FDA WEEKLY INTELLIGENCE

FDA Intelligence

Coverage: 2026-08-13 – 2026-08-19 (drug approval date basis)

Published: August 23, 2026

Plan: Individual Plan

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FDA WEEKLY INTELLIGENCE • ASIAN MEDTECH & PHARMA TRACKER

FDA Weekly Report — Week 34, 2026

Coverage: 2026-08-13 – 2026-08-19 (drug approval date basis)

Published: August 23, 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 2026-08-02 to 2026-08-08.

Note: the issue number ("Week 34, 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 was marked by a surge in novel product approvals, with the FDA clearing three new molecular entities-IBERDOMIDE (ZENBEXUS), FLORQUINITAU F18 (TAUKLARIFY), and pariglasgene brecaparvovec-opnr (GENGLYCOS)-along with one original PMA for a high-risk medical device. However, this positive momentum was tempered by significant manufacturing quality concerns, as recently disclosed Class I recall data cited particulate matter from Sunny Pharmtech Inc. and cross-contamination at JB Chemicals and Pharmaceuticals Ltd.

3	3	1	55	1
NME Approvals	Total Drug Approvals	Efficacy Supplements	Device Clearances	PMA Originals

16

Asian Co. Events

🌏 Asian Company Watch — FDA Activity This Week

Coverage: drugs 2026-08-13–2026-08-19, devices 2026-08-02–2026-08-08 (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).

+ 1 additional device clearance(s) in low-priority categories (e.g. wheelchairs, mobility scooters) not shown individually here — full detail is available in the accompanying Excel data set.

GLENMARK PHARMS LTD India

> FLUTICASONE PROPIONATE

GLENMARK PHARMS LTD — Generic approval (ANDA) for FLUTICASONE PROPIONATE (FLUTICASONE PROPIONATE).

BIOCON BIOLOGICS INC India

> USTEKINUMAB (YESINTEK)

BIOCON BIOLOGICS INC — Drug approval (NDA/BLA) for USTEKINUMAB (YESINTEK).

LUPIN India

> PITOLISANT HYDROCHLORIDE

LUPIN — Generic approval (ANDA) for PITOLISANT HYDROCHLORIDE (PITOLISANT HYDROCHLORIDE).

GEMSS HEALTHCARE CO., LTD. South Korea

> XLITE

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

GEMSS HEALTHCARE CO., LTD. received a 510(k) clearance for XLITE. FDA classifies this device as: System, X-Ray, Mobile.

Duplex International Trading Limited China

LED Light Therapy Masks (3 models)

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

China-based Duplex International Trading Limited obtained 510(k) clearance for its over-the-counter LED light therapy masks designed for wrinkle reduction.

Intelligence: This clearance is indicative of a trend where Chinese manufacturers are targeting the growing US consumer aesthetics and at-home beauty device market with FDA-cleared products.

Shenzhen Qianyu Technology Co., Ltd. China

LED Light Therapy Mask (6 models)

📈 1st clearance in 2026 (7 total since 2022) — established filer

Shenzhen Qianyu Technology Co., Ltd. from China received 510(k) clearance for several models of its over-the-counter LED light therapy masks for wrinkle reduction.

Intelligence: The clearance of multiple models suggests a strategy by the Chinese device maker to offer a broad product line for the competitive US at-home aesthetic device segment.

Xiamen Inno Medical Technology Co., Ltd. China

CAD - Lower GI (EC07-01)

🆕 First FDA clearance — new US market entrant

Xiamen Inno Medical Technology Co., Ltd. received a 510(k) clearance for CAD - Lower GI (EC07-01). FDA classifies this device as: Gastrointesinal Lesion Software Detection System.

Tianjin Huahong Technology Co., Ltd. China

Huahong Sharps Container (HHR-I, HHR-II)

📈 4th clearance in 2026 (14 total since 2021) — established filer

Tianjin Huahong Technology Co., Ltd., a Chinese company, obtained 510(k) clearance for its line of sharps disposal containers.

Intelligence: This clearance for a fundamental hospital supply item may support the company's entry into the US healthcare consumables market, which is often characterized by high-volume sales.

Edan Instruments, Inc. China

> Telemetry Monitor (iT30, iT50)

📈 3rd clearance in 2026 (94 total since 2004) — established filer

Edan Instruments, Inc. received a 510(k) clearance for Telemetry Monitor (iT30, iT50). FDA classifies this device as: Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms).

