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Pediatric information added to labeling of over 141 drugs, biologics in 2025

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The Food and Drug Administration (FDA) continues efforts to increase the availability of pediatric use information in the labeling for drugs and biologics.

Between January and December 2025, pediatric use information was added to the labeling of more than 141 drugs and biologics.

A pediatric labeling change refers to any update to a product's labeling to add information about safety, effectiveness or dosing in children. Many, but not all, labeling changes represent a new FDA approval for an indication in children.

Noteworthy pediatric approvals in the U.S. by FDA in 2025 include:

Ajovy (fremanezumab-vfrm) subcutaneous injection was approved for the preventive treatment of episodic migraine in pediatric patients 6 years and older who weigh at least 45 kilograms (kg). It is the first calcitonin gene-related peptide antagonist approved for the preventive treatment of episodic migraine in children.

Baqsimi (glucagon) nasal powder was approved for the treatment of severe hypoglycemia in pediatric patients 1 year and older with diabetes. It was originally approved for patients 4 years and older with diabetes. It is the first nasally administered glucagon to treat severe hypoglycemia.

Blujepa (gepotidacin) oral tablets and Nuzolvence (zoliflodacin) granules for oral suspension were approved for the treatment of uncomplicated urogenital gonorrhea in patients 12 years and older weighing at least 45 kg (gepotidacin) or 35 kg (zoliflodacin). These approvals provide additional treatment options for urogenital gonorrhea given the global rise in gonococcal drug resistance. Because of limited clinical safety data, gepotidacin is for patients who have few or no other treatment choices.

Brinsupri (brensocatib) oral tablets were approved for treatment of non-cystic fibrosis bronchiectasis in patients 12 years and older. It is the first drug approved for this indication.

Itvisma (onasemnogene abeparvovec-brve) intrathecal injection, an adeno-associated virus vector-based gene therapy, was approved for treatment of spinal muscular atrophy (SMA) in patients 2 years and older with a confirmed mutation in the survival motor neuron 1 gene. It is the first gene therapy for SMA for patients 2 years and older.

Linzess (linaclotide) oral capsules were approved for the treatment of irritable bowel syndrome with constipation (IBS-C) in patients 7 years and older. It is the first treatment approved for IBS-C in pediatric patients. Linaclotide is also approved in patients 6 years and older for treatment of functional constipation.

Neffy (epinephrine) nasal spray was approved in a new 1 mg of epinephrine per spray dosage form for emergency treatment of type 1 allergic reactions, including anaphylaxis, in pediatric patients 4 years and older weighing 15 kg to less than 30 kg. It was originally approved for this indication in adult and pediatric patients weighing 30 kg or more in a 2 mg epinephrine per spray dosage form. It is the first non-injection epinephrine to treat anaphylaxis.

Odactra (house dust mite allergen extract) sublingual tablets were approved in patients 5 years and older as immunotherapy for the treatment of house dust mite-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites or by positive skin testing to licensed house dust mite allergen extracts. This immunotherapy was previously approved for patients 12 years and older.

Opzelura (ruxolitinib) topical cream was approved for short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised pediatric patients 2 years and older whose disease is not controlled with topical prescription therapies, or when those therapies are not advisable. It was previously approved for this indication in pediatric patients 12 years and older. It is the first topical Janus kinase (JAK) inhibitor approved for pediatric atopic dermatitis.

Vimkunya (chikungunya vaccine, recombinant) intramuscular injection was approved for the prevention of disease caused by chikungunya virus in patients 12 years and older. It is the first chikungunya vaccine approved for individuals as young as 12 years.

Additional examples of pediatric product approvals in 2025

Trade name (generic name)	Indication and labeling change	Pediatric labeling change date
Dextenza (dexamethasone) ophthalmic insert	Treatment of ocular inflammation and pain following ophthalmic surgery and treatment of ocular itching associated with allergic conjunctivitis in patients 2 years and older	April 7, 2025
Modeyso (dordaviprone)* oral capsules	Treatment of patients 1 year and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy (first approved systemic therapy for H3 K27M-mutant diffuse midline glioma)	Aug. 6, 2025
Dupixent (dupilumab) subcutaneous injection	Treatment of patients 12 years and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment	April 17, 2025
Eliquis Sprinkle and Eliquis tablets (apixaban) for oral suspension	Treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric patients from birth and older after at least five days of initial anticoagulant treatment	April 17, 2025
Forzinity (elamipretide)* subcutaneous injection	Improve muscle strength in patients with Barth syndrome weighing at least 30 kg (first FDA approval for this indication)	Sept. 19, 2025
Inzirqo (hydrochlorothiazide) oral suspension	Treatment of hypertension in patients alone or in combination with other antihypertensive agents to lower blood pressure and treatment of edema associated with congestive heart failure, hepatic cirrhosis and renal disease including the nephrotic syndrome (new oral suspension dosage form for hydrochlorothiazide)	Jan. 28, 2025
Mounjaro (tirzepatide) subcutaneous injection	Adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus	Dec. 19, 2025
Simponi (golimumab)* subcutaneous injection	Treatment of moderately to severely active ulcerative colitis in patients weighing at least 15 kg	Oct. 7, 2025
Sivextro (tedizolid phosphate) oral tablets	Treatment of acute bacterial skin and skin structure infections caused by designated susceptible microorganisms in patients at least 26 weeks' gestational age and weighing at least 1 kg	April 4, 2025

Soliris (eculizumab)* intravenous injection	Treatment of generalized myasthenia gravis in patients 6 years and older who are anti-acetylcholine receptor antibody positive	Feb. 28, 2025
Tremfya (guselkumab) subcutaneous or intravenous injection	Treatment of patients 6 years and older who weigh at least 40 kg with moderate-to-severe plaque psoriasis and who are candidates for systemic therapy or phototherapy and treatment of patients 6 years and older who weigh at least 40 kg with active psoriatic arthritis	Sept. 26, 2025

* Designated as an orphan product

The FDA's Office of Pediatric Therapeutics and Office of New Drug's Division of Pediatrics and Maternal Health contributed to this article.

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