

FDA Weekly Report — Week 28, 2026

Coverage: 2026-06-26 – 2026-07-02 (FDA publish date basis)

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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

This week's FDA activity was defined by a quiet period for novel drugs, contrasted by robust developments in medical devices and label expansions. The sole new drug approval was the New Molecular Entity LUMVOA (veligrotug), while five successful efficacy supplements highlight the continued industry focus on lifecycle management to expand market access for existing assets. A high volume of device clearances, including five original PMAs for high-risk products, indicates sustained innovation in medtech, and significant activity from Asian-based firms underscores their expanding role in the US regulatory landscape. No significant Warning Letters were identified within this week's reporting scope.

1

NME Approvals

1

Total Drug
Approvals

5

New Indications

203

510(k)
Clearances

5

PMA Originals

64

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).



Honeynaps Co., Ltd. South Korea

SOMNUM (SOMNUM)



Shenzhen Changkun Technology Co., Ltd. China

Electric breast pump (6 models)



Ziree Co., Ltd. China

Laser Hair Growth Devices (15 models)



Shenzhen Dongdixin Technology Co., Ltd. China

TENS 7000 Rechargeable 4 Channel



Vistar Medical Supplies Co., Ltd. China

DVT Garment



Seers Technology Co., Ltd. South Korea

mobiCARE Cardiac Monitoring System (4 models)



Weyo Surgical Technology, Ltd. China

Insufflator (6 models)



Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

China

A5 Anesthesia System



Shenzhen Qinyi Electronic Technology Co., Ltd.

China

Wearable breast pump (3 models)



Shanghai Waylong Intelligent Technology Co., Ltd.

China

Smart Electric Wheelchair (4 models)



Hangzhou Jimushi Meditech Co., Ltd.

China

Hydrophilic coated intermittent nalaton...



Olympus Medical Systems Corporation

Japan

HD Camera Head OLYMPUS CH-S200-08-LB



Hangzhou AGS MedTech Co., Ltd.

China

Single-use Balloon Dilatation Catheter...



CG Bio Co., Ltd.

South Korea

CURASYS 2 (EMDN0003)



Microlife Corporation

Taiwan

Microlife Digital Peak Flow Meter, Model PF200B



Guangdong Yong Yi Rehabilitation Equipment Technology Co., Ltd.

China

Caregiver-assisted wheelchair



Guangdong Yong Yi Rehabilitation Equipment Technology Co., Ltd.

China

Manual Wheelchair



Shenzhen Ziqing Medical Equipment Co., Ltd.

China

Wrist Blood Pressure Monitor (XW-05)



Shantou Institute of Ultrasonic Instruments Co., Ltd.

China

Portable DR Imaging System



Shenzhen Konmed Technology Co., Ltd.

China

Pelvic Muscle Trainer (KM510, KM516B)



Zhejiang Innuovo Rehabilitation Devices Co., Ltd.

China

Power Wheelchair (3 models)



MegaGen Implant Co., Ltd.

South Korea

MegaGen Zygoma Dental Implant System



Micro-Energy Medical Technology Co., Ltd.

China

Hemolase Fiber



GC America, Inc. South Korea

SRGC-06



Suzhou and Science & Technology Development Corp. China

AND Medical Femoral Nail System



Vieworks Co., Ltd. South Korea

VIVIX-S 4386W (FXRD-4386WA)



Guangzhou Rebornendo Medical Instrument Co., Ltd. China

Curing Light (M-Cure 6)



FUJIFILM Healthcare Americas Corporation Japan

Synapse PACS (7.6.0)



Guangdong Newdermo Biotech Co., Ltd. China

LED Light Therapy Mask (6 models)



Shenzhen Root Innovation Technology Co., Ltd. China

Momcozy Wearable Breast Pump (5 models)



Oeness Biotech Co., Ltd. Taiwan

Bonvadis®



Shenzhen Root Innovation Technology Co., Ltd. China

Momcozy Wearable Breast Pump (5 models)



Hua Yue Medical Technology Co., Ltd.

China

Assisted Reproduction Laser System



Beijing Fule Science & Technology Development Co., Ltd.

China

Fule Metallic Lockable Intramedullary...



