FDA WEEKLY INTELLIGENCE • ASIAN MEDTECH & PHARMA TRACKER

FDA Weekly Report — Week 30, 2026

Coverage: 2026-07-16 – 2026-07-22 (FDA publish date basis)

Published: July 25, 2026

Note: FDA typically publishes approvals 1–2 weeks after decision date. This report reflects the latest available data as of publication.

This Week at FDA

The FDA's drug approval pipeline was quiet this week with no novel drugs approved, placing the strategic emphasis on lifecycle management as three products secured commercially significant label expansions. This lull in approvals contrasted with a robust medical device sector, which saw one high-risk PMA approval and a steady flow of 510(k) clearances, while a spike in enforcement activity, marked by five significant Warning Letters, signals heightened compliance risk across the industry. A notable concentration of regulatory events involving Asian firms further underscores their growing US market presence, presenting key strategic considerations for partnership and investment.

0	0	3	52	1
NME Approvals	Total Drug Approvals	New Indications	510(k) Clearances	Major PMA Approvals

8

Asian Co. Events

🌏 Asian Company Watch — FDA Activity This Week

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).

🇨🇳 SteriLance Medical (Suzhou), Inc. China

Lancing Device (5 models)

SteriLance Medical, a company based in Suzhou, China, received 510(k) clearance for a series of lancing devices used for capillary blood sampling.

Intelligence: This clearance for multiple models of a fundamental diabetes care device could position the Chinese manufacturer to compete in the high-volume, price-sensitive segment of the US point-of-care diagnostics market.

🇰🇷 GC America, Inc. South Korea

Cytrans™ Elashield

The US subsidiary of South Korea's GC Group has received 510(k) clearance for Cytrans Elashield, a liquid bandage for minor cuts and scrapes.

Market Impact: With this over-the-counter wound care product, GC Group's US entity may be seeking to leverage its existing dental and healthcare distribution channels to expand into the broader consumer first-aid market.

🇨🇳 Beijing Infervision Healthcare Medical Technology Co., Ltd. China

InferOperate Suite

Beijing Infervision Healthcare has gained 510(k) clearance for its InferOperate Suite, a software platform for 3D medical image processing and surgical planning.

Strategic View: This clearance for a sophisticated surgical planning software suite suggests Chinese AI-driven medtech firms are moving beyond diagnostic imaging analysis and into higher-value, pre-operative clinical decision support tools for the US market.

🇨🇳 Yongkang Ruihe Metal Product Co., Ltd. China

Electric wheelchair (XW-LY007)

Chinese manufacturer Yongkang Ruihe Metal Product Co. received 510(k) clearance for its model XW-LY007 electric wheelchair.

Competitive Implication: As one of two recent clearances for the company, this event may support an effort to establish a portfolio of personal mobility devices for the US durable medical equipment (DME) market.

🇨🇳 Yongkang Ruihe Metal Product Co., Ltd. China

Mobility Scooter (R200)

Yongkang Ruihe Metal Product Co. secured a 510(k) clearance for its R200 model mobility scooter.

Commercial Outlook: Following its electric wheelchair clearance, this addition of a mobility scooter broadens the company's product offerings and could strengthen its position as a potential supplier for US distributors of home healthcare and mobility aids.

🇨🇳 Ningbo Resshidi Medical Devices Co., Ltd. China

Electric Wheelchair

Ningbo Resshidi Medical Devices Co., a Chinese company, has obtained 510(k) clearance for an electric wheelchair.

Intelligence: The entry of another Chinese manufacturer into the cleared electric wheelchair space highlights the increasing competition from Asia in the US market for durable medical equipment, potentially impacting pricing and supply chain dynamics for domestic distributors.

🇰🇷 DiaDent Group International South Korea

DIA-CEM

South Korea's DiaDent Group International received 510(k) clearance for DIA-CEM, a self-adhesive resin cement used for dental restorations.

Market Impact: This clearance for a key dental consumable reinforces the Korean company's established position in the endodontic and restorative materials segment, adding another product to its portfolio for US dental practices.

🇨🇳 Zhejiang Lumbre Electric Appliance Co., Ltd. China

> Electric Wheelchair (DY611A-2, DY612A-1)

Zhejiang Lumbre Electric Appliance Co. from China has received 510(k) clearance for two models of its electric wheelchair.

> **Strategic View:** By securing clearance for multiple wheelchair models simultaneously, this Chinese manufacturer could be positioning itself to offer a range of options to US durable medical equipment providers, competing on portfolio breadth.

💊 Drug Approvals

0 new drug approvals this week (0 NMEs). 3 efficacy supplements. 8 generics (ANDA).

New Indications (Efficacy Supplements)

TILDRAKIZUMAB-ASMN ILUMYA **New Formulation** SUN PHARMA GLOBAL

WHAT IT IS

Tildrakizumab-asmn is an IL-23 inhibitor monoclonal antibody administered via subcutaneous injection.

