

## Pediatric Exclusivity Granted

April 2016

(No Recent Changes)

	Drug	Date of Exclusivity	Sponsor	Indication(s)
1.	Abacavir	12/14/98	Glaxo	HIV
2.	Albuterol	8/27/08	GSK	Treatment and prevention of bronchospasm in children from birth to <4 years of age with obstructive airway disease
3.	Alendronate	4/28/03	Merck	Osteogenesis imperfecta
4.	Alfuzosin	9/7/10	Sanofi Aventis	Treatment of patients 2 - 16 yrs with elevated detrusor leak point pressure associated with a known neurological disorder (e.g., spina bifida)
5.	Almotriptan	1/13/09	Johnson & Johnson	Acute treatment of migraine headache in adolescents, ages 12 to 17 years
6.	Amlodipine	11/27/01	Pfizer	Hypertension
7.	Ammonium Lactate	10/1/99	Westwood-Squibb	Ichthyosis vulgaris candidiasis
8.	Amphetamine Mixed Salts	10/28/04	Shire	ADHD
9.	Anagrelide	5/25/04	Shire	Thrombocytopenia secondary to myeloproliferative disorders
10.	Anastrozole	11/14/07	AstraZeneca	Male pubertal patients with gynecomastia and female pediatric patients with McCune-Albright syndrome with progressive precocious puberty.
11.	Aripiprazole	11/14/07	Otsuka	Schizophrenia; Bipolar Depression
12.	Asenapine	3/3/15	Forest Labs	Schizophrenia & bipolar disorder
13.	Atazanavir	6/23/15	Bristol-Myers Squibb	HIV-1 Infection
14.	Atomoxetine	12/18/01	Lilly	Attention Deficit Hyperactivity Disorder
15.	Atorvastatin	2/22/02	Pfizer	Hypercholesterolemia
16.	Atovaquone/Proguanil	8/6/03	GSK	Prevention of Malaria
17.	Azelastine	8/11/99	Asta	Itching associated with allergic conjunctivitis
18.	Azelastine*	3/23/15	Meda	Perennial and seasonal allergic rhinitis

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19.	Azelastine/ Fluticasone	3/23/15	Meda	Perennial and seasonal allergic rhinitis
20.	Balsalazide	8/23/06	Salix	Ulcerative colitis
21.	Benazepril	7/2/03	Novartis	Hypertension
22.	Bendamustine	5/24/12	Cephalon	Relapsed or refractory acute leukemia
23.	Betaxolol ** (effective 6/07 when it rev'd HW exclu)	2/28/07	Falcon	Treatment of elevated intraocular pressure
24.	Bicalutamide	9/19/08	AstraZeneca	Treatment of gonadotropin-independent precocious puberty in boys with testotoxicosis
25.	Bisoprolol	4/19/00	Lederle	Hypertension
26.	Bivalirudin	6/17/09	The Medicines Company	Use as an anticoagulant in children during percutaneous intravascular procedures for the management of congenital heart disease
27.	Bortezomib	8/14/15	Millennium	Acute lymphocytic leukemia (ALL)
28.	Brimonidine	10/10/01	Allergan	Lower intraocular pressure
29.	Brinzolamide	6/28/06	Alcon	Treatment of elevated intraocular pressure
30.	Budesonide	11/12/02	AstraZeneca	Asthma & allergic rhinitis
31.	Buspirone	5/22/00	Bristol-Myers	Generalized anxiety disorder
32.	Busulfan	3/12/02	Orphan Medical	Conditioning regimen for allogeneic bone marrow transplant
33.	Calcitriol	2/16/01	Abbott	Hypocalcemia management in patients on hemodialysis
34.	Candesartan	7/20/09	AstraZeneca	Reduce blood pressure
35.	Capecitabine	8/28/13	Hoffman-La Roche	Non-disseminated intrinsic diffuse brain stem gliomas
36.	Carboplatin	4/30/04	BMS	Refractory tumors
37.	Carvedilol	11/8/06	GSK	Heart failure
38.	Caspofungin	4/15/08	Merck & Co	Fungal Infections

