FDA WEEKLY INTELLIGENCE

FDA Intelligence

Coverage: 2026-08-06 – 2026-08-12 (drug approval date basis)

Published: August 16, 2026

Plan: Individual Plan

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FDA WEEKLY INTELLIGENCE • ASIAN MEDTECH & PHARMA TRACKER

FDA Weekly Report — Week 33, 2026

Coverage: 2026-08-06 – 2026-08-12 (drug approval date basis)

Published: August 16, 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 2026-07-25 to 2026-07-31.

Note: the issue number ("Week 33, 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

A quiet week for drug approvals, with no new molecular entities or other novel therapies cleared, contrasted with progress in medical devices, which saw one De Novo authorization and one PMA approval. This regulatory lull was overshadowed by a significant manufacturing issue highlighted in the latest recall data, involving a Class I recall for JB Chemicals and Pharmaceuticals Ltd due to product cross-contamination. The period was otherwise uneventful from an enforcement perspective, with no significant Warning Letters identified, though activity from Asian companies remained steady.

0	0	0	75	1
NME Approvals	Total Drug Approvals	Efficacy Supplements	Device Clearances	PMA Originals

17

Asian Co. Events

🌏 Asian Company Watch — FDA Activity This Week

Coverage: drugs 2026-08-06–2026-08-12, devices 2026-07-25–2026-07-31 (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).

AUROBINDO PHARMA LTD India

> TRIAMCINOLONE ACETONIDE

AUROBINDO PHARMA LTD — Generic approval (ANDA) for TRIAMCINOLONE ACETONIDE (TRIAMCINOLONE ACETONIDE).

> **Intelligence:** This approval is one of several for Aurobindo in a short period, reflecting a consistent strategy to expand its portfolio of generic pharmaceuticals available in the US.

AUROBINDO PHARMA India

> BRIVARACETAM (BRIVARACETAM)

AUROBINDO PHARMA — Generic approval (ANDA) for BRIVARACETAM (BRIVARACETAM).

AUROBINDO PHARMA India

> VANCOMYCIN HYDROCHLORIDE

AUROBINDO PHARMA — Generic approval (ANDA) for VANCOMYCIN HYDROCHLORIDE (VANCOMYCIN HYDROCHLORIDE).

LUPIN India

> SODIUM ZIRCONIUM CYCLOSILICATE

LUPIN — Generic approval (ANDA) for SODIUM ZIRCONIUM CYCLOSILICATE (SODIUM ZIRCONIUM CYCLOSILICATE).

> **Intelligence:** This generic approval for a complex oral suspension product demonstrates Lupin's capability in developing and manufacturing more challenging generic formulations for the US market.

DR REDDYS India

LORATADINE

DR REDDYS — Generic approval (ANDA) for LORATADINE (LORATADINE AND PSEUDOEPHEDRINE SULFATE).

Intelligence: The approval for a common OTC product could help Dr. Reddy's broaden its presence in the US consumer health and retail pharmacy channels.

Samsung Medison Co., Ltd. South Korea

V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8…

📈 3rd clearance in 2026 (73 total since 2011) — established filer

🔗 Predicate: K250999 (Samsung Medison Co., Ltd., KR)

Samsung Medison Co., Ltd. received a 510(k) clearance for V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System; V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System; V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System; V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System; V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System. FDA classifies this device as: System, Imaging, Pulsed Doppler, Ultrasonic.

Shanghai United Imaging Healthcare Co., Ltd. China

uMI Panvivo (uMI Panvivo M)

📈 6th clearance in 2026 (84 total since 2018) — established filer

🔗 Predicate: K241166 (Shanghai United Imaging Healthcare Co., Ltd., CN)

Shanghai United Imaging Healthcare Co., Ltd. received a 510(k) clearance for uMI Panvivo (uMI Panvivo M). FDA classifies this device as: System, Tomography, Computed, Emission.

