FDA WEEKLY INTELLIGENCE

FDA Intelligence

Coverage: 2026-08-27 – 2026-09-02 (drug approval date basis)

Published: September 05, 2026

Plan: Individual Plan

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FDA WEEKLY INTELLIGENCE • ASIAN MEDTECH & PHARMA TRACKER

FDA Weekly Report — Week 36, 2026

Coverage: 2026-08-27 – 2026-09-02 (drug approval date basis)

Published: September 05, 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 2026-08-10 to 2026-08-16.

Note: the issue number ("Week 36, 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 highlighted by the approval of two New Molecular Entities, including MIMRYLO (rusfertide acetate), alongside approvals for three new indications and one indication expansion for existing therapies, creating significant new commercial opportunities. The medical device sector saw one high-risk PMA approval, while a notable volume of 24 regulatory actions involved Asian companies, underscoring their growing presence in the US market. On the compliance front, recently disclosed Class I recall data revealed serious quality control failures at firms including Victory Medical Center Pharmacy and Liebel-Flarsheim Company LLC for issues ranging from microbial contamination to particulate matter. Separately, the agency issued five significant Warning Letters, indicating a steady pace of enforcement actions.

2	4	6	65	1
NME Approvals	Total Drug Approvals	Efficacy Supplements	Device Clearances	PMA Originals

24

Asian Co. Events

🌏 Asian Company Watch — FDA Activity This Week

Coverage: drugs 2026-08-27–2026-09-02, devices 2026-08-10–2026-08-16 (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).

+ 2 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.

CIPLA India

> POMALIDOMIDE

CIPLA — Generic approval (ANDA) for POMALIDOMIDE.

DR REDDYS India

> POMALIDOMIDE

DR REDDYS — Generic approval (ANDA) for POMALIDOMIDE.

MACLEODS PHARMS LTD India

> MAGNESIUM SULFATE (2 models)

MACLEODS PHARMS LTD — Generic approval (ANDA) for MAGNESIUM SULFATE (SODIUM SULFATE, POTASSIUM SULFATE AND MAGNESIUM SULFATE).

PHARMAESSENTIA CORP Taiwan

> ROPEGINTERFERON ALFA-2B-NJFT (BESREMI)

PHARMAESSENTIA CORP — Drug approval (NDA/BLA) for ROPEGINTERFERON ALFA-2B-NJFT (BESREMI).

TAKEDA PHARMACEUTICALS U.S.A., INC. Japan

> RUSFERTIDE ACETATE (MIMRYLO)

The US entity of Takeda Pharmaceuticals received FDA approval for Mimrylo (rusfertide), an injectable drug for treating erythrocytosis in adults with polycythemia vera.

Shenzhen Goodwind Technology Development Co., Ltd. China

Eye Recovery Pro (PH-e03)

📈 1st clearance in 2026 (3 total since 2022) — established filer

🔗 Predicate: K233556 (Shenzhen Kaiyan Medical Equipment Co., Ltd., CN)

Shenzhen Goodwind Technology Development Co. received 510(k) clearance for an over-the-counter, light-based device intended for wrinkle reduction.

Intelligence: This clearance positions the Chinese manufacturer to compete in the growing US direct-to-consumer aesthetic device market.

Shenzhen Jianchao Intelligent Technology Co., Ltd. China

Hair Removal Device (2 models)

📈 2nd clearance in 2026 (5 total since 2023) — established filer

🔗 Predicate: K241881 (Shenzhen Junmei Technology Co., Ltd., CN)

Shenzhen Jianchao Intelligent Technology Co. obtained 510(k) clearance for a light-based, over-the-counter hair removal device.

Intelligence: Securing a 510(k) for an OTC aesthetic device may enable this Chinese company to pursue various US distribution channels, including online retail and direct marketing.