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39.	Celecoxib	8/23/06	Pfizer	JRA
40.	Cetirizine	3/13/02	Pfizer	Allergic rhinitis/urticaria
41.	Ciprofloxacin	12/18/03	Bayer	Complicated UTI, Acute pyelonephritis
42.	Ciprofloxacin Ophthalmic	1/10/03	Alcon	Bacterial conjunctivitis
43.	Citalopram	7/12/02	Forest	Depression
44.	Clofarabine	7/14/04	Ilex	Refractory Leukemias
45.	Clopidogrel	1/20/11	Sanofi Aventis	Reduction of the incidence of thrombosis in children with systemic to pulmonary artery shunts for palliation of cyanotic congenital heart disease
46.	Colesevelam	2/17/09	Daiichi Sankyo	Treatment of patients diagnosed with heterozygous familial hypercholesterolemia (heFH)
47.	Cromolyn Sodium	11/2/99	Pharmacia & Upjohn	Allergic rhinitis
48.	Darunavir	6/7/11	Tibotec	Treatment of HIV
49.	Desflurane	9/13/06	Baxter	Anesthesia
50.	Desloratadine	2/12/03	Schering	Allergic rhinitis/urticaria
51.	Dexmedetomidine	3/12/13	Hospira	Loading and maintenance infusion for sedation in intubated and mechanically ventilated pediatric patients
52.	Didanosine	8/13/01	Bristol-Myers	Treatment of HIV
53.	Difluprednate	3/21/13	Alcon	Treatment of post-operative inflammation following cataract surgery
54.	Docetaxel	3/17/10	Sanofi Aventis	Solid Tumors
55.	Dorzolamide	1/5/04	Merck	Reduction in intraocular pressure
56.	Duloxetine	7/2/12	Eli Lilly	Major depressive disorder (MDD)
57.	Efavirenz	1/29/13	BMS	Treatment of HIV-1
58.	Eltrombopag	8/14/15	Novartis	Thrombocytopenia in children with chronic idiopathic thrombocytopenia purpura (ITP)
59.	Emtricitabine	5/24/06	Gilead	Treatment of HIV-1
60.	Enalapril	2/2/00	Merck	Hypertension
61.	Entecavir	12/5/13	BMS	Chronic Hepatitis B Virus Infection

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62.	Eplerenone	10/24/07	Pfizer	Hypertension
63.	Erlotinib	3/18/15	OSI Pharmaceuticals	Treatment of cancer (recurrent ependymoma)
64.	Ertapenem	2/11/05	Merck	Meningitis; hospital acquired pneumonia, intra-abdominal infection, or acute pelvic infection; CAP, cUTI, or skin and soft tissue infection
65.	Esmolol	8/22/03	Baxter	Hypertension
66.	Esomeprazole**	5/1/09	AstraZeneca	Treatment of gastroesophageal reflux disease (GERD)
67.	Eszopiclone	6/29/12	Sunovion	Insomnia in children with ADHD
68.	Etodolac	12/6/99	Wyeth Ayerst	Juvenile Rheum/Arthritis
69.	Everolimus	7/10/12	Novartis	Treatment of patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA)
70.	Ezetimibe	2/14/08	MSP Singapore	Heterozygous familial hypercholesterolemia
71.	Famciclovir	9/21/09	Novartis	Treatment of children 1 month – 12 years of age w/ herpes simplex (HSV) & 1 – 12 years w/ varicella zoster (VSV)
72.	Famotidine	11/21/00	Merck	Gastro-esophageal reflux
73.	Felodipine	8/30/01	Astra Zeneca	Hypertension
74.	Fentanyl	1/29/03	Alza	Chronic pain
75.	Fexofenadine	1/27/03	Aventis	Allergic rhinitis/urticaria
76.	Finaxofloxacin	8/25/14	Alcon	Acute otitis externa (AOE)
77.	Fluconazole	1/21/04	Pfizer	Tinea capitis
78.	Fludarabine	4/3/03	Berlex	Refractory/relapse acute leukemia
79.	Fluoxetine	11/15/00	Lilly	Depression & Obsessive Compulsive Disorder
80.	Fluticasone	2/25/03	GSK	Asthma & atopic dermatitis
81.	Fluvastatin	12/15/05	Novartis	Familial Hypercholesterolemia
82.	Fluvoxamine	1/3/00	Solvay	Obsessive Compulsive Disorder
83.	Fosamprenavir	1/10/12	ViiV	HIV