Nipro Medical Corporation Japan

ELISIO™-HX

📈 3rd clearance in 2026 (35 total since 2005) — established filer

🔗 Predicate: K260533 (Nipro Medical Corporation, US)

Japanese firm Nipro Medical Corporation received 510(k) clearance for its ELISIO-HX hemodialyzer, a device for filtering blood during dialysis with an expanded solute removal profile.

Intelligence: The clearance of a hemodialyzer with specific performance claims may support Nipro's efforts to differentiate its product line in the competitive US renal care market.

NeuroLogica Corp., a Samsung Company South Korea

BodyTom Elite (NL4000)

🆕 First FDA clearance — new US market entrant

🔗 Predicate: K170238 (Neurologica Corporation, A Subsidiary of Samsung Electronics, US)

NeuroLogica Corp., a Samsung Company received a 510(k) clearance for BodyTom Elite (NL4000). FDA classifies this device as: System, X-Ray, Tomography, Computed.

T&R BIOFAB CO., Ltd. South Korea

TnR Cranial Implant

📈 1st clearance in 2026 (2 total since 2023) — established filer

🔗 Predicate: K051093 (Osteopore, Inc., US)

South Korea's T&R BIOFAB CO., Ltd. secured 510(k) clearance for its TnR Cranial Implant, a methyl methacrylate device used for cranioplasty.

Intelligence: This clearance provides a US market entry point for the Korean company into the specialized field of patient-specific neurosurgical implants.

IMGFAX CO., LTD. China

Handheld Ultrasound Scanner

🆕 First FDA clearance — new US market entrant

🔗 Predicate: K241161 (Leltek, Inc., TW)

Chinese company IMGFAX CO., LTD. obtained 510(k) clearance for its handheld ultrasound scanner.

Intelligence: The entry of another handheld ultrasound device from a Chinese manufacturer could increase competitive pressure in the rapidly growing point-of-care ultrasound (POCUS) segment in the US.

Rayence Co., Ltd. South Korea

0909FCE, 0909FCE-HS

📈 1st clearance in 2026 (39 total since 2011) — established filer

🔗 Predicate: K240371 (Rayence Co., Ltd., KR)

South Korea's Rayence Co., Ltd. received 510(k) clearance for its solid-state digital X-ray imagers, also known as flat panel detectors.

Intelligence: Rayence's continued clearance of new flat-panel detector models strengthens its position as a component supplier within the digital radiography supply chain for the US market.

Suzhou Haowei Medical Technology Co., Ltd. China

UniPearls® Embolic Microspheres

📈 1st clearance in 2026 (2 total since 2023) — established filer

🔗 Predicate: K231554 (Suzhou Haowei Medical Technology Co., Ltd., CN)

Suzhou Haowei Medical Technology from China gained 510(k) clearance for its UniPearls Embolic Microspheres, which are used to block blood flow in vascular procedures.

Intelligence: This clearance allows a new Chinese entrant into the US interventional radiology market for embolic agents, a category with applications in treating tumors and controlling bleeding.

Shanghai Hulu Devices Co., Ltd. China

Smart Wireless Stethoscope

📈 1st clearance in 2026 (3 total since 2018) — established filer

🔗 Predicate: K220470 (Shanghai Hulu Devices Co., Ltd., CN)

Shanghai Hulu Devices Co., Ltd. of China received 510(k) clearance for its line of smart wireless electronic stethoscopes.

Intelligence: The introduction of a wireless, electronic stethoscope from a Chinese medtech firm may support the growing trend of digital health and remote patient monitoring tools in the US primary care and cardiology markets.

Olympus Medical Systems Corporation Japan

EVIS EUS Ultrasound Gastrointestinal Videoscope

📈 3rd clearance in 2026 (83 total since 2004) — established filer

🔗 Predicate: K251859 (Olympus Medical Systems Corporation, JP)

Olympus Medical Systems Corporation received a 510(k) clearance for EVIS EUS Ultrasound Gastrointestinal Videoscope (Olympus GF-UE190). FDA classifies this device as: Endoscopic Ultrasound System, Gastroenterology-Urology.

Samsung Electronics Co., Ltd. South Korea

Hearing Aid Feature

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

Samsung Electronics received 510(k) clearance for air-conduction hearing aid software.