Hangzhou AGS MedTech Co., Ltd. China

Hemoclip (511 series, 543 series)

📈 3rd clearance in 2026 (19 total since 2018) — established filer

Hangzhou AGS MedTech Co., Ltd. received a 510(k) clearance for Hemoclip (511 series, 543 series). FDA classifies this device as: Hemostatic Metal Clip For The Gi Tract.

Beijing Nubway S&T Co., Ltd. China

Q Switched Nd:YAG Laser machine

📈 3rd clearance in 2026 (5 total since 2025) — established filer

🔗 Predicate: K152856 (Laseroptek Co., Ltd., KR)

Beijing Nubway S&T Co., Ltd. received a 510(k) clearance for Q Switched Nd:YAG Laser machine (QLQW-01). FDA classifies this device as: Powered Laser Surgical Instrument.

BeamWorks, Inc. South Korea

CadAI-B Dx

🆕 First FDA clearance — new US market entrant

🔗 Predicate: K210670 (Taihao Medical, Inc., TW)

South Korean company BeamWorks, Inc. received 510(k) clearance for CadAI-B Dx, a computer-assisted detection and diagnosis software for identifying potentially cancerous lesions.

Intelligence: This clearance for an AI-powered diagnostic software highlights the growing presence of Korean medtech firms in the competitive US medical imaging AI market.

Fujifilm Corporation Japan

BA-004CC

📈 10th clearance in 2026 (67 total since 2018) — established filer

Fujifilm Corporation received a 510(k) clearance for BA-004CC. FDA classifies this device as: Transducer, Ultrasonic, Diagnostic.

Nihon Kohden Corporation Japan

GF-310R Multigas Unit (GF-310R)

📈 2nd clearance in 2026 (20 total since 2015) — established filer

🔗 Predicate: K110594 (Nihon Kohden Corp., US)

Japanese medical device manufacturer Nihon Kohden Corporation received 510(k) clearance for its multigas unit, a device for analyzing respiratory gases like carbon dioxide.

Intelligence: This clearance for a patient monitoring component may support Nihon Kohden's strategy of providing integrated solutions for operating rooms and critical care settings in the US.

Hangzhou Ruidi Biotechnology, Ltd. China

Steep Pulse Ablation Instrument

🆕 First FDA clearance — new US market entrant

🔗 Predicate: K183385 (Angiodynamics, US)

Hangzhou Ruidi Biotechnology, Ltd. received a 510(k) clearance for Steep Pulse Ablation Instrument (including Disposable Sterile Steep Pulse Probe) (SPA-C02); Disposable Sterile Steep Pulse Probe (NPA-DJ01); Probe connection line (NPA-LX-02). FDA classifies this device as: Low Energy Direct Current Thermal Ablation System.

Menicon Co., Ltd. Japan

> MeniSept 3% Hydrogen Peroxide Cleaning…

📈 1st clearance in 2026 (41 total since 1989) — established filer

🔗 Predicate: K191872 (Menicon Co, Ltd., JP)

Japanese eye care company Menicon Co., Ltd. obtained 510(k) clearance for a hydrogen peroxide-based cleaning and disinfecting solution for soft contact lenses.

> **Intelligence:** Gaining clearance for a lens care solution complements Menicon's existing contact lens business in the US, allowing the company to offer a more complete product ecosystem.

Beijing Winkonlaser Technology Limited China

> High Intensity Focused Electromagnetic Stimulation Device

📈 1st clearance in 2026 (2 total since 2024) — established filer

🔗 Predicate: K250038 (Zhengzhou PZ Laser Slim Technology Co., Ltd., CN)

Beijing Winkonlaser Technology Limited received a 510(k) clearance for High Intensity Focused Electromagnetic Stimulation Device (FE60). FDA classifies this device as: Stimulator, Muscle, Powered, For Muscle Conditioning.

Guangzhou Heygears IMC., Inc. China

> UltraPrint Flexible Denture UV

📈 2nd clearance in 2026 (4 total since 2022) — established filer

🔗 Predicate: K250617 (Sprintray, Inc., US)

Guangzhou Heygears received 510(k) clearance for a flexible UV resin used for relining, repairing, and rebasing dentures.

