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New pediatric labeling information available for 52 products

by from the Food and Drug Administration's Office of Pediatric Therapeutics and the Division of Pediatric & Maternal Health

New pediatric information was added to the labeling of 43 drugs, six vaccines and three blood products in 2016. The spectrum of approved agents to treat pediatric patients continues to expand (see table).

There are new pediatric drug therapies for conditions including:

- type 1 and 2 diabetes mellitus,
- HIV,
- chronic moderate to severe plaque psoriasis,
- lower limb spasticity,
- mildly to moderately active Crohn's disease,
- acute otitis media with tympanostomy tubes,
- partial onset seizures,
- inhalational anthrax and
- asthma.

A new biologic, Afstyla (antihemophilic factor [recombinant], single chain), was approved for the prophylaxis and treatment of bleeding episodes as well as the perioperative management of bleeding in adolescents and adults with hemophilia A.

The dosing regimen for Trumenba (active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B) was revised to include a two-dose schedule (a dose administered at 0 and 6 months). The three-dose schedule also was modified from administration at 0, 2 and 6 months to administration at 0, 1-2 and 6 months.

New pediatric formulations were approved, including an oral suspension of Fycompa (perampanel) and an oral solution and two lower dose strength tablets of Selzentry (maraviroc).

Studies of six drugs did *not* demonstrate efficacy in children, including Cinqair (reslizumab) for asthma studied in patients 12-17 years of age, Avelox (moxifloxacin hydrochloride) for complicated intra-abdominal infections, Lyrica (pregabalin) for fibromyalgia, Ativan (lorazepam) injection for status epilepticus, Canasa (mesalamine) suppositories for mildly to moderately active ulcerative proctitis and Effient (prasugrel) for vaso-occlusive crises in pediatric patients with sickle cell disease.

In addition, important safety information was added to the labeling for Varibar Pudding that specifies that the drug is contraindicated in pediatric patients with tracheo-esophageal fistula.

Examples of products with new pediatric labeling changes

Trade name (generic name)	Indication and labeling change	Pediatric labeling date
Drugs		
Tresiba	(insulin) Improve glycemic control in type 1	December



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degludec) and type 2 diabetes mellitus in 2016 Ryzodeg 70/30 (insulin degludec/insulin aspart)		pediatric patients 1 year and older	
Selzentry (maraviroc)		Treatment of only CCR5-tropic HIV-1 infection in patients 2 years of age and older weighing at least 10 kilograms	November 2016
Enbrel (etanercept)		Chronic moderate to severe plaque psoriasis in patients ages 4 to 17 years who are candidates for systemic therapy or phototherapy	November 2016
Dysport (abobotulinumtoxinA)		Treatment of lower limb spasticity in pediatric patients 2 years of age and older	July 2016
Entocort EC (budesonide)		Treatment of mild to moderate active Crohn's disease in patients 8 years of age and older	April 2016
Otovel otic solution (ciprofloxacin and flucloxacilone acetamide)		Treatment of acute otitis media with tympanostomy tubes in pediatric patients 6 months of age and older	April 2016
Fycompa (perampanel)		New oral suspension approved for adjunctive therapy for the treatment of partial-onset seizures in patients with epilepsy 12 years of age and older and as adjunctive therapy for the treatment of primary generalized tonic-clonic seizures in patients with epilepsy 12 years of age and older	April 2016
Anthim (obitoximab)		Treatment of inhalational anthrax in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax in pediatric patients	March 2016
Cinqair (reslizumab)		Efficacy <i>not</i> established for asthma in patients 12 to 17 years	March 2016
Center for Biologics Evaluation and Research (CBER) blood products			
Afstyla (antihemophilic factor [recombinant], single chain)		Indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for 1) on-demand treatment and control of bleeding	May 2016



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	episodes, 2) routine prophylaxis to reduce the frequency of bleeding episodes and 3) perioperative management of bleeding	
CBER vaccines Trumenba (meningococcal group B vaccine)	Labeling was revised to include a two-dose schedule (a dose administered at 0 and 6 months) and a modification of the three-dose schedule from administration at 0, 2 and 6 months to administration at 0, 1-2 and 6 months	April 2016

Resource

- [Full information on pediatric labeling changes since 1998.](#)