Xiamen High Top Electronic Technology Co., Ltd. China

> Air Compression Massager (HY-1165)

📈 1st clearance in 2026 (2 total since 2022) — established filer

🔗 Predicate: K182668 (Rapid Reboot Recovery Products, LLC, US)

Xiamen High Top received 510(k) clearance for a powered inflatable tube massager.

💊 Drug Approvals

0 new drug approvals this week (0 NMEs). 0 efficacy supplements. 9 generics (ANDA).

🩺 Medical Devices

Coverage period for this section: **2026-07-25 to 2026-07-31** — FDA publishes device decisions later than drug approvals, so this differs from the report period (2026-08-06 to 2026-08-12) and is anchored to the latest available device data.

510(k) clearances: **74** (plus 1 separate De Novo authorization). PMA (premarket approval) totals **61**, broken down below — Original/Panel-Track represent new or significant changes.

PMA Original: **1** | Panel-Track: **0** | 30-Day Notice: **48** | Other: **12**

PMA Approvals

PGDx elio tissue complete CDx — Personal Genome Diagnostics, Inc.

> Next generation sequencing oncology panel for detecting somatic or germline variants in cancer patients.

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

Device	Applicant	Date
Air Compression Massager (HY-1165) FDA classifies this device as: Massager, Powered Inflatable Tube.	Xiamen High Top Electronic Technology Co., Ltd.	2026-07-27
V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8… FDA classifies this device as: System, Imaging, Pulsed Doppler, Ultrasonic.	Samsung Medison Co., Ltd.	2026-07-28
uMI Panvivo (uMI Panvivo M) FDA classifies this device as: System, Tomography, Computed, Emission.	Shanghai United Imaging Healthcare Co., Ltd.	2026-07-28
ELISIO™-HX A hemodialyzer with expanded solute removal profile for renal treatment.	Nipro Medical Corporation	2026-07-28
CaRi-Heart De Novo Caristo Diagnostics, Ltd. received FDA clearance for this device.	Caristo Diagnostics, Ltd.	2026-07-28
BodyTom Elite (NL4000) FDA classifies this device as: System, X-Ray, Tomography, Computed.	NeuroLogica Corp., a Samsung Company	2026-07-28
TnR Cranial Implant FDA classifies this device as: Methyl Methacrylate For Cranioplasty.	T&R BIOFAB CO., Ltd.	2026-07-30

Handheld Ultrasound Scanner FDA classifies this device as: System, Imaging, Pulsed Doppler, Ultrasonic.	IMGFAX CO., LTD.	2026-07-30
0909FCE, 0909FCE-HS FDA classifies this device as: Solid State X-Ray Imager (Flat Panel/Digital Imager).	Rayence Co., Ltd.	2026-07-31
UniPearls® Embolic Microspheres FDA classifies this device as: Device, Vascular, For Promoting Embolization.	Suzhou Haowei Medical Technology Co., Ltd.	2026-07-31

* Full 75-item 510(k)/De Novo dataset available in the Excel file attached to this issue.