Joytech Healthcare Co., Ltd. China

> Arm-type Fully Automatic Digital Blood…

🔗 Predicate: K230566 (Joytech Healthcare Co. , Ltd., CN)

Joytech Healthcare received 510(k) clearance for an arm-type automatic digital system measuring non-invasive blood pressure.

Mediclus Co., Ltd. South Korea

> Any-Cem

📈 6th clearance in 2026 (15 total since 2023) — established filer

🔗 Predicate: K073209 (Kerr Corporation, US)

Mediclus Co., Ltd. received a 510(k) clearance for Any-Cem. FDA classifies this device as: Cement, Dental.

Jiangsu Enjosim Medical Technology Co., Ltd. China

> Disposable Pen Injector (2 models)

🆕 First FDA clearance — new US market entrant

🔗 Predicate: K240961 (Wuxi Nest Biotechnology Co., Ltd., CN)

Jiangsu Enjosim received 510(k) clearance for a disposable pen injector, which is a piston syringe.

BMC Medical Co., Ltd. China

> Portable Oxygen Concentrator (2 models)

📈 2nd clearance in 2026 (6 total since 2014) — established filer

🔗 Predicate: K230052 (Inogen, Inc., US)

BMC Medical received 510(k) clearance for a portable oxygen concentrator, which generates oxygen.

Beijing Kreate Medical Co., Ltd. China

> Redermax® Antibacterial Wound Matrix

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

🔗 Predicate: K251582 (Beijing Kreate Medical Co., Ltd., CN)

Beijing Kreate Medical received 510(k) clearance for Redermax®, an antibacterial wound dressing matrix.

Scivita Medical Technology Co., Ltd. China

> Single-use Flexible Ureteroscope

📈 2nd clearance in 2026 (13 total since 2019) — established filer

🔗 Predicate: K243708 (Scivita Medical Technology Co., Ltd., CN)

Scivita Medical received 510(k) clearance for a single-use flexible ureteroscope and its accessories.

💊 Drug Approvals

4 new drug approvals this week (2 NMEs). 6 efficacy supplements. 8 generics (ANDA).

New Drug Approvals (NDA / BLA)

NDA220106 NME Priority Review Orphan Drug — PRIOVANT THERAPEUTICS INC

APPROVED INDICATION

New indication for Lisraya for the treatment of dermatomyositis in adult patients. [approval letter]

WHY IT MATTERS

This approval marks Priovant's first commercial product, establishing the company in the orphan autoimmune space.

RUSFERTIDE ACETATE MIMRYLO NME Priority Review Orphan Drug

TAKEDA PHARMACEUTICALS U.S.A., INC.

WHAT IT IS

Novel molecular entity, administered by injection, received FDA Priority Review and Orphan Drug designation.

APPROVED INDICATION

New indication for Mimrylo for the treatment of erythrocytosis in adults with polycythemia vera (PV). [approval letter]

BICTEGRAVIR/LENACAPAVIR BIXLENVO New Formulation Priority Review

GILEAD SCIENCES

WHAT IT IS

This new combination product, administered as oral tablets, received FDA Priority Review.

APPROVED INDICATION

New indication for Bixlenvo for HIV-1 treatment in virologically suppressed adults on a stable regimen without known resistance, replacing their current regimen. [approval letter]

NDA221443 **New Formulation** GILEAD SCIENCES INC

WHAT IT IS

This new co-packaged combination product is administered as oral tablets.

APPROVED INDICATION

New indication for Bixlenvo Sunlenca Starter Pack for initiating Bixlenvo in virologically suppressed adults with HIV-1 on a stable regimen without known resistance. [approval letter]

WHY IT MATTERS

This co-packaged starter kit is a commercial tool designed to facilitate patient initiation onto the new Bixlenvo regimen. Its approval is a necessary operational step for the launch of the main combination product.