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84.	Fosinopril	1/27/03	Bristol-Myers Squibb	Hypertension
85.	Fulvestrant	2/1/11	AstraZeneca	Treatment of progressive precocious puberty in girls with McCune-Albright Syndrome
86.	Gabapentin	2/2/00	Parke Davis	Epilepsy
87.	Gatifloxacin	5/19/09	Allergan	Treatment of bacterial conjunctivitis in peds 0 - 1 month of age
88.	Gemcitabine	1/27/05	Lilly	Refractory or relapsed leukemia and non-Hodgkin's lymphoma
89.	Glimepiride	6/9/05	Aventis	Type II Diabetes
90.	Glyburide/ Metformin* **	10/8/03	BMS	Diabetes Mellitus
91.	Guanfacine	10/17/14	Shire	Attention Deficit Hyperactivity Disorder (ADHD)
92.	Ibuprofen	7/1/98	McNeil	Fever, aches/pains cold symptoms
93.	Ibuprofen**	7/1/98	Whitehall	Fever, aches/pains cold symptoms
94.	Ibuprofen/ pseudoephedrine	9/19/01	Whitehall	Cold, flu, sinus symptoms
95.	Imatinib Mesylate	6/9/06	Novartis	Philadelphia positive (Ph+) leukemia
96.	Imiquimod	12/13/06	3M	Molluscum contagiosum
97.	Insulin Aspart Recombinant	5/24/05	Novo Nordisk	Type I Diabetes
98.	Insulin Glargine	7/12/99	Aventis	Diabetes Mellitus
99.	Irbesartan	9/16/04	Sanofi-Synthelabo	Hypertension
100.	Irinotecan	3/10/04	Pharmacia & Upjohn	Refractory tumors
101.	Isotretinoin	6/12/01	Hoffman-La Roche	Severe recalcitrant nodular acne
102.	Ixabepilone	4/5/11	BMS	Solid Tumors
103.	Ketorolac	9/6/01	Allergan	Itching associated with allergic conjunctivitis
104.	Lamivudine	9/22/00	Glaxo	HIV

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105.	Lamivudine **	7/25/01	Glaxo/SK	Hepatitis B
106.	Lamotrigine	2/14/07	GSK	Partial seizures
107.	Lansoprazole	7/15/08	Tap Pharmaceutic al Products, Inc.	Treatment of Gastroesophageal Reflux Disease (GERD)
108.	Leflunomide	11/10/03	Aventis	JRA
109.	Levetiracetam	6/3/08	UCB Inc.	Partial seizures
110.	Levobetaxolol	6/28/06	Alcon	Treatment of elevated intraocular pressure
111.	Levocetirizine	8/25/09	UCB	Treatment of allergic rhinitis and urticaria in children 6 months to < 6 years of age
112.	Levofloxacin	3/14/07	Ortho McNeil	Community acquired pneumonia
113.	Linezolid	2/11/05	Pharmacia Upjohn	Skin and skin structure infections; suspected resistant gram positive infections; VRE infections; CSF shunts
114.	Lisinopril	11/19/01	Astra Zeneca	Hypertension
115.	Lisinopril	11/19/01	Merck	Hypertension
116.	Lopinavir/ Ritonavir§	3/7/08	Abbott	HIV
117.	Loratadine	8/14/00	Schering	Allergic rhinitis/urticaria
118.	Losartan	3/20/02	Merck	Hypertension
119.	Loteprednol/ Tobramycin	12/28/10	Bausch & Lomb	Treatment of superficial bacterial ocular infection
120.	Lovastatin	7/17/01	Merck	Hypercholesterolemia
121.	Meloxicam	4/15/05	Boehringer Ingelheim	JRA
122.	Memantine	6/16/14	Forest Labs	Autism & Autism Spectrum Disorder (ASD)
123.	Metformin	3/15/00	Bristol-Myers	Diabetes Mellitus
124.	Methylphenidate	12/4/03	McNeil	ADHD
125.	Metoprolol	7/27/06	AstraZeneca	Hypertension
126.	Midazolam	9/18/98	Hoffman-La Roche	Sedation/anxiolysis Amnesia