Roen Surgical, Inc. South Korea

> Zamenix™ P

🆕 First FDA clearance — new US market entrant

Roen Surgical, Inc. received a 510(k) clearance for Zamenix™ P. FDA classifies this device as: Ureteroscope And Accessories, Flexible/Rigid.

Lakong Medical Devices Co., Ltd. China

> Dental Unit (2 models)

🆕 First FDA clearance — new US market entrant

Lakong Medical Devices Co., Ltd. received a 510(k) clearance for Dental Unit (MP2000-550LED-2.0, LP2100-550LED-2.0). FDA classifies this device as: Unit, Operative Dental.

Yadu Medical (Henan) Co., Ltd. China

> Surgical Gown Level2 (6 models)

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

Yadu Medical (Henan) Co., Ltd. of China received 510(k) clearance for its Level 2 surgical gowns.

> **Intelligence:** Securing clearance for personal protective equipment like surgical gowns allows the Chinese manufacturer to supply the high-volume US hospital and surgical center market.

Hangzhou Qiantang Longyue Biotechnology Co., Ltd. China

> Safety Sterile Hypodermic Needles (28 models)

📈 2nd clearance in 2026 (6 total since 2023) — established filer

Hangzhou Qiantang Longyue Biotechnology Co., Ltd. from China received 510(k) clearance for a wide range of its safety sterile hypodermic needles.

> **Intelligence:** The clearance covering numerous needle gauges and lengths suggests the company is prepared to serve a broad set of clinical applications in the US general hospital supply market.

Shenzhen Chuangtong Yigou Technology Co., Ltd. China

> LED Light Therapy Mask (7 models)

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

Shenzhen Chuangtong Yigou Technology Co., Ltd., a Chinese firm, gained 510(k) clearance for its line of over-the-counter LED light therapy masks for wrinkle reduction.

> **Intelligence:** This is another example of a Chinese manufacturer securing FDA clearance to enter the US direct-to-consumer market for aesthetic light-based devices.

Fujifilm Corporation Japan

> EW10-EC02 Endoscopy Support Program

📈 9th clearance in 2026 (66 total since 2018) — established filer

Fujifilm Corporation received a 510(k) clearance for EW10-EC02 Endoscopy Support Program. FDA classifies this device as: Gastrointesinal Lesion Software Detection System.

💊 Drug Approvals

3 new drug approvals this week (3 NMEs). 1 efficacy supplement. 9 generics (ANDA).

New Drug Approvals (NDA / BLA)

IBERDOMIDE ZENBEXUS **NME** **Priority Review** **Orphan Drug** BRISTOL MYERS SQUIBB

APPROVED INDICATION

New indication for adult patients with multiple myeloma after at least one prior therapy including a proteasome inhibitor and an immunomodulatory agent. [approval letter]

FLORQUINITAU F18 TAUKLARIFY **NME** CERVEAU TECHNOLOGIES INC A LANTHEUS CO

WHAT IT IS

This novel molecular entity is a radioactive diagnostic drug for positron emission tomography.

APPROVED INDICATION

New indication for identifying tau neurofibrillary tangle pathology in adults with cognitive impairment being evaluated for Alzheimer’s disease. [approval letter]

pariglasgene brecaparvovec-opnr GENGLYCOS (pariglasgene brecaparvovec-opnr)

NME Ultragenyx Pharmaceutical Inc.

APPROVED INDICATION

New indication to reduce daily cornstarch intake in adult and pediatric patients 8 years and older with glycogen storage disease type Ia (GSDIa). [approval letter]

Efficacy Supplements

USTEKINUMAB YESINTEK **Efficacy Supplement (Classification Unavailable)**

BIOCON BIOLOGICS INC

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]

WHY IT MATTERS

This marks a significant US commercial milestone for India-based Biocon, a major global biosimilar developer.

🩺 Medical Devices

Coverage period for this section: **2026-08-02 to 2026-08-08** — FDA publishes device decisions later than drug approvals, so this differs from the report period (2026-08-13 to 2026-08-19) and is anchored to the latest available device data.

510(k) clearances: **55**. PMA (premarket approval) totals **51**, broken down below — Original/Panel-Track represent new or significant changes.

PMA Original: **1** | Panel-Track: **0** | 30-Day Notice: **27** | Other: **23**

PMA Approvals

DilightTM (roflufocon E) Overnight Orthokeratology Contact Lens

Tianjin MasterVision Technology Co., Ltd.

> An overnight orthokeratology contact lens for temporary vision correction.