⚠️ Warning Letters

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

🔴 Drug Recalls

Drug Recalls (Top Items) (showing 10 rows covering 41 of 49 total recalls in the latest available recall data (2026-07-22 to 2026-08-05); 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
JB Chemicals and Pharmaceuticals Ltd	Cetirizine Hydrochloride Tablets USP 5 mg, 100-count bottle, Manufactured by: Unique Pharmaceuticals Labs, (A Div. of J.B. Chemicals & Pharmaceuticals, Ltd.), Mumbai 400 030, India. Distributed by: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816, NDC 16571-401-10.	Cross Contamination with Other Products: Customer complaints for appearance of discolored tablets and red dots observed on Cetirizine Hydrochloride Tablets USP 5 mg. Determined to be Ranitidine.	Class I
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
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
Glenmark Pharmaceuticals Inc., USA	Azelaic Acid Gel, 15%, 50 gram tubes, For Topical Use only, Rx only, Distributed by: Glenmark Pharmaceuticals Inc., USA, Elmwood Park, NJ 07407, NDC 68462-626-52.	CGMP Deviations: Product quality complaints concerning abnormal texture or consistency (described as grainy, gritty, or sandy) were received.	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
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
Fresenius Kabi USA, LLC	Naropin (ropivacaine hydrochloride Injection, USP), 0.5%, 100 mg per 20 mL (5 mg per mL), Twenty-five, 20 mL Single-Dose Vials, Rx only, Fresenius Kabi, Lake Zurich, IL 60047 NDC Tray: 63323-286-23; NDC Vial: 63323-286-05 (+3 similar recalls, same company & reason, grouped)	Presence of Particulate Matter: Hair was found in products	Class II
MYLAN PHARMACEUTICALS INC	Mycophenolate Mofetil for Injection USP, 500 mg/Vial, Single Dose Vial, 4 vials per carton, Rx only, Manufactured for: Mylan Institutional LLC, Morgantown, WV, 26505 USA, Made in India, NDC 67457-386-00.	Presence of precipitate	Class II

📋 FDA Guidance & Regulatory Actions

13 FDA regulatory documents this week.

Determination That ANSAID (Flurbiprofen) Tablets, 50 Milligrams and 100 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness (2026-08-14 • Notice)

This notice determines that ANSAID (Flurbiprofen) tablets were not withdrawn from sale for safety or effectiveness reasons, affecting generic drug manufacturers seeking bioequivalent versions.

Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments (2026-08-14 • Notice)

This notice announces a public meeting and requests comments on the reauthorization of the Prescription Drug User Fee Act (PDUFA), affecting pharmaceutical companies developing prescription drugs.

Determination That LASIX (Furosemide) Tablets, 20 Milligrams, 40 Milligrams, and 80 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness (2026-08-14 • Notice)

This notice determines that LASIX (Furosemide) tablets were not withdrawn from sale for safety or effectiveness reasons, affecting generic drug manufacturers seeking bioequivalent versions.

Container Closure Systems for Human Drugs and Biological Products; Draft Guidance for Industry; Availability (2026-08-14 • Notice)

This notice announces the availability of draft guidance on container closure systems for human drugs and biological products, affecting pharmaceutical and biologics manufacturers.

Kremers Urban Pharmaceuticals, Inc.; Grant of Hearing Request Regarding a Proposal To Withdraw Approval of an Abbreviated New Drug Application for Extended-Release Methylphenidate Tablets (2026-08-13 • Notice)

This notice grants a hearing request regarding a proposal to withdraw approval for an Abbreviated New Drug Application (ANDA) for extended-release methylphenidate tablets, affecting Kremers Urban Pharmaceuticals and generic drug manufacturers.

Guide To Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce; Guidance for Industry; Availability (2026-08-12 • Rule)

This final rule adopts a guide to minimize biological hazards in ready-to-eat fresh-cut produce. It affects producers and distributors of fresh-cut produce.

Reauthorization of the Generic Drug User Fee Amendments; Public Meeting; Request for Comments (2026-08-11 • Notice)

This notice announces a public meeting and requests comments on the reauthorization of the Generic Drug User Fee Amendments (GDUFA), affecting generic drug manufacturers.

Substances Generally Recognized as Safe (2026-08-11 • Proposed Rule)

This proposed rule concerns substances generally recognized as safe (GRAS), affecting food manufacturers and ingredient suppliers.

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 (Baclofen) oral solution was not withdrawn from sale for safety or effectiveness reasons, affecting generic drug manufacturers seeking bioequivalent versions.

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

This notice establishes the regulatory review period FDA uses to calculate a potential patent-term extension for BRINSUPRI, to be decided by the USPTO. It affects the patent holder and generic drug developers.

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

This notice establishes the regulatory review period FDA uses to calculate a potential patent-term extension for DAYVIGO, to be decided by the USPTO. It affects the patent holder and generic drug developers.