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127.	Milrinone	9/24/01	Sanofi-Syhelabo	Prevent heart failure after cardiopulmonary bypass
128.	Modafinil	3/21/06	Cephalon	Narcolepsy
129.	Mometasone	11/7/01	Schering	Corticosteroid responsive dermatoses/ Allergic rhinitis
130.	Montelukast	12/10/01	Merck	Asthma
131.	Moxifloxacin Ophth	1/10/03	Alcon	Bacterial conjunctivitis
132.	Nabumetone	8/30/01	Glaxo/SK	Juvenile Rheum/Arthritis
133.	Nefazodone	6/27/02	Bristol-Myers	Depression
134.	Nelfinavir	9/4/03	Agouron	HIV
135.	Nevirapine	12/17/01	Boehringer Ingelheim	Perinatal transmission of HIV infection
136.	Nitric Oxide	11/2/10	INO Therapeutics	Provide ventilatory assistance to preterm neonates with respiratory distress and reduce the risk of chronic lung disease (CLD) in preterm neonates at high risk of developing CLD
137.	Norgestimat e/ ethinyl estradiol	12/18/03	Johnson & Johnson	Bone mineral density in anorexia nervosa patients
138.	Octreotide	1/12/06	Novartis	Hypothalamic obesity
139.	Ofloxacin	3/12/03	Allergan	Bacterial conjunctivitis
140.	Olanzapine	1/10/07	Lilly	Adolescent-Onset Bipolar disorder and Adolescent-Onset Schizophrenia
141.	Olmesartan	10/7/09	Daiichi Sankyo	Treatment of hypertension in pediatric patients 1 – 16 years of age
142.	Olopatadine	8/12/09	Alcon	Allergic rhinitis
143.	Olopatadine **	12/16/14	Alcon	Allergic conjunctivitis
144.	Omeprazole	5/1/01	Astra Zeneca	Gastro-esophageal reflux
145.	Ondansetron	12/1/04	Glaxo	Nausea
146.	Orlistat	9/12/03	Roche	Obesity
147.	Oseltamivir	3/22/04	Roche	Influenza A & B
148.	Oxaliplatin	9/27/06	Sanofi-Aventis	Refractory tumors

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149.	Oxaprozin	12/6/99	Searle	Juvenile Rheum/Arthritis
150.	Oxcarbazepine	3/2/05	Novartis	Partial seizures
151.	Oxybutynin	2/8/02	Alza	Detrusor hyperreflexia
152.	Paliperidone	1/5/11	Ortho-McNeil-Janssen	Treatment of adolescent schizophrenia
153.	Palonosetron	4/10/14	Helsinn	Prevention of postoperative nausea and vomiting (PONV) and chemotherapy induced nausea and vomiting (CINV)
154.	Pantoprazole	2/17/09	Wyeth	Short-term treatment of Symptomatic GERD in pediatric patients
155.	Paricalcitol	12/8/03	Abbott	End Stage Renal Disease
156.	Paroxetine	6/27/02	GSK	Depression & OCD
157.	Pemetrexed	12/3/10	Eli Lilly	Treatment of pediatric patients with refractory and recurrent solid tumors, including osteosarcoma, Ewing sarcoma/peripheral PNET, rhabdomyosarcoma, and neuroblastoma
158.	Pemirolast	8/11/99	Santen	Allergic conjunctivitis
159.	Pimecrolimus	9/24/01	Novartis	Atopic dermatitis
160.	Pravastatin	7/10/02	Bristol-Myers	Hypercholesterolemia
161.	Propofol	8/11/99	Zeneca	Anesthetic
162.	Quetiapine	1/23/09	AstraZeneca	Treatment of schizophrenia and bipolar mania in pediatric patients
163.	Quinapril	6/7/02	Parke-Davis	Hypertension
164.	Rabeprazole	12/4/12	Eisai	Healing & maintenance of healing of GERD & improvement of GERD symptoms in children 1 to 11 years of age
165.	Ranitidine	1/19/99	Glaxo	Gastro-esophageal reflux
166.	Remifentanyl	3/15/00	Abbott	Anesthetic
167.	Ribavirin/Interferon A	5/9/01	Schering	Chronic Hepatitis C
168.	Risedronate	4/24/09	Procter & Gamble	Prevent vertebral and non-vertebral fractures in children with moderate-to-severe osteogenesis imperfecta (OI)
169.	Risperidone	2/28/07	Janssen	Adolescent-Onset Schizophrenia; Bipolar