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

Device	Applicant	Date
XLITE FDA classifies this device as: System, X-Ray, Mobile.	GEMSS HEALTHCARE CO., LTD.	2026-08-03
LED Light Therapy Masks (3 models) An over-the-counter light-based device for wrinkle reduction.	Duplex International Trading Limited	2026-08-04
LED Light Therapy Mask (6 models) An over-the-counter light-based device for wrinkle reduction.	Shenzhen Qianyu Technology Co., Ltd.	2026-08-04
CAD - Lower GI (EC07-01) A software system for detecting gastrointestinal lesions.	Xiamen Inno Medical Technology Co., Ltd.	2026-08-05
Huahong Sharps Container (HHR-I, HHR-II) A sharps container for safe disposal of medical sharps in hospitals.	Tianjin Huahong Technology Co., Ltd.	2026-08-05
Telemetry Monitor (iT30, iT50) FDA classifies this device as: Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms).	Edan Instruments, Inc.	2026-08-06
Manual Wheelchair (H008, PCK7) FDA classifies this device as: Wheelchair, Mechanical.	Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.	2026-08-06
Zamenix™ P FDA classifies this device as: Ureteroscope And Accessories, Flexible/Rigid.	Roen Surgical, Inc.	2026-08-07

Dental Unit (2 models) FDA classifies this device as: Unit, Operative Dental.	Lakong Medical Devices Co., Ltd.	2026-08-07
Metrix COVID Test; Metrix COVID Test Pro An over-the-counter molecular test for detecting SARS-CoV-2 from clinical specimens.	Aptitude Medical Systems, Inc.	2026-08-07

* Full 55-item 510(k)/De Novo dataset available in the Excel file attached to this issue.

⚠️ Warning Letters

Total this week: **6** | Significant (manufacturing/GMP, or not classifiable as unapproved/labeling-only): **6** | Unapproved/labeling ONLY (no manufacturing-quality finding; mostly supplement/personal-import cases): **0**

United States **3** | India **2** | China **1**

📊 YTD 2026: only 6 of 46 letters (13%) could be assigned a country this year — too small a classified sample for a meaningful country breakdown (omitted).

Tianjin Kilo Pharmaceutical Sci-tech Co., Ltd. (CDER) China

Inaccurate or false information on product labeling (misbranding).

K.C. Pharmaceuticals, Inc. (CDER) United States

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

Suretec Innovations, LLC (CDER) United States

Inaccurate or false information on product labeling (misbranding).

Eugia Pharma Specialities Limited (CDER) India

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

Auriga Research Pvt. Ltd. (CDER) India

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

Safrel Pharmaceuticals LLC (CDER) United States

Additionally, the firm did not provide required drug listing information for a specific product, leading to misbranding (21 U.S.C. 360(j), 352(o)).

🔴 Drug Recalls

Drug Recalls (Top Items) (showing 10 rows covering 31 of 45 total recalls in the latest available recall data (2026-07-29 to 2026-08-12); 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
Sunny Pharmtech Inc.	Cyclophosphamide for Injection, USP, 2 gram/vial, One Single-Dose Vial, Rx only, Manufactured for: Long Grove Pharmaceuticals, LLC, Rosemont, IL 60018. Manufactured in Taiwan, NDC 81298-8114-1	Presence of Particulate Matter; identified as stainless steel	Class I
Sunny Pharmtech Inc.	Cyclophosphamide for Injection, USP, 1 gram/vial, One Single-Dose Vial, Rx only, Manufactured for: Long Grove Pharmaceuticals, LLC, Rosemont, IL 60018. Manufactured in Taiwan, NDC 81298-8112-1	Presence of Particulate Matter; identified as stainless steel	Class I
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
Zydus Pharmaceuticals (USA) Inc	Mirabegron Extended-Release Tablets, 25 mg, 30-count bottle, Rx only, Manufactured by: Zydus Lifesciences Ltd., Matoda, Ahmedabad, India, Distributed by: Zydus Pharmaceuticals (USA) Inc., Pennington, NJ 08534, NDC 70710-1159-3.	CGMP: Due to Out of Specification (OOS) result for N-Nitroso Mirabegron impurity.	Class II
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

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
Precision Dose Inc.	Glycopyrrolate Oral Solution, 1 mg/5 mL, delivers 5 mL, Rx only, Pkg: Precision Dose, Inc, S. Beloil, IL 61080, unit-dose oral syringes, NDCs 68094-073-01 (oral syringe) and 68094-073-58 (case).	Failed Impurities/Degradation Specifications	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
Aurobindo Pharma USA Inc	Dicyclomine Hydrochloride Capsules, USP, 10mg, 1, 000 bottles, Rx only, Distributed by: Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Road, East Windsor, NJ 08520, Made in India, NDC 59651-719-99	shortfill; reports of empty capsules.	Class II

📋 FDA Guidance & Regulatory Actions

11 FDA regulatory documents this week.

Advisory Committee; Oncologic Drugs Advisory Committee; Renewal (2026-08-21 • Notice)

This notice announces the renewal of the Oncologic Drugs Advisory Committee, which advises FDA on oncologic drug regulation. It affects pharmaceutical companies developing cancer treatments.

Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal (2026-08-20 • Notice)

This notice announces the renewal of the Cardiovascular and Renal Drugs Advisory Committee, advising FDA on cardiovascular and renal drug regulation. It affects pharmaceutical companies developing related treatments.

Advisory Committee; Endocrinologic and Metabolic Drugs Advisory Committee; Renewal (2026-08-20 • Notice)

This notice announces the renewal of the Endocrinologic and Metabolic Drugs Advisory Committee, advising FDA on endocrinologic and metabolic drug regulation. It affects pharmaceutical companies developing related treatments.

Potency Assessment of Active Immunotherapy Products; Draft Guidance for Industry; Availability (2026-08-20 • Notice)

This notice announces the availability of a draft guidance for industry on potency assessment of active immunotherapy products. It affects manufacturers developing these biological products.

Frequently Asked Questions-Developing Potential Cellular and Gene Therapy Products; Final Guidance for Industry; Availability (2026-08-20 • Notice)

This notice announces the availability of final guidance addressing frequently asked questions for developing potential cellular and gene therapy products. It affects companies in the cell and gene therapy sector.

Determining Whether To Submit an ANDA or a 505(b)(2) Application; Draft Guidance for Industry; Availability (2026-08-18 • Notice)

This notice announces the availability of draft guidance for industry on determining whether to submit an ANDA or a 505(b)(2) application. It affects pharmaceutical companies developing generic or hybrid drug products.

Testosterone Use in Menopausal Women; Public Workshop; Request for Comments (2026-08-18 • Notice)

This notice announces a public workshop and requests comments on testosterone use in menopausal women. It affects pharmaceutical companies, healthcare providers, and researchers involved with hormone therapies.

Medical Devices; Classification of Accessories Distinct From Other Devices; Proposed List of Accessories Suitable for Class I; Request for Comments (2026-08-17 • Proposed Rule)

This proposed rule outlines the classification of medical device accessories distinct from other devices, including a proposed list suitable for Class I. It affects medical device manufacturers producing accessories.

Gastroenterology-Urology Devices; Reclassification of Diagnostic Endoscopic Light Source Systems To Be Renamed Cystoscopic Systems Intended as an Aid for Detection of Bladder Cancer (2026-08-17 • Proposed Rule)

This proposed rule reclassifies diagnostic endoscopic light source systems, renaming them cystoscopic systems for bladder cancer detection. It affects manufacturers of gastroenterology-urology devices.

Hematology and Pathology Devices; Reclassification of In Situ Hybridization Test Systems for Use With a Corresponding Approved Oncology Therapeutic Product (2026-08-17 • Rule)

This rule reclassifies in situ hybridization test systems for use with corresponding approved oncology therapeutic products. It affects manufacturers of hematology and pathology diagnostic devices.

Determination of Regulatory Review Period for Purposes of Patent Extension; BIZENGRI (2026-08-17 • Notice)

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

📅 Upcoming FDA Regulatory Event Calendar

📝 Weekly Outlook

This week's notable events include Zilganersen (2026-09-22) and zilurgisertib (2026-09-26). Also, zanidatamab's PDUFA target action date is 2 days away. 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
2026-09-22 in 30d	★★★★★	Zilganersen	PDUFA
2026-09-26 in 34d	★★★★★	zilurgisertib	PDUFA
2026-09-30 in 38d	★★★★★	apitegromab	PDUFA
2026-08-25 in 2d	★★★★☆	zanidatamab	PDUFA
2026-08-25 in 2d	★★★★☆	zanidatamab	PDUFA

🆕 Changes Since Last Week

Category	Count
🆕 New (PDUFA 0 / AdCom 3 / Guidance 0)	3
📅 Postponed / rescheduled	0
🗑️ Removed / withdrawn	1

New this week (PDUFA / AdCom)

