproved new drug product.

Dabur India Limited (CDER) **India**

CGMP (Current Good Manufacturing Practice) violations at the manufacturing facility; product deemed adulterated.

Maria E. De La Torre Silva, M.D. (CDER) **United States**

Clinical investigator regulatory requirements (specific details are not available from this listing alone).

Woodbine Products Company Inc. (CDER) **United States**

CGMP (Current Good Manufacturing Practice) violations at the manufacturing facility; product deemed adulterated.

● Drug Recalls

Drug Recalls (Top Items) (showing 10 rows covering 46 of 57 total recalls in the latest available recall data (2026-07-15 to 2026-07-29); recalls from the same company for the same reason are grouped into one row. Full list available in the accompanying Excel data file.)

Note: "Recalling Firm" is the firm that filed the recall with the FDA (openFDA's recalling_firm field) — it is not necessarily the actual manufacturer, which may differ from the firm named in the Product column.

Recalling Firm	Product	Reason	Class
Rohto-Mentholatum (Vietnam) Co., Ltd.	Rohto Cooling Eye Drops Max Strength (naphazoline hydrochloride 0.03%, polysorbate 90, 0.2%), Sterile 0.4 FL OZ (13 mL), Distributed by: The Mentholatum Company, Orchard Park, NY 14127, Made in Vietnam, UPC 310742011012, NDC 10742-8158-1 (+7 similar recalls, same company & reason, grouped)	Lack of Assurance of Sterility	Class II
Reliance Life Sciences Private Limited	Pemetrexed for Injection 500mg/Vial, 1 50 mL Single-Dose Vial per carton, For intravenous use only, Rx only, Manufactured for: Somerset Therapeutics, LLC., Somerset, NJ 08873 NDC: 70069-0835-01 (+3 similar recalls, same company & reason, grouped)	Lack of Sterility Assurance	Class II
Chiesi USA, Inc.	CLEVIPREX (clevidipine injectable emulsion) 50 mg/100 mL (0.5 mg/mL), 10 Single Use Vials, Rx Only, Manufactured for: Chiesi USA, Inc., Cary, NC 27518, by Fresenius Kabi, Graz, Austria, NDC 10122-611-10.	Lack of Assurance of Sterility	Class II
CareFusion 213, LLC	BD Chloraprep Clear, (2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol), 60 x 1 mL applicators/carton, 0.03fl oz (1 mL) each, STERILE SOLUTION, CareFusion 123, LLC, El Paso, TX, subsidiary of Beckton, Dickson and Co. NDC 54365-400-31	Lack of Assurance of Sterility: Affected product may exhibit an open or incomplete seal on the packaging of the applicator	Class II
Shimoga Chemicals	Clomiphene Citrate USP Active Pharmaceutical Ingredient (CAS : 50-41-9), Net Weight a)1 KG (NDC 84849-000-01), b) 500 g (NDC 84849-000-02), (c) 100 g (NDC 84849-000-03), Rx Only, Shimoga Chemicals Address -W-57A, MIDC Kupwad Samgli, Maharashtra, 416436, India.	cGMP deviations	Class II
Major Pharmaceuticals	Levothyroxine Sodium Tablets, USP, 75 mcg (0.075 mg), 10 Tablets (10 x 1) unit dose blisters per carton, Rx only, Packaged and Distributed by: MAJOR PHARMACEUTICALS, Indianapolis, IN 46268 USA. Distributed by Cardinal Health, Dublin, OH 43017. NDC Bag: 55154-3560-0; NDC Blister: 0904-6951-61 (+11 similar recalls, same company & reason, grouped)	Subpotent Drug	Class II