Foshan Pingchuang Medical Technology Co., Ltd.

China

Non-Sterile Ultrasound Gel; Sterile...



Socko Medical Co., Ltd.

Taiwan

"Socko" Vimax Spinal Fixation System



Honsun (Nantong) Co., Ltd.

China

Portable Oxygen Concentrator



Shenzhen Kaiyan Medical Equipment Co., Ltd.

China

LED Neck Beauty Mask (4 models)



Zdeer Technology (Henan) Co., Ltd.

China

Laser Hair Growth Device (9 models)



Hubei Yjt Technology Co., Ltd.

China

Laser Hair Growth System (5 models)



Zhejiang Decans Medical Devices Co., Ltd.

China

HERA Interlocking Intramedullary...



Hivox Biotech, Inc. Taiwan

TENS / EMS DEVICE (2 models)



Fujifilm Corporation Japan

FUJIFILM Endoscope Model EB-840S;...



Hunan Ruijiong Biotech Co., Ltd. China

KT Airway Clearance Device II



Medpark Co., Ltd. South Korea

BOSS



Crescom Co., Ltd. South Korea

MediAI-OA



Zhongshan Sulenz Intelligent Technology Co., Ltd. China

Electric Wheelchair (S500-6)



Zdeer Technology (Henan) Co., Ltd. China

Bone Conduction Hearing Aid (38 models)



Medyssey Co., Ltd. South Korea

NeckTune™ 3D SA Cervical Cage



Beijing Fule Science & Technology Development Co., Ltd. China

Fule Interbody Fusion Cage System



JPI Healthcare Co., Ltd. South Korea

DRE Duo



Gimbo Medical Technology Shenzhen Co., Ltd. China

Giftlife Single Lumen Oocyte Retrieval...



LG Electronics Inc. South Korea

Medical Monitor (40HT513D)



Sanhe LEFIS Electronics Co., Ltd. China

Intense Pulsed Light Therapy Device



Whill, Inc. Japan

WHILL (WHILL Model C2)



Dyne Medical Group, Inc. South Korea

DYNE PORT



Polybell (Guangzhou) Limited China

Electric Breast Pump (13 models)



SteriLance Medical (Suzhou), Inc. China

Disposable Blood Lancet (Soft)



Changzhou Boen Zhongding Medical Technology Co., Ltd. China

Dental X-ray System



Avita Corporation Taiwan

AViTA Breast Pump



Shenzhen Magnet Technology Co., Ltd. China

Bone Conduction Hearing Aid (3 models)



Nagy Oral Technology Qinhuangdao Co., Ltd. China

Fluoride Varnish (Type A, Type C)



Hass Corp. South Korea

Rosetta SM, Rosetta SP



Hitachi High-Tech Corp. Japan

PROBEAT-CR

1 new drug approvals this week (1 NMEs). 5 efficacy supplements. 17 generics (ANDA).

New Drug Approvals (NDA / BLA)

VELIGROTUG

LUMVOA

NME

Priority Review

VIRIDIAN THERAPEUTICS INC

WHAT IT IS

Novel PDGFR α inhibitor; IV infusion; FDA Priority Review.

WHY IT MATTERS

As a new molecular entity for thyroid eye disease, this approval positions Viridian as a potential challenger to Amgen's blockbuster TEPEZZA. Its commercial success will likely depend on demonstrating a more convenient dosing profile compared to the established intravenous incumbent.

New Indications (Efficacy Supplements)

LETROZOLE AND RIBOCICLIB

KISQALI FEMARA CO-PACK

New Formulation

Priority Review

NOVARTIS

WHAT IT IS

This co-pack combines an aromatase inhibitor and a CDK4/6 inhibitor, administered orally, with FDA Priority Review.

Adults with HR-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence.

WHY IT MATTERS

This adjuvant approval for early breast cancer represents a major market expansion for Kisqali, moving it into a much larger patient population with longer treatment duration. It positions Novartis to directly challenge Eli Lilly's Verzenio for market leadership in this lucrative setting, where Pfizer's Ibrance previously failed.