Efficacy Supplements

ROPEGINTERFERON ALFA-2B-NJFT BESREMI

Efficacy Supplement (New Indication) **Orphan Drug** PHARMAESSENTIA CORP

APPROVED INDICATION

New indication for the treatment of adults with essential thrombocythemia. [approval letter]

WHY IT MATTERS

This second U.S. indication in a myeloproliferative neoplasm expands the commercial footprint for Taiwan-based PharmaEssentia, building on its initial polycythemia vera approval. The expansion into essential thrombocythemia could help solidify its product's position within the hematology-oncology market.

USTEKINUMAB USTEKINUMAB

Efficacy Supplement (New Indication) **Orphan Drug** JANSSEN BIOTECH

APPROVED INDICATION

New indication for the treatment of pediatric patients 2 years and older with moderately to severely active ulcerative colitis. [approval letter]

WHY IT MATTERS

This pediatric label expansion for ulcerative colitis is a key lifecycle management move for ustekinumab ahead of expected biosimilar competition. Securing use in younger patient populations could help defend market share as the adult market becomes more crowded.

LENACAPAVIR SODIUM SUNLENCA Efficacy Supplement (New Indication)

GILEAD SCIENCES INC

WHAT IT IS

Lenacapavir sodium is available as oral tablets.

APPROVED INDICATION

Labeling update for the treatment of HIV-1 in virologically suppressed adults on a stable antiretroviral regimen with no known or suspected resistance. [approval letter]

WHY IT MATTERS

A successful combination could be critical for defending Gilead's HIV franchise against long-acting injectable competition from ViiV Healthcare.

LENACAPAVIR SODIUM SUNLENCA Efficacy Supplement (Indication Expansion)

GILEAD SCIENCES INC

APPROVED INDICATION

Expands the use of Sunlenca for HIV-1 treatment in virologically suppressed adults on a stable antiretroviral regimen. [approval letter]

WHY IT MATTERS

A successful combination could be critical for defending Gilead's HIV franchise against long-acting injectable competition from ViiV Healthcare.

TIRZEPATIDE MOUNJARO Efficacy Supplement (Classification Unavailable)

ELI LILLY AND CO

WHAT IT IS

Tirzepatide's mechanism of action and formulation are not specified in the provided excerpt.

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]

TIRZEPATIDE MOUNJARO Efficacy Supplement (Classification Unavailable)

ELI LILLY AND CO

WHAT IT IS

Tirzepatide's mechanism of action and formulation are not specified in the provided excerpt.

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: **2026-08-10 to 2026-08-16** — FDA publishes device decisions later than drug approvals, so this differs from the report period (2026-08-27 to 2026-09-02) and is anchored to the latest available device data.

510(k) clearances: **65**. PMA (premarket approval) totals **31**, broken down below — Original/Panel-Track represent new or significant changes.

PMA Original: **1** | Panel-Track: **1** | 30-Day Notice: **22** | Other: **7**

PMA Approvals

BAGUERA®C Cervical Disc Prosthesis

Spineart USA, Inc.

> An intervertebral disc prosthesis designed for cervical spine replacement.

TruSight Oncology Comprehensive

Illumina, Inc.

> A next-generation sequencing oncology panel for detecting somatic or germline variants in cancer.

510(k) / De Novo Clearances (10-item excerpt, prioritizing Asian-company items — not date-ordered)

Device	Applicant	Date
Eye Recovery Pro (PH-e03) Light based over-the-counter wrinkle reduction device for cosmetic skin treatment.	Shenzhen Goodwind Technology Development Co., Ltd.	2026-08-10
Hair Removal Device (2 models) Light based over-the-counter hair removal device for cosmetic use.	Shenzhen Jianchao Intelligent Technology Co., Ltd.	2026-08-10
Hemoclip (511 series, 543 series) FDA classifies this device as: Hemostatic Metal Clip For The Gi Tract.	Hangzhou AGS MedTech Co., Ltd.	2026-08-10
Stelo Glucose Biosensor System Over-the-counter integrated continuous glucose monitor for non-intensive glucose management.	Dexcom, Inc.	2026-08-11
Q Switched Nd:YAG Laser machine FDA classifies this device as: Powered Laser Surgical Instrument.	Beijing Nubway S&T Co., Ltd.	2026-08-11