Bell Pharmaceuticals, Inc	QC Quality Choice, Carbamide Peroxide, 6.5%, 0.5 FL. OZ. (15 mL) a) Washer Bulb included (NDC 63868-026-15); b) 1 bottle (NDC 63868-027-16), Distributed by C.D.M.A., Inc., 43157 W. Nine Mile, Novi, MI 48376. (+10 similar recalls, same company & reason, grouped)	SubPotent Drug: low pH and significantly reduced assay (~0.6% vs expected ~6 7%).	Class II
Gasco Industrial Corp.	Gasco Isopropyl Alcohol 70%, Net Contents: 1 US Gallon (3.78 L), Manufactured by: Gasco Industrial Corp., PO Box 1360, Gurabo, PR 00778, Made in USA (+5 similar recalls, same company & reason, grouped)	Subpotent drug	Class II
Padagis US LLC	Nystatin Cream USP, (100, 000 USP Nystatin Units), NET WT 15 g, Rx only, 15 g tube, Manufactured by Padagis, Yeruham, Israel, NDC 45802-059-35	Subpotent Drug: Low out of specification assay results performed during long-term stability testing.	Class II
ONESOURCE SPECIALTY PHARMA LIMITED	Methohexital Sodium for Injection, USP 500 mg Multiple Dose Vial, Rx Only, Manufactured by: OneSource Specialty, Pharma Limited, Bengaluru - 561 203, India, Manufactured for: Avet Pharmaceuticals Inc., East Brunswick, NJ 08816, NDC 23155-893-31	Failed Impurities/Degradation Specifications	Class II

 FDA Guidance & Regulatory Actions

15 FDA regulatory documents this week.

[Determination That OZOBAX \(Baclofen\) Oral Solution, 5 Milligrams/5 Milliliters Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness](#) (2026-08-10 • Notice)

This Notice determines that OZOBAX oral solution was not withdrawn for safety or effectiveness reasons. It affects manufacturers of generic Baclofen oral solution seeking Abbreviated New Drug Applications (ANDAs).

[Determination of Regulatory Review Period for Purposes of Patent Extension; BRINSUPRI](#) (2026-08-10 • Notice)

This Notice determines the regulatory review period for BRINSUPRI, impacting its patent extension. It affects the pharmaceutical manufacturer of BRINSUPRI.

[Determination of Regulatory Review Period for Purposes of Patent Extension; DAYVIGO](#) (2026-08-10 • Notice)

This Notice determines the regulatory review period for DAYVIGO, impacting its patent extension. It affects the pharmaceutical manufacturer of DAYVIGO.

[Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments-GRAIL, Inc. Galleri](#) (2026-08-10 • Notice)

This Notice announces a meeting and requests comments regarding GRAIL, Inc.'s Galleri, a multi-cancer early detection in vitro diagnostic. It affects medical device manufacturers, particularly those in molecular and clinical genetics.

[Radiology Devices; Reclassification of Digital Breast Tomosynthesis System](#) (2026-08-10 • Proposed Rule)

This Proposed Rule suggests reclassifying digital breast tomosynthesis systems. It affects manufacturers of radiology devices used for breast imaging.

[Authorization of Emergency Use of an In Vitro Diagnostic Device in Response to an Outbreak of Mpox; Availability](#) (2026-08-06 • Notice)

This Notice announces the availability of an Emergency Use Authorization for an in vitro diagnostic device for Mpox. It affects manufacturers of diagnostic tests for infectious diseases.

[Medical Devices; Radiology Devices; Classification of the Fludeoxyglucose F18-Guided Radiation Therapy System](#) (2026-08-06 • Rule)

This Rule classifies the Fludeoxyglucose F18-Guided Radiation Therapy System. It affects manufacturers of radiology and radiation therapy medical devices.

[Micro-Tracers, Inc.; Response to Objections and Requests for a Public Hearing](#) (2026-08-05 • Rule)

This Rule responds to objections and requests for a public hearing concerning Micro-Tracers, Inc. It affects the animal feed industry and related manufacturers.

[Establishment of a Quantitative Medicine Innovation Network: Scope, Feasibility, and Opportunities; Request for Information](#) (2026-08-05 • Notice)

This Notice requests information on establishing a Quantitative Medicine Innovation Network. It affects pharmaceutical companies, researchers, and technology developers interested in quantitative medicine.

Modification of Certain Terminology in Title 21; Reopening of the Comment Period (2026-08-03 • Proposed Rule)

This Proposed Rule reopens the comment period for modifying certain terminology in Title 21. It affects all FDA-regulated industries subject to Title 21 regulations.