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 of the Medical Devices Advisory Committee's Molecular and Clinical Genetics Panel, establishing a public docket and requesting comments on GRAIL, Inc.'s Galleri device. It affects medical device manufacturers, particularly those in genetic diagnostics.

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

This proposed rule concerns the reclassification of digital breast tomosynthesis systems, affecting manufacturers of radiology devices and medical imaging equipment.

📅 Upcoming FDA Regulatory Event Calendar

📝 Weekly Outlook

This week's notable events include Deramiocel (2026-08-22) and Zilganersen (2026-09-22). 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
2026-08-22 in 6d	★★★★★	Deramiocel	PDUFA
2026-09-22 in 37d	★★★★★	Zilganersen	PDUFA
2026-09-26 in 41d	★★★★★	zilurgisertib	PDUFA
2026-09-30 in 45d	★★★★★	apitegromab	PDUFA
2026-08-25 in 9d	★★★★☆	zanidatamab	PDUFA

🆕 Changes Since Last Week

Category	Count
🆕 New (PDUFA 33 / AdCom 2 / Guidance 0)	35
📅 Postponed / rescheduled	0
🗑️ Removed / withdrawn	27

New this week (PDUFA / AdCom) (showing top 10 of 35)

- [PDUFA] Deramiocel (2026-08-22)
- [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] INO-3107 (2026-10-30)
- [PDUFA] ivonescimab (2026-11-14)
- [PDUFA] BBP-418 (2026-11-27)

Removed / withdrawn (showing top 10 of 27)

- [AdCom] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Advisory Committees
- [PDUFA] Deramiocel
- [PDUFA] Deramiocel
- [PDUFA] zanidatamab
- [PDUFA] zanidatamab
- [PDUFA] Zilganersen
- [PDUFA] zilurgisertib
- [PDUFA] apitegromab
- [PDUFA] Bepirovirsen
- [PDUFA] ivonescimab

🗓️ 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
2026-09-23 in 38d	★★★☆☆	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
2026-10-16 in 61d	★★★☆☆	Gastroenterology-Urology Devices; Reclassification of Diagnostic Endoscopic Light Source Systems To Be Renamed Cystoscopic Systems Intended as an Aid for Detection of Bladder Cancer	—	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
2026-08-22 in 6d	★★★★★	Deramiocel	CAPRICOR THERAPEUTICS, INC.	cardiomyopathy in patients with Duchenne muscular dystrophy	SEC 8-K
2026-08-25 in 9d	★★★★☆	zanidatamab	Jazz Pharmaceuticals plc	first-line (1L) gastroesophageal adenocarcinoma (GEA)	SEC 8-K (Press Re
2026-08-25 in 9d	★★★★☆	zanidatamab	Zymeworks Inc.	first-line (1L) HER2-positive (HER2+) locally advanced or metastatic gastroesophageal adenocarcinoma (GEA)	SEC 8-K (Press Re
2026-09-22 in 37d	★★★★★	Zilganersen	Ionis Pharmaceuticals, Inc.	Alexander disease (AxD)	SEC 8-K (Press Re
2026-09-26 in 41d	★★★★★	zilurgisertib	Mirum Pharmaceuticals, Inc.	fibrodysplasia ossificans progressiva (FOP)	SEC 8-K (Press Re
2026-09-30 in 45d	★★★★★	apitegromab	Scholar Rock	spinal muscular atrophy (SMA)	SEC 8-K (Press Re
2026-10-26 in 71d	★★★★★	Bepirovirsen	IONIS PHARMACEUTICALS INC (IONS) (CIK 0000874015)	chronic hepatitis B (CHB)	SEC 8-K (Press Re
2026-10-30 in 75d	★★★★★	INO-3107	INOVIO PHARMACEUTICALS, INC.	Recurrent Respiratory Papillomatosis (RRP)	SEC 8-K (Press Re