CadAI-B Dx FDA classifies this device as: Radiological Computer Assisted Detection/Diagnosis Software For Lesions Suspicious For Cancer.	BeamWorks, Inc.	2026-08-12
BA-004CC FDA classifies this device as: Transducer, Ultrasonic, Diagnostic.	Fujifilm Corporation	2026-08-12
GF-310R Multigas Unit (GF-310R) FDA classifies this device as: Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase.	Nihon Kohden Corporation	2026-08-12
Steep Pulse Ablation Instrument FDA classifies this device as: Low Energy Direct Current Thermal Ablation System.	Hangzhou Ruidi Biotechnology, Ltd.	2026-08-12
MeniSept 3% Hydrogen Peroxide Cleaning… Accessories for soft lens products, used for cleaning and disinfecting contact lenses.	Menicon Co., Ltd.	2026-08-13

* Full 65-item 510(k)/De Novo dataset available in the Excel file attached to this issue.

Device Recalls

(6 total, 2026-08-10 to 2026-08-11)

Company	Product	Reason	Class
Baxter Healthcare Corporation	Baxter Novum IQ Syringe Pump, Model Number 40800BAXUS	A software issue that may occur during a Volume/Time (VOT) multi-syringe infusion when a syringe reaches empty and is replaced while a Volume To Be Infused (VTBI) remains.	
Baxter Healthcare Corporation	Baxter Novum IQ Syringe Pump, Loaner, Model Number 40800BAXUSL	A software issue that may occur during a Volume/Time (VOT) multi-syringe infusion when a syringe reaches empty and is replaced while a Volume To Be Infused (VTBI) remains.	
Fresenius Medical Care Renal Therapies Group, LLC	5008X Standard HD Pre-Flush Standard Blood Tubing Set Part Number 03-5110-6	Heightened probability of blood leak from the connection between the Arterial Alpha Clip and the main line or pump segment. Leak during treatment may lead to blood loss and hypovolemia.	
Fresenius Medical Care Renal Therapies Group, LLC	5008X HD/HDF Standard Blood Tubing Set Part Number 03-5300-3	Heightened probability of blood leak from the connection between the Arterial Alpha Clip and the main line or pump segment. Leak during treatment may lead to blood loss and hypovolemia.	

Fresenius Medical Care Renal Therapies Group, LLC	5008X HD/HDF with CLiC Blood Tubing Set Part number 03-5300-3C	Heightened probability of blood leak from the connection between the Arterial Alpha Clip and the main line or pump segment. Leak during treatment may lead to blood loss and hypovolemia.
Fresenius Medical Care Renal Therapies Group, LLC	5008X HD/HDF with Twister Blood Tubing Set Part Number 03-5350-8	Heightened probability of blood leak from the connection between the Arterial Alpha Clip and the main line or pump segment. Leak during treatment may lead to blood loss and hypovolemia.

Note: "Class" is blank because openFDA's device recall data does not include a classification field for these records.

⚠️ Warning Letters

Total this week: **10** | Significant (manufacturing/GMP, or not classifiable as unapproved/labeling-only): **5** | Unapproved/labeling ONLY (no manufacturing-quality finding): **5**

United States **7** | India **2** | Germany **1**

📊 YTD 2026: only 17 of 57 letters (30%) could be assigned a country this year — too small a classified sample for a meaningful country breakdown (omitted).

Reliance Life Sciences Private Limited (CDER) India

> Marketing of an unapproved new drug product. Misbranding under the FD&C Act (the specific grounds are not available from this classification tag alone).