Ricardo Andres Acuna: Final Debarment Order (2026-08-03 • Notice)

This Notice announces a Final Debarment Order for Ricardo Andres Acuna. It affects individuals and entities involved in the pharmaceutical industry.

Angela Anatilde Baquero: Final Debarment Order (2026-08-03 • Notice)

This Notice announces a Final Debarment Order for Angela Anatilde Baquero. It affects individuals and entities involved in the pharmaceutical industry.

Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts; Draft Guidance for Industry; Availability (2026-08-03 • Notice)

This Notice announces the availability of Draft Guidance on container closure systems for biosimilar and interchangeable biosimilar products. It affects manufacturers of biosimilar and interchangeable biosimilar drugs.

Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs; Guidance for Industry; Availability (2026-08-03 • Notice)

This Notice announces the availability of Guidance on assessing adhesion for transdermal and topical delivery systems in ANDAs. It affects generic drug manufacturers developing transdermal and topical products.

Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for ANDAs; Revised Draft Guidance for Industry; Availability (2026-08-03 • Notice)

This Notice announces the availability of Revised Draft Guidance on irritation and sensitization potential for transdermal and topical delivery systems in ANDAs. It affects generic drug manufacturers developing transdermal and topical products.



Upcoming FDA Regulatory Event Calendar



Weekly Outlook

This week's notable events include iberdomide (2026-08-17) and Deramioceol (2026-08-22). In the Guidance Agenda, CDER's Generics category has the most items (24).

This text is generated mechanically from existing aggregate data (priority, countdown, category counts). It contains no forecasts or speculation.

★ This Week's Spotlight (Editor's Picks)

Selected mechanically by priority tier and proximity (days until event) — the notable items for this week.

Date	Priority	Event	Type
2026-08-17 in 6d	★★★★★	iberdomide	PDUFA
2026-08-22 in 11d	★★★★★	DeramioceI	PDUFA
2026-09-22 in 42d	★★★★★	Zilganersen	PDUFA
2026-09-26 in 46d	★★★★★	zilurgisertib	PDUFA
2026-09-30 in 50d	★★★★★	Apitegromab	PDUFA

Changes Since Last Week

Category	Count
 New (PDUFA 24 / AdCom 3 / Guidance 0)	27
 Postponed / rescheduled	0
 Removed / withdrawn	0

New this week (PDUFA / AdCom) (showing top 10 of 27)

- [PDUFA] iberdomide (2026-08-17)
- [PDUFA] zanidatamab (2026-08-25)
- [PDUFA] zanidatamab (2026-08-25)
- [PDUFA] Zilganersen (2026-09-22)
- [PDUFA] zilurgisertib (2026-09-26)
- [PDUFA] Apitegromab (2026-09-30)
- [PDUFA] Bepirovirsen (2026-10-26)
- [PDUFA] Povetacicept (pove) (2026-11-30)
- [PDUFA] zanzalintinib (2026-12-03)
- [PDUFA] Quimilza TM (2026-12-12)

📅 Upcoming FDA Schedule (Official, Not Predicted)

This section contains no forecasts. It lists only officially announced FDA events, each linked to its primary source.

Date	Priority	Advisory Committee / Topic	Product / Company	Source
2026-09-04 in 24d	★★★★☆	Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Advisory Committees	—	Federal Register
2026-09-16 in 36d	★★★★☆	Pediatric Advisory Committee (PAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments	—	Federal Register
2026-09-23 in 43d	★★★★☆	Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments-GRAIL, Inc. Galleri	—	Federal Register

 PDUFA Target Action Dates Disclosed by Sponsors

This list is compiled from information disclosed by companies in SEC filings, official press releases, and investor materials. It is not a comprehensive official schedule published by FDA. Dates may change, be delayed, or be withdrawn. Always verify against the primary source linked below before making investment, regulatory, or business decisions.