WHY IT MATTERS

This label expansion into psoriatic arthritis is a critical step for Sun Pharma's specialty business, positioning ILUMYA to compete in a lucrative but crowded immunology market. The approval may demonstrate the company's growing capability to execute on complex biologic development in the US, potentially signaling further ambitions in this space.

IPTACOPAN FABHALTA **New Formulation** **Priority Review** NOVARTIS

WHAT IT IS

Iptacopan is a first-in-class oral Factor B inhibitor, granted FDA Priority Review.

Adults with paroxysmal nocturnal hemoglobinuria.

WHY IT MATTERS

The approval in IgA nephropathy establishes Fabhalta as the first complement inhibitor for this disease, offering a new mechanistic approach that could challenge recently launched therapies. This second major indication validates Novartis's oral complement platform beyond rare hematology, potentially unlocking a pipeline-in-a-product opportunity across multiple renal diseases.

REZAFUNGIN REZZAYO **New Formulation** MUNDIPHARMA

WHAT IT IS

Rezafungin is a novel echinocandin antifungal administered via intravenous infusion.

Adults with candidemia and invasive candidiasis.

WHY IT MATTERS

This approval for prophylaxis in transplant patients significantly expands Rezzayo's market opportunity beyond its initial, more limited treatment indication. Its once-weekly dosing is expected to be a key differentiator against daily antifungals, potentially capturing market share by offering a more convenient option for a vulnerable patient population.

🩺 Medical Devices

510(k) clearances: **52** | PMA total: **39** — Original: **1**, Panel-Track: **0**, 30-Day Notice: **25**, Other supplements: **13**

Major PMA Approvals

Belotero® Intense (+) Lidocaine

Merz North America, Inc.

> Hyaluronic acid dermal filler for correcting deep facial wrinkles and folds, containing lidocaine for comfort.

510(k) Clearances (most recent 10)

Device	Applicant	Date
Lancing Device (5 models) Lancing device for obtaining capillary blood samples, primarily for glucose monitoring.	SteriLance Medical (Suzhou), Inc.	2026-07-06
Cytrans™ Elashield Medical device - Dental material for use as a protective liner or base in dental restorations.	GC America, Inc.	2026-07-06
InferOperate Suite Medical device - AI-powered software for surgical planning and guidance, enhancing procedural efficiency.	Beijing Infervision Healthcare Medical Technology Co., Ltd.	2026-07-07
Electric wheelchair (XW-LY007) Electric wheelchair providing mobility assistance for individuals with limited or impaired ambulation.	Yongkang Ruihe Metal Product Co., Ltd.	2026-07-07
Mobility Scooter (R200) Mobility scooter offering independent transportation for individuals with reduced walking ability.	Yongkang Ruihe Metal Product Co., Ltd.	2026-07-07
Electric Wheelchair Electric wheelchair providing mobility assistance for individuals with limited or impaired ambulation.	Ningbo Resshidi Medical Devices Co., Ltd.	2026-07-08
DIA-CEM Medical device - Dental cement for luting indirect restorations like crowns, bridges, and inlays.	DiaDent Group International	2026-07-09
Electric Wheelchair (DY611A-2, DY612A-1) Electric wheelchair providing mobility assistance for individuals with limited or impaired ambulation.	Zhejiang Lumbre Electric Appliance Co., Ltd.	2026-07-10
Plum Vagiceuticals™ Vaginal… Vaginal suppositories for moisturizing and alleviating symptoms associated with vaginal dryness.	PCCA, Inc.	2026-07-06

INDIRA CLOUD VIEWER Medical device - Software for viewing and managing medical images or patient data in a cloud environment.	INDIGO TECHNOLOGIES	2026-07-06

* Full 52-item 510(k) dataset available in the Excel file attached to this issue.

⚠️ Warning Letters

Total this week: **5** | Significant (manufacturing/GMP): **5** | Unapproved/labeling: **0**

Shimoga Chemicals (CDER)

> Violations of Current Good Manufacturing Practice (CGMP) for active pharmaceutical ingredients led to adulterated products.

Almon Healthcare Private Limited (CDER)

> Failure to adhere to CGMP standards for active pharmaceutical ingredients resulted in adulterated products.

Island Kinetics, Inc. d.b.a. CoValence Laboratories (CDER)

> Manufacturing of finished pharmaceutical products with CGMP violations, including the sale of unapproved new drugs that were misbranded and adulterated.

BioMylz Pvt. Ltd. (CDER)

> Finished pharmaceutical products were found to be adulterated and misbranded due to CGMP deficiencies.

Pratik Doshi, M.D. / Alembic Pharmaceuticals Ltd. (CDER)

> Deficiencies were identified in the conduct of in vivo bioavailability and bioequivalence clinical studies.