Jabil Inc. (CDER) United States

> CGMP (Current Good Manufacturing Practice) violations at the manufacturing facility. Deemed adulterated under the FD&C Act (a legal status that follows from CGMP non-conformance; it does not by itself indicate that product failed specifications).

Shoolin Pharma Chem LLP (CDER) India

> CGMP (Current Good Manufacturing Practice) violations at the manufacturing facility. Deemed adulterated under the FD&C Act (a legal status that follows from CGMP non-conformance; it does not by itself indicate that product failed specifications).

Fresenius Medical Care AG & Co. KGaA (CDER) Germany

> CGMP (Current Good Manufacturing Practice) violations at the manufacturing facility. Deemed adulterated under the FD&C Act (a legal status that follows from CGMP non-conformance; it does not by itself indicate that product failed specifications).

PReye, LLC (CDER) United States

> Marketing of an unapproved new drug product. Misbranding under the FD&C Act (the specific grounds are not available from this classification tag alone).

🔴 Drug Recalls

Drug Recalls (Top Items) (showing 10 rows covering 24 of 28 total recalls in the latest available recall data (2026-08-12 to 2026-08-19); 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
Victory Medical Center Pharmacy	Glutathione (MDV), 200 mg/mL, 30 mL vial, each mL contains Glutathione 200 mg, Ascorbic Acid 20 mg, Benzyl Alcohol 1.5%, Na Hydroxide (Ph Adjust) in sterile water for injection, VMC.	Microbial Contamination of Sterile Products - out of specifications results were obtained for bacterial endotoxin.	Class I
Buy-Herbal	Kian Pee Wan Capsules, 30-count bottles	Marketed Without an Approved NDA/ANDA: Product contains undeclared drug ingredients dexamethasone and cyproheptadine.	Class I
Liebel-Flarsheim Company LLC	Optiray Imaging Bulk Package-350, Ioversol Injection 74%, 350 mg/mL Organically Bound Iodine, 500 mL Multiple-Dose Vial, Rx only, Sterile Solution, Manufactured by: Liebel-Flarsheim Company LLC, Raleigh, NC 27616, Made in USA, NDC 0019-1333-65.	Presence of Particulate Matter: comprising polyethylene and other plastic materials, stainless steel and glass.	Class I
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
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

Prestige Brands Holdings	CLEAR EYES Maximum Itchy Eye Relief, 0.5 fl oz (15 mL) per dropper bottle, Sterile, Dist. by Medtech Products Inc., Tarrytown, NY 10591, a Prestige Consumer Healthcare Company. NDC: 67172-999-01 UPC 6 78112 65920 3	Lack of assurance of sterility. The recall is due to potential contamination	Class II
Shoolin Pharma Chem LLP ⚠️ Also appears in Warning Letters this week	SILDENAFIL CITRATE USP, 0.100 KG, 100 gm-bag Net Wt, RX ONLY “FOR Prescription Compounding Only“, Shoolin Pharma Chem LLP, Block/Survey no 408, B/H Ratnamani Tubes, Near Maruti Inox, Indrad, Kadi, Mahesana, Gujarat, 382715, India, (CAS NO. 171599-83-0) NDC 85702-001-05 (+4 similar recalls, same company & reason, grouped)	CGMP Deviations:Noted during FDA inspection	Class II
Apollo Care, LLC	SEMAGLUTIDE 7.5mg (5mg/mL), Glycine 7.5 mg (5mg/mL), 1.5 mL Sterile Multi-Dose Vial, Rx Only, For Subcutaneous Injection Only, APOLLO care, 3801 Mojave Ct, Ste 102, Columbia, MO 65202. NDC 71170-721-01 (+10 similar recalls, same company & reason, grouped)	Presence of Particulate Matter; identified as a nylon/polyamide and silk/proteinaceous-type material	Class II
Heritage Pharmaceuticals Inc	CLINDAMYCIN PALMITATE HYDROCHLORIDE FOR ORAL SOLUTION, USP, 75 mg/5 mL, Rx Only, 100 mL, Distributed by: Avet Pharmaceuticals Inc., East Brunswick, NJ 08816, NDC 23155-603-51	Presence of Foreign Substance: presence of particles and white flakes in the reconstituted bottles.	Class II

📋 FDA Guidance & Regulatory Actions

7 FDA regulatory documents this week.

Advancing Development of Botanical Drug Products; Request for Information (2026-09-04 • Notice)

This notice requests information to advance the development of botanical drug products. It affects pharmaceutical companies and researchers involved in botanical drug development.