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				Disorder
170.	Ritonavir	6/14/05	Abbott	HIV
171.	Rizatriptan	9/20/11	Merck	Migraine headaches
172.	Rocuronium	4/3/08	Organon	Anesthesia
173.	Rofecoxib	2/18/04	Merck	JRA
174.	Rosiglitazone	12/9/04	SB Pharmco	Type II Diabetes
175.	Rosuvastatin	7/7/09	AstraZeneca	Adjunct to diet to reduce cholesterol and ApoB levels in children 10-17 years of age
176.	Rufinamide	1/13/15	Eisai	Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS)
177.	Salmeterol	3/9/06	GSK	Asthma
178.	Sapropterin	3/13/14	BioMarin	Treatment to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to BH4-responsive phenylketonuria (PKU)
179.	Saquinavir	10/26/10	Hoffman-La Roche Inc.	Treatment of HIV infection in pediatric patients in combination with other antiretroviral agents
180.	Sertraline	2/1/02	Pfizer	Depression
181.	Sevoflurane	8/2/00	Abbott	Anesthetic
182.	Sibutramine	10/6/04	Abbott	Pediatric Obesity
183.	Sildenafil	2/9/12	Pfizer	Treatment of pulmonary arterial hypertension (PAH)
184.	Simvastatin	2/22/02	Merck	Hypercholesterolemia
185.	Sirolimus	11/17/04	Wyeth	Prevention of organ rejection following renal transplantation
186.	Sodium ferric gluconate complex	3/24/04	Watson	Iron deficiency due to chronic hemodialysis
187.	Sotalol	1/6/00	Berlex Lab	Arrhythmias
188.	Stavudine	8/13/01	Bristol-Myers	HIV
189.	Sumatriptan	2/18/04	GSK	Migraine
190.	Sumatriptan/ Naproxen	4/16/15	GSK/Pernix	Migraine

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191.	Tamoxifen	5/16/02	AstraZeneca	McCune-Albright Syndrome
192.	Tamsulosin	9/17/09	Boehringer Ingelheim	Treatment of 2 – 16 year olds w/ elevated detrusor leak point pressure associated w/ a known neurological disorder (e.g., spina bifida)
193.	Technetium Tc99 sestamibi	1/11/08	BMS	Kawasaki's disease
194.	Temozolomide	11/20/02	Schering	Refractory/relapse malignancies
195.	Temsirolimus	2/28/12	Pfizer	Treatment of relapsed/refractory solid tumors
196.	Tenofovir	9/6/11	Gilead	HIV
197.	Terbinafine	12/4/06	Novartis	Tinea capitis
198.	Testosterone	8/22/07	Unimed Pharmaceuticals,	Delayed onset of puberty in boys
199.	Timolol	2/28/07	Alcon	Treatment of elevated intraocular pressure
200.	Tipranavir	3/7/08	Boehringer Ingelheim	HIV
201.	Tolterodine	1/5/04	Pfizer	Detrusor hyperreflexia/ overactive bladder
202.	Topiramate	7/24/08	Ortho-McNeil-Janssen Pharmaceuticals, Inc.	- Mono- and adjunctive therapy for partial onset or primary generalized tonic-clonic seizures (epilepsy) - Adjunctive therapy for seizures associated w/ Lennox-Gastaut syndrome
203.	Topotecan	11/20/02	GlaxoSK	Refractory/relapse malignancies
204.	Tramadol	4/19/00	R.W. Johnson	Post-surgical pain
205.	Valacyclovir	2/26/08	GSK	Herpes simplex virus infection
206.	Valganciclovir	7/24/08	Hoffman-La Roche Inc.	Treatment & prevention of Cytomegalovirus (CMV) Disease
207.	Valproic acid	12/14/07	Abbott	Migraine, Bipolar disorder, Epilepsy
208.	Valsartan	8/8/07	Novartis	Hypertension
209.	Venlafaxine	12/2/02	Wyeth-Ayerst	Depression/ OCD
210.	Vigabatrin	10/3/13	Lundbeck	Intractable Complex Partial Seizures & Infantile Spasm
211.	Vinorelbine	8/15/02	GSK	Leukemia/lymphoma

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212.	Zoledronic acid	12/21/07	Novartis	Severe osteogenesis imperfecta
213.	Zolmitriptan	12/18/03	AstraZeneca	Migraine
214.	Zolpidem	11/20/06	Sanofi Aventis	Insomnia

❖ This is the first period of Pediatric Exclusivity for glyburide and a second period for metformin.

§ This is the first period of Pediatric Exclusivity for lopinavir and a second period for ritonavir.

\*\* A second period of Pediatric Exclusivity was granted for this moiety.