🔴 Drug Recalls

Product	Reason	Class
Methohexital Sodium for Injection, USP 500 mg Mult	Failed Impurities/Degradation Specifications	Class II
Gasco Isopropyl Alcohol 70%, Net Contents: 1 US Ga	Subpotent drug	Class II
Gasco Isopropyl Alcohol 70%, 32 oz (946 mL) Gasco	Subpotent drug	Class II
Drogueria San Juan Puerto Rico Isopropyl Alcohol 7	Subpotent drug	Class II
Clomiphene Citrate USP Active Pharmaceutical Ingre	cGMP deviations	Class II
Pemetrexed for Injection 500mg/Vial, 1 50 mL Singl	Lack of Sterility Assurance	Class II
Gasco Isopropyl Alcohol 70%, Net Contents: 16 Oz.	Subpotent drug	Class II
Drogueria San Juan Puerto Rico Isopropyl Alcohol 7	Subpotent drug	Class II
Bortezomib for Injection 3.5mg/Vial, 10 mL per Sin	Lack of Sterility Assurance	Class II
Pemetrexed for Injection 100mg/Vial, 1 10 mL Singl	Lack of Sterility Assurance	Class II

📋 FDA Guidance & Regulatory Actions

11 FDA regulatory documents this week.

Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments-Biologics License Application (BLA) 125827, From Replimune, Inc. for Vusolimogene Oderparepvec (2026-07-24 • Notice)

This notice announces a public meeting and requests comments on BLA 125827 for Vusolimogene Oderparepvec. It affects biologics manufacturers, particularly those developing gene therapies.

Cellular, Tissue, and Gene Therapies Advisory Committee; Amendment of Notice-Biologics License Application (BLA) 125842 From Capricor, Inc. for Deramiocel (Human Allogeneic Cardiosphere-Derived Cells) (2026-07-24 • Notice)

This notice amends a previous announcement regarding BLA 125842 for Deramiocel. It affects biologics manufacturers, especially those developing human allogeneic cell therapies.

Francis Esteban Matos: Final Debarment Order (2026-07-24 • Notice)

This notice announces a final debarment order against Francis Esteban Matos. It affects individuals and pharmaceutical companies, preventing the debarred individual from providing services related to drug product applications.

Medical Devices; Orthopedic Devices; Classification of the Intraoperative Surgical Angle Measurement Tool (2026-07-24 • Rule)

This final rule classifies the Intraoperative Surgical Angle Measurement Tool. It affects medical device manufacturers producing orthopedic surgical instruments.

Medical Devices; General Hospital and Personal Use Devices; Classification of the Diabetes Digital Behavioral Therapeutic Device (2026-07-24 • Rule)

This final rule classifies the Diabetes Digital Behavioral Therapeutic Device. It affects medical device manufacturers developing digital therapeutics for diabetes management.

Medical Devices; Immunology and Microbiology Devices; Classification of the Over-the-Counter Test To Detect SARS-CoV-2 From Clinical Specimens (2026-07-24 • Rule)

This final rule classifies the Over-the-Counter Test to Detect SARS-CoV-2. It affects medical device manufacturers producing OTC diagnostic tests for infectious diseases.

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Prognostic Test for Assessment of Chronic Kidney Disease Progression (2026-07-24 • Rule)

This final rule classifies the Prognostic Test for Assessment of Chronic Kidney Disease Progression. It affects medical device manufacturers of clinical chemistry diagnostic tests.

FDA's Strategy Document on Facilitating Chemistry, Manufacturing, and Controls Readiness for Products With Accelerated Clinical Development (2026-07-23 • Notice)

This notice announces FDA's strategy document on facilitating Chemistry, Manufacturing, and Controls readiness. It affects pharmaceutical and biologics manufacturers with products undergoing

accelerated clinical development.

Advisory Committee; Peripheral and Central Nervous System Drugs Advisory Committee; Termination and Reestablishment (2026-07-23 • Notice)

This notice announces the termination and reestablishment of the Peripheral and Central Nervous System Drugs Advisory Committee. It affects pharmaceutical companies developing neurological drugs.

Determination That RASUVO (Methotrexate) Solution, 27.5 Milligrams/0.55 Milliliter (27.5 Milligrams/0.55 Milliliter), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness (2026-07-22 • Notice)

This notice determines that RASUVO (Methotrexate) Solution was not withdrawn for safety or effectiveness reasons. It affects generic drug manufacturers seeking to market a generic version.

Expedited Investigational New Drug Pilot Program; Request for Information; Extension of the Comment Period (2026-07-21 • Notice)

This notice announces an extension of the comment period for a Request for Information on the Expedited Investigational New Drug Pilot Program. It affects pharmaceutical companies and researchers.

FDA Weekly Intelligence

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

Auto-generated • 2026-07-25 01:09 UTC

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