RIBOCICLIB

KISQALI

New Formulation

Priority Review

NOVARTIS

WHAT IT IS

This CDK4/6 inhibitor is administered orally, with FDA Priority Review.

Adults with HR-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence.

WHY IT MATTERS

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ROFLUMILAST

ZORYVE

New Formulation

ARCUTIS

WHAT IT IS

This selective phosphodiesterase-4 inhibitor is applied topically as a cream.

Adults and pediatric patients 9 years and older with seborrheic dermatitis.

WHY IT MATTERS

By securing a label expansion into the large atopic dermatitis market, Arcutis could significantly broaden Zoryve's revenue base beyond psoriasis. Its once-daily, steroid-free profile may position it as a competitive alternative to Pfizer's twice-daily Eucrisa and a potentially safer option compared to topical JAK inhibitors with boxed warnings.

RISANKIZUMAB-RZAA

SKYRIZI

New Formulation

ABBVIE INC

WHAT IT IS

This IL-23 inhibitor, a humanized monoclonal antibody, is administered via subcutaneous injection.

Adults with moderately to severely active ulcerative colitis.

WHY IT MATTERS

This approval in ulcerative colitis is a critical component of AbbVie's strategy to transition its immunology franchise from the biosimilar-exposed Humira to Skyrizi. Expanding into another major IBD indication is expected to help defend AbbVie's market leadership and capture share from competitors like Johnson & Johnson's Stelara.

VIMSELTINIB

ROMVIMZA

New Formulation

DECIPHERA PHARMS

WHAT IT IS

This selective oral tyrosine kinase inhibitor targeting KIT and PDGFR α is administered orally.

WHY IT MATTERS

This approval positions Romvimza to potentially become the new standard of care for TGCT, as it enters the market without the severe liver toxicity warning that has limited the use of its only direct competitor, Turalio. For Deciphera, this provides a second commercial product and a significant opportunity to capture the majority of the market for this rare disease.

510(k) clearances: **203** | PMA Original: **5** | Panel-Track: **2** | 30-Day Notice: **67**

PMA Approvals

AMDS Hybrid Prosthesis

Artivion, Inc.

Cardiovascular prosthesis for surgical repair of aortic pathologies.

Centralized Lung Evaluation System (CLES)

Lung Bioengineering, Inc.

Lung assessment system for evaluating donor lung viability prior to transplantation.

HepQuant SHUNT® Liver Diagnostic Test

Hepquant, LLC

In vitro diagnostic test for assessing liver function and portosystemic shunting.

saypha® ChiQ™

Croma-Pharma GmbH

Dermal filler for improving skin smoothness and hydration.

VENTANA PTEN (SP218) RxDx Assay

Ventana Medical Systems, Inc. (Roche Tissue Diagnostics)

In vitro diagnostic assay for detecting PTEN protein expression as a companion diagnostic.

ETHIZIA Hemostatic Patch

ETHICON, Inc.

Surgical hemostatic device for controlling bleeding during various surgical procedures.

SKINVIVE by JUVEDERM®

Allergan

Dermal filler for improving skin smoothness and hydration.

510(k) Clearances (most recent 10)

Device	Applicant	Date
MIST IC Medical device - dental milling system for fabricating dental prosthetics.	Imagine Milling Technologies, LLC	2026-06-27

BraiN20® (BraiN20) Neurological monitoring device for assessing brain activity and function.	Time IS Brain, S.L.	2026-06-27
SOMNUM (SOMNUM) Sleep monitoring device for diagnosing and managing sleep disorders.	Honeynaps Co., Ltd.	2026-06-27
BioHorizons CEREC Compatible Ti-Bases Dental implant components for supporting CAD/CAM fabricated dental prosthetics.	BioHorizons Implant Systems, Inc.	2026-06-26
VERTICALE® Navigation Instruments Surgical navigation instruments for guiding orthopedic procedures.	Silony Medical GmbH	2026-06-26
PhAST instrument and PhAST Blood... In vitro diagnostic system for rapid identification of Gram-negative bacteria from blood cultures.	Phast Corp.	2026-06-26
i-STAT Crea cartridge with the i-STAT 1... Point-of-care diagnostic system for rapid measurement of creatinine in blood.	Abbott Point of Care, Inc.	2026-06-26
LightningWire Transseptal Puncture System Cardiac access system for performing transseptal punctures during electrophysiology procedures.	ElectroWire Medical	2026-06-26
Arterial Pressure Monitoring Set/Tray Vascular monitoring kit for continuous measurement of arterial blood pressure.	Spectrum Vascular	2026-06-26
Arthrex FiberButton Orthopedic fixation device for ligament and tendon repair in arthroscopic surgery.	Arthrex, Inc.	2026-06-26

* Full 203-item 510(k) dataset available in the Excel file attached to this issue.