Confirmed (exact date disclosed)

Target Action Date	Priority	Product	Company	Indication	Source
2026-08-17 in 6d	★★★★★	iberdomide	Bristol Myers Squibb	relapsed or refractory multiple myeloma	SEC 8-K (Press Release)
2026-08-22 in 11d	★★★★★	Deramiciel	CAPRICOR THERAPEUTICS, INC.	cardiomyopathy in patients with Duchenne muscular dystrophy	SEC 8-K
2026-08-25 in 14d	★★★★☆	zanidatamab	Jazz Pharmaceuticals plc	first-line (1L) gastroesophageal adenocarcinoma (GEA)	SEC 8-K (Press Release)
2026-08-25 in 14d	★★★★☆	zanidatamab	Zymeworks Inc.	first-line (1L) HER2-positive (HER2+) locally advanced or metastatic gastroesophageal adenocarcinoma (GEA)	SEC 8-K (Press Release)
2026-09-22 in 42d	★★★★★	Zilganersen	Ionis Pharmaceuticals, Inc.	Alexander disease (AxD)	SEC 8-K (Press Release)
2026-09-26 in 46d	★★★★★	zilurgisertib	Mirum Pharmaceuticals, Inc.	fibrodysplasia ossificans progressiva (FOP)	SEC 8-K (Press Release)
2026-09-30 in 50d	★★★★★	Apitegromab	Scholar Rock	spinal muscular atrophy (SMA)	SEC 8-K (Press Release)
2026-10-26 in 76d	★★★★★	Bepirovirsen	Ionis Pharmaceuticals, Inc.	chronic hepatitis B (CHB)	SEC 8-K (Press Release)
2026-11-14 in 95d	★★★★★	ivonescimab	Summit Therapeutics Inc.	EGFR-mutated, locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) who were previously treated with a third-generation EGFR tyrosine kinase inhibitor (TKI)	SEC 8-K (Press Release)

2026-11-27 in 108d	★★★★★	BBP-418	BridgeBio Pharma, Inc.	limb-girdle muscular dystrophy type 2I/R9 (LGMD2I/R9)	SEC 8-K (Press Release)
2026-11-30 in 111d	★★★★★	Povetacept (pove)	Vertex	immunoglobulin A nephropathy (IgAN)	SEC 8-K (Press Release)
2026-12-03 in 114d	★★★★★	zanzalintinib	EXELIXIS, INC.	metastatic colorectal cancer	SEC 8-K (Press Release)
2026-12-12 in 123d	★★★★★	Quimilza TM	Vanda Pharmaceuticals Inc.	Generalized Pustular Psoriasis (GPP)	SEC 8-K (Press Release)
2026-12-17 in 128d	★★★★★	relacorilant	Corcept Therapeutics Incorporated	Cushing's syndrome	SEC 8-K (Press Release)
2026-12-27 in 138d	★★★★★	relutrigine	Praxis Precision Medicines, Inc.	SCN2A and SCN8A DEEs	SEC 8-K (Press Release)
2027-01-06 in 148d	★★★★☆	ANKTIVA	ImmunityBio, Inc.	BCG-unresponsive NMIBC with papillary disease without CIS	SEC 8-K (Press Release)
2027-01-21 in 163d	★★★★★	zeleciment rostudirsen	Dyne Therapeutics, Inc.	Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping	SEC 8-K
2027-01-29 in 171d	★★★★★	Ulixacaltamide	Praxis Precision Medicines, Inc.	Essential Tremor (ET)	SEC 8-K (Press Release)
2027-02-23 in 196d	★★★★☆	ZORYVE cream 0.05%	Arcutis Biotherapeutics, Inc.	mild to moderate atopic dermatitis in infants aged 3 to 24 months	SEC 8-K (Press Release)
2027-02-27 in 200d	★★★★★	zipalertinib	Cullinan Therapeutics, Inc.	EGFR ex20ins NSCLC	SEC 8-K (Press Release)
2027-02-28 in 201d	★★★★☆	VOXZOGO	BioMarin Pharmaceutical Inc.	achondroplasia	SEC 8-K (Press Release)
2027-03-11 in 212d	★★★★☆	Reblozyl	Bristol Myers Squibb	myelofibrosis- associated anemia	SEC 8-K (Press Release)
2027-04-01 in 233d	★★★★★	Pitolisant GR (Gastro- resistant) Tablets	Harmony Biosciences	narcolepsy	SEC 8-K (Press Release)

