

Pediatric Exclusivity Granted

September 2012
(No 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	Thrombocythemia 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.	Atomoxetine	12/18/01	Lilly	Attention Deficit Hyperactivity Disorder
13.	Atorvastatin	2/22/02	Pfizer	Hypercholesterolemia
14.	Atovaquone/ Proguanil	8/6/03	GSK	Prevention of Malaria
15.	Azelastine	8/11/99	Asta	Itching associated with allergic conjunctivitis
16.	Balsalazide	8/23/06	Salix	Ulcerative colitis
17.	Benazepril	7/2/03	Novartis	Hypertension
18.	Bendamustine	5/24/12	Cephalon	Relapsed or refractory acute leukemia
19.	Betaxolol ** (effective 6/07	2/28/07	Falcon	Treatment of elevated intraocular pressure

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20.	Bicalutamide	9/19/08	AstraZeneca	Treatment of gonadotropin-independent precocious puberty in boys with testotoxicosis
21.	Bisoprolol	4/19/00	Lederle	Hypertension
22.	Bivalirudin	6/17/09	The Medicines Company	Use as an anticoagulant in children during percutaneous intravascular procedures for the management of congenital heart disease
23.	Brimonidine	10/10/01	Allergan	Lower intraocular pressure
24.	Brinzolamide	6/28/06	Alcon	Treatment of elevated intraocular pressure
25.	Budesonide	11/12/02	AstraZeneca	Asthma & allergic rhinitis
26.	Buspirone	5/22/00	Bristol-Myers	Generalized anxiety disorder
27.	Busulfan	3/12/02	Orphan Medical	Conditioning regimen for allogeneic bone marrow transplant
28.	Calcitriol	2/16/01	Abbott	Hypocalcemia management in patients on hemodialysis
29.	Candesartan	7/20/09	AstraZeneca	Reduce blood pressure
30.	Carboplatin	4/30/04	BMS	Refractory tumors
31.	Carvedilol	11/8/06	GSK	Heart failure
32.	Caspofungin	4/15/08	Merck & Co	Fungal Infections
33.	Celecoxib	8/23/06	Pfizer	JRA
34.	Cetirizine	3/13/02	Pfizer	Allergic rhinitis/urticaria
35.	Ciprofloxacin	12/18/03	Bayer	Complicated UTI, Acute pyelonephritis
36.	Ciprofloxacin Opth	1/10/03	Alcon	Bacterial conjunctivitis
37.	Citalopram	7/12/02	Forest	Depression
38.	Clofarabine	7/14/04	Ilex	Refractory Leukemias
39.	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
40.	Colesevelam	2/17/09	Daiichi Sankyo	Treatment of patients diagnosed with heterozygous familial hypercholesterolemia (heFH)
41.	Cromolyn	11/2/99	Pharmacia &	Allergic rhinitis

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	Sodium		Upjohn	
42.	Darunavir	6/7/11	Tibotec	Treatment of HIV
43.	Desflurane	9/13/06	Baxter	Anesthesia
44.	Desloratadine	2/12/03	Schering	Allergic rhinitis/urticaria