Determination That PHENAPHEN WITH CODEINE NO. 3 (Acetaminophen; Codeine Phosphate) Oral Capsules, 325 Milligrams and 30 Milligrams, and PHENAPHEN WITH CODEINE NO. 4 (Acetaminophen; Codeine Phosphate) Oral Capsules, 325 Milligrams and 60 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness (2026-09-03 • Notice)

This notice determines that PHENAPHEN WITH CODEINE NO. 3 and NO. 4 were not withdrawn for safety or effectiveness. It affects generic drug manufacturers seeking to market equivalent products.

Determination That CARAFATE (Sucralfate) Oral Suspension, 1 Gram/10 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness (2026-09-02 • Notice)

This notice determines that CARAFATE oral suspension was not withdrawn for safety or effectiveness. It affects generic drug manufacturers seeking to market equivalent products.

Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosage; Draft Guidance for Industry; Availability (2026-09-02 • Notice)

This notice announces draft guidance on pharmacokinetics in patients with impaired hepatic function, covering study design and dosage impact. It affects pharmaceutical companies developing drugs for patients with liver impairment.

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; GENGLYCOS (parisglasgene brecaparvovec-opnr) (2026-09-02 • Notice)

This notice announces the issuance of a priority review voucher for GENGLYCOS, a rare pediatric disease product. It affects the sponsor of GENGLYCOS and other developers of rare pediatric disease therapies.

Determination That NAMENDA (Memantine Hydrochloride) Tablets, 5 Milligrams and 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness (2026-09-01 • Notice)

This notice determines that NAMENDA tablets were not withdrawn for safety or effectiveness. It affects generic drug manufacturers seeking to market equivalent products.

Rahim Shafa; Denial of Hearing; Final Debarment Order (2026-08-31 • Notice)

This notice announces a final debarment order for Rahim Shafa, following a denial of hearing. It affects Rahim Shafa, prohibiting participation in drug product applications.

📅 Upcoming FDA Regulatory Event Calendar

📝 Weekly Outlook

This week's notable events include Zilganersen (2026-09-22) and zilurgisertib (2026-09-26). 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	Company	Type
2026-09-22 in 17d	★★★★★	Zilganersen	Ionis Pharmaceuticals, Inc.	PDUFA
2026-09-26 in 21d	★★★★★	zilurgisertib	Mirum Pharmaceuticals, Inc.	PDUFA
2026-09-30 in 25d	★★★★★	apitegromab	Scholar Rock	PDUFA
2026-10-26 in 51d	★★★★★	Bepirovirsen	IONIS PHARMACEUTICALS INC (IONS) (CIK 0000874015)	PDUFA
2026-10-30 in 55d	★★★★★	INO-3107	INOVIO PHARMACEUTICALS, INC.	PDUFA

🆕 Changes Since Last Week

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

Date changes

- [PDUFA] encaleret: 2027-05-08 → 2027-05-07 (moved up)