Warning Letters

Total this week: **13** | Significant (manufacturing/GMP): **0** | Unapproved/labeling: **13**

Drug Recalls

Product	Reason	Class
Lacosamide Tablets, USP, C V, 100mg, Rx only, 60-c	Presence of a Foreign Tablets: Complaint received, possible mix-up of Selexipag	Class II
Corlanor (ivabradine) tablets, 7.5mg, 60-count bot	Presence of Foreign Substance.	Class II
Corlanor (ivabradine) tablets, 5 mg, packaged in a	Presence of Foreign Substance.	Class II
BD Chloraprep Clear, (2% w/v chlorhexidine gluconate)	Lack of Assurance of Sterility: Due to wrinkles in the paper lidding which may b	Class II
Fenofibrate Capsules, USP 200 mg, Rx only, 100 Cap	CGMP Deviations	Class II
Sensipar (cinacalcet) Tablets, 60mg, 30-count bott	CGMP Deviations	Class II
Povi-One, 10% Povidone-Iodine Oral Antiseptic, Pac	sub potency	Class II
DULOXETINE D/R, a) 30 mg (NDC 61919-482-30), 30 Ca	CGMP Deviations: Presence of N-nitroso-duloxetine impurity above FDA recommended	Class II
BD Chloraprep FREPP Clear, (2% w/v chlorhexidine g	Lack of Assurance of Sterility: Due to wrinkles in the paper lidding which may b	Class II
Total Parental Nutrition - Pediatric PN Patient-Sp	Incorrect product formulation: bag did not contain copper and famotidine per lab	Class II

FDA Guidance & Regulatory Actions

6 FDA regulatory documents this week.

[Determination That TOVALT ODT \(Zolpidem Tartrate\) Orally Disintegrating Tablets, 5 Milligrams and 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness](#) (2026-07-09 • Notice)

This Notice states that TOVALT ODT (Zolpidem Tartrate) was not withdrawn for safety or effectiveness reasons. It affects generic drug manufacturers seeking to file ANDAs for this product.

[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](#) (2026-07-08 • Notice)

This Notice announces a public meeting and requests comments on BLA 125827 for Vusolimogene Oderparepvec. It affects biopharmaceutical companies developing cellular, tissue, and gene therapies.

[Medical Device User Fee Amendments; Public Meeting; Request for Comments](#) (2026-07-08 • Notice)

This Notice announces a public meeting and requests comments on the Medical Device User Fee Amendments. It affects the medical device industry, particularly manufacturers subject to MDUFA fees.

[Endo Operations Limited, et al.; Withdrawal of Approval of 34 New Drug Applications](#) (2026-07-06 • Notice)

This Notice announces the withdrawal of approval for 34 New Drug Applications from Endo Operations Limited and other companies. It affects the pharmaceutical industry, particularly the listed NDA holders.

[Expedited Investigational New Drug Pilot Program; Request for Information; Correction](#) (2026-07-06 • Notice)

This Notice provides a correction to a previous request for information on the Expedited Investigational New Drug Pilot Program. It affects pharmaceutical and biotechnology companies developing new drugs.

[Determination That VASOPRESSIN IN SODIUM CHLORIDE \(vasopressin\) 0.9%, Injection, 50 units/50 milliliters \(1 unit/milliliters\) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness](#) (2026-07-06 • Notice)

This Notice states that VASOPRESSIN IN SODIUM CHLORIDE was not withdrawn for safety or effectiveness reasons. It affects generic drug manufacturers seeking to file ANDAs for this product.

FDA Weekly Intelligence

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

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