- [AdCom] Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal (2026-08-27)
- [AdCom] Advisory Committee; Endocrinologic and Metabolic Drugs Advisory Committee; Renewal (2026-08-27)
- [AdCom] Advisory Committee; Oncologic Drugs Advisory Committee; Renewal (2026-09-01)

Removed / withdrawn

- [AdCom] 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

🗓️ 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
2026-08-27 in 4d	★★★☆☆	Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee; Renewal	—	Federal Register
2026-08-27 in 4d	★★★☆☆	Advisory Committee; Endocrinologic and Metabolic Drugs Advisory Committee; Renewal	—	Federal Register
2026-09-01 in 9d	★★★☆☆	Advisory Committee; Oncologic Drugs Advisory Committee; Renewal	—	Federal Register
2026-10-16 in 54d	★★★☆☆	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
2026-08-25 in 2d	★★★★☆	zanidatamab	Jazz Pharmaceuticals plc	first-line (1L) gastroesophageal adenocarcinoma (GEA)	SEC 8-K (Press Re
2026-08-25 in 2d	★★★★☆	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 30d	★★★★★	Zilganersen	Ionis Pharmaceuticals, Inc.	Alexander disease (AxD)	SEC 8-K (Press Re
2026-09-26 in 34d	★★★★★	zilurgisertib	Mirum Pharmaceuticals, Inc.	fibrodysplasia ossificans progressiva (FOP)	SEC 8-K (Press Re
2026-09-30 in 38d	★★★★★	apitegromab	Scholar Rock	spinal muscular atrophy (SMA)	SEC 8-K (Press Re
2026-10-26 in 64d	★★★★★	Bepirovirsen	IONIS PHARMACEUTICALS INC (IONS) (CIK 0000874015)	chronic hepatitis B (CHB)	SEC 8-K (Press Re
2026-10-30 in 68d	★★★★★	INO-3107	INOVIO PHARMACEUTICALS, INC.	Recurrent Respiratory Papillomatosis (RRP)	SEC 8-K (Press Re

2026-11-14 in 83d	★★★★★	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 96d	★★★★★	BBP-418	BridgeBio Pharma, Inc.	LGMD2I/R9	SEC 8-K (Press Re
2026-11-27 in 96d	★★★★★	—	BridgeBio Disclosed in BridgeBio Pharma, Inc.'s filing	—	SEC 8-K (Press Re
2026-11-30 in 99d	★★★★★	Povetacicept	Vertex	immunoglobulin A nephropathy (IgAN)	SEC 8-K (Press Re
2026-12-03 in 102d	★★★★★	zanzalintinib	Exelixis, Inc.	metastatic colorectal cancer	SEC 8-K (Press Re
2026-12-12 in 111d	★★★★★	Quimilza TM	Vanda Pharmaceuticals Inc.	Generalized Pustular Psoriasis (GPP)	SEC 8-K (Press Re
2026-12-27 in 126d	★★★★★	relutrigine	Praxis Precision Medicines, Inc.	SCN2A and SCN8A developmental and epileptic encephalopathies (DEEs)	SEC 8-K (Press Re
2026-12-30 in 129d	★★★★★	bezuclastinib	Cogent Biosciences, Inc.	NonAdvSM	SEC 8-K (Press Re
2027-01-06 in 136d	★★★★☆	ANKTIVA	ImmunityBio, Inc.	BCG-unresponsive NMIBC with papillary disease without CIS	SEC 8-K (Press Re
2027-01-21 in 151d	★★★★★	z-rostudirsen	Dyne Therapeutics, Inc.	Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping	SEC 8-K (Press Re
2027-01-29 in 159d	★★★★★	ulixacaltamide	Praxis Precision Medicines, Inc.	Essential Tremor	SEC 8-K (Press Re

2027-02-23 in 184d	★★★★☆	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 188d	★★★★★	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 189d	★★★★☆	VOXZOGO	BioMarin Pharmaceutical Inc.	achondroplasia	SEC 8-K (Press Re
2027-04-01 in 221d	★★★★★	Pitolisant GR	Harmony Biosciences Holdings, Inc.	narcolepsy	SEC 8-K (Press Re
2027-04-28 in 248d	★★★★★	Varegacestat	Immunome, Inc.	desmoid tumors	SEC 8-K (Press Re
2027-05-01 in 251d	★★★★★	AXS-12	Axsome Therapeutics, Inc.	cataplexy in narcolepsy	SEC 8-K (Press Re
2027-05-08 in 258d	★★★★★	encaleret	BridgeBio Pharma, Inc.	ADH1	SEC 8-K (Press Re
2027-05-27 in 277d	★★★★★	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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