🗓️ 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
2026-09-16 in 11d	★★★☆☆	Pediatric Advisory Committee (PAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments	—	Federal Register
2026-09-23 in 18d	★★★☆☆	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
2026-09-22 in 17d	★★★★★	Zilganersen	Ionis Pharmaceuticals, Inc.	Alexander disease (AxD)	SEC 8-K (Press Release)
2026-09-26 in 21d	★★★★★	zilurgisertib	Mirum Pharmaceuticals, Inc.	fibrodysplasia ossificans progressiva (FOP)	SEC 8-K (Press Release)
2026-09-30 in 25d	★★★★★	apitegromab	Scholar Rock	spinal muscular atrophy (SMA)	SEC 8-K (Press Release)
2026-10-26 in 51d	★★★★★	Bepirovirsen	IONIS PHARMACEUTICALS INC (IONS) (CIK 0000874015)	chronic hepatitis B (CHB)	SEC 8-K (Press Release)
2026-10-30 in 55d	★★★★★	INO-3107	INOVIO PHARMACEUTICALS, INC.	Recurrent Respiratory Papillomatosis (RRP)	SEC 8-K (Press Release)
2026-11-14 in 70d	★★★★★	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 Release)
2026-11-22 in 78d	★★★★★	Deramiocel	Capricor Therapeutics	Duchenne muscular dystrophy (DMD)	SEC 8-K (Press Release)
2026-11-27 in 83d	★★★★★	BBP-418	BridgeBio Pharma, Inc.	LGMD2I/R9	SEC 8-K (Press Release)
2026-11-30 in 86d	★★★★★	Povetacicept	Vertex	immunoglobulin A nephropathy (IgAN)	SEC 8-K (Press Release)

2026-12-03 in 89d	★★★★★	zanzalintinib	Exelixis, Inc.	metastatic colorectal cancer	SEC 8-K (Press Release)
2026-12-12 in 98d	★★★★★	Quimilza TM	Vanda Pharmaceuticals Inc.	Generalized Pustular Psoriasis (GPP)	SEC 8-K (Press Release)
2026-12-27 in 113d	★★★★★	relutrigine	Praxis Precision Medicines, Inc.	SCN2A and SCN8A developmental and epileptic encephalopathies (DEEs)	SEC 8-K (Press Release)
2026-12-30 in 116d	★★★★★	bezuclastinib	Cogent Biosciences, Inc.	NonAdvSM	SEC 8-K (Press Release)
2027-01-06 in 123d	★★★★☆	ANKTIVA	ImmunityBio, Inc.	BCG-unresponsive NMIBC with papillary disease without CIS	SEC 8-K (Press Release)
2027-01-21 in 138d	★★★★★	z-rostudirsen	Dyne Therapeutics, Inc.	Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping	SEC 8-K (Press Release)
2027-01-29 in 146d	★★★★★	ulixacaltamide	Praxis Precision Medicines, Inc.	Essential Tremor	SEC 8-K (Press Release)
2027-02-23 in 171d	★★★★☆	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 175d	★★★★★	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 Release)
2027-02-28 in 176d	★★★★☆	VOXZOGO	BioMarin Pharmaceutical Inc.	achondroplasia	SEC 8-K (Press Release)
2027-04-01 in 208d	★★★★★	Pitolisant GR	Harmony Biosciences Holdings, Inc.	narcolepsy	SEC 8-K (Press Release)

2027-04-28 in 235d	★★★★★	Varegacestat	Immunome, Inc.	desmoid tumors	SEC 8-K (Press Release)
2027-05-01 in 238d	★★★★★	AXS-12	Axsome Therapeutics, Inc.	cataplexy in narcolepsy	SEC 8-K (Press Release)
2027-05-07 in 244d	★★★★★	encaleret	BridgeBio Pharma, Inc.	autosomal dominant hypocalcemia type 1, or ADH1	SEC 8-K (Press Release)
2027-05-27 in 264d	★★★★★	obexelimab	Zenas BioPharma, Inc.	Immunoglobulin G4-Related Disease (IgG4-RD)	SEC 8-K (Press Release)

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

Expected Timing	Priority	Product	Company	Source
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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Representative	Hitoshi Tada
Business Address	Casabella Kokusai Plaza Bldg. #707, 1-1-18 Isobedori, Chuo-ku, Kobe-shi, Hyogo 651-0084, Japan
Phone	+81 90-2062-8461
Email	info@troy-technical.jp