2027-05-01 in 263d	★★★★★	AXS-12	Axsome Therapeutics, Inc.	cataplexy in narcolepsy	SEC 8-K (Press Release)
2027-05-08 in 270d	★★★★★	encaleret	BridgeBio Pharma, Inc.	autosomal dominant hypocalcemia type 1 (ADH1)	SEC 8-K (Press Release)
2027-05-13 in 275d	★★★★★	mezigdomide	Bristol Myers Squibb	relapsed or refractory multiple myeloma (RRMM)	SEC 8-K (Press Release)

Partially disclosed (quarter / month / half-year only)

Expected Timing	Priority	Product	Company	Source
August 2026	★★★★★	rusfertide	Protagonist Therapeutics, Inc	SEC 8-K (Press Release)
2028 (timing TBD)	★★★★★	Pitolisant HD (high dose)	Harmony Biosciences	SEC 8-K (Press Release)
2028 (timing TBD)	★★★★★	WAKIX (pitolisant)	Harmony Biosciences	SEC 8-K (Press Release)
2028 (timing TBD)	★★★★★	EPX-100 (clemizole hydrochloride)	Harmony Biosciences	SEC 8-K (Press Release)

Annual Guidance Development Plans (CDER/CBER/CDRH)

Each center publishes an annual list of guidance topics it is considering. Individual items have no committed publication date, and FDA does not guarantee every listed topic will be issued.

CDER (CY2026) — 85 items • [Official page](#)

By category: Generics (24), Pharmaceutical Quality/CMC (10), Clinical/Medical (9), Administrative/Procedural (8), Compounding (8), Biosimilars (6) and more

- Drug and Device Manufacture Communications with Payors, Formulary Committees, and Small Entities - Questions and Answers; Revised Draft
- Engaging with FDA to Discuss the Use of Digital Health Technologies in Clinical Investigations of Drug and Biological Products
- Exclusivity for First Interchangeable Biosimilar Biological Products
- Expedited Programs: Fast Track, Breakthrough Therapy, and Priority Review
- NDC Creation, Assignment, Listing and Appropriate Use for Human Drugs, Including Biological Products
- Priority Review Voucher Programs

+79 more (see official page for the full list)

CBER (CY2026) — 35 items • [Official page](#)

By category: Therapeutic Products (19), Vaccines and Allergens (9), Blood and Blood Components (5), Other (2)

- Considerations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method; Guidance for Industry
- Collection of Platelets by Automated Methods; Draft Guidance for Industry
- Recommendations for Testing Blood Donations for Hepatitis B Virus; Guidance for Industry
- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry
- Recommendations for Testing Blood Donations for Human T-lymphotropic Viruses I and II; Draft Guidance for Industry
- Frequently Asked Questions - Cell and Gene Therapy Products; Guidance for Industry

+29 more (see official page for the full list)

CDRH (FY2026) — 20 items • [Official page](#)

By category: UC (9) **(NEW +9)**, A (8) **(NEW +8)**, B (3) **(NEW +3)**

- Validation of Diagnostic Tests for Emerging Pathogens following a Declaration and Determination under Section 564
- Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices
- Predetermined Change Control Plans for Medical Devices
- Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle
- Enforcement Discretion Policy for Premarket and Other Requirements for NIOSH-Approved Air Purifying Respirators
- Menstrual Products - Labeling and Performance Testing Recommendations

+14 more (see official page for the full list)

Priority (★) criteria

- ★★★★★ Major approval decision / highest market impact
- ★★★★☆ AdCom tied to a specific product / initial BLA-NDA approval-related
- ★★★☆☆ Advisory Committee (general business, not tied to a specific product)
- ★★☆☆☆ Committee administration / procedural notice
- ★☆☆☆☆ Administrative/procedural public meeting

FDA Weekly Intelligence

Data sources: openFDA • Federal Register • FDA.gov official publications

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