2026-11-14 in 90d	★★★★★	ivonescimab	Summit Therapeutics Inc.	EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who were previously treated with a third-generation EGFR TKI	SEC 8-K (Press Re
2026-11-27 in 103d	★★★★★	BBP-418	BridgeBio Pharma, Inc.	LGMD2I/R9	SEC 8-K (Press Re
2026-11-27 in 103d	★★★★★	—	BridgeBio Disclosed in BridgeBio Pharma, Inc.'s filing	—	SEC 8-K (Press Re
2026-11-30 in 106d	★★★★★	Povetacicept	Vertex	immunoglobulin A nephropathy (IgAN)	SEC 8-K (Press Re
2026-12-03 in 109d	★★★★★	zanzalintinib	Exelixis, Inc.	metastatic colorectal cancer	SEC 8-K (Press Re
2026-12-12 in 118d	★★★★★	Quimilza TM	Vanda Pharmaceuticals Inc.	Generalized Pustular Psoriasis (GPP)	SEC 8-K (Press Re
2026-12-27 in 133d	★★★★★	relutrigine	Praxis Precision Medicines, Inc.	SCN2A and SCN8A developmental and epileptic encephalopathies (DEEs)	SEC 8-K (Press Re
2026-12-30 in 136d	★★★★★	bezuclastinib	Cogent Biosciences, Inc.	NonAdvSM	SEC 8-K (Press Re
2027-01-06 in 143d	★★★★☆	ANKTIVA	ImmunityBio, Inc.	BCG-unresponsive NMIBC with papillary disease without CIS	SEC 8-K (Press Re
2027-01-21 in 158d	★★★★★	z-rostudirsen	Dyne Therapeutics, Inc.	Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping	SEC 8-K (Press Re
2027-01-29 in 166d	★★★★★	ulixacaltamide	Praxis Precision Medicines, Inc.	Essential Tremor	SEC 8-K (Press Re

2027-02-23 in 191d	★★★★☆	ZORYVE cream 0.05%	Arcutis Biotherapeutics, Inc.	mild to moderate atopic dermatitis in infants aged 3 to 24 months	SEC 8-K (Press Re
2027-02-27 in 195d	★★★★★	zipalertinib	Cullinan Therapeutics, Inc. (CGEM) (CIK 0001789972)	locally advanced or metastatic EGFR ex20ins NSCLC whose disease has progressed on or after platinum-based chemotherapy, with or without amivantamab	SEC 8-K (Press Re
2027-02-28 in 196d	★★★★☆	VOXZOGO	BioMarin Pharmaceutical Inc.	achondroplasia	SEC 8-K (Press Re
2027-04-01 in 228d	★★★★★	Pitolisant GR	Harmony Biosciences Holdings, Inc.	narcolepsy	SEC 8-K (Press Re
2027-04-28 in 255d	★★★★★	Varegacestat	Immunome, Inc.	desmoid tumors	SEC 8-K (Press Re
2027-05-01 in 258d	★★★★★	AXS-12	Axsome Therapeutics, Inc.	cataplexy in narcolepsy	SEC 8-K (Press Re
2027-05-08 in 265d	★★★★★	encaleret	BridgeBio Pharma, Inc.	ADH1	SEC 8-K (Press Re
2027-05-27 in 284d	★★★★★	obexelimab	Zenas BioPharma, Inc.	Immunoglobulin G4-Related Disease (IgG4-RD)	SEC 8-K (Press Re

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

Expected Timing	Priority	Product	Company	Source
August 2026	★★★★★	rusfertide	Protagonist Therapeutics	SEC 8-K (Press Release)
September 2026	★★★★★	Ameluz	Biofrontera Inc.	SEC 8-K (Press Release)
2028 (timing TBD)	★★★★★	Pitolisant HD	Harmony Biosciences Holdings, Inc.	SEC 8-K (Press Release)
2028 (timing TBD)	★★★★★	WAKIX (pitolisant)	Harmony Biosciences Holdings, Inc.	SEC 8-K (Press Release)

2028 (timing TBD)	★★★★★	EPX-100 (clemizole hydrochloride)	Harmony Biosciences Holdings, Inc.	SEC 8-K (Press Release)
2028 (timing TBD)	★★★★★	Pitolisant	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 Allergenics (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), |A (7), |B (3), ||A (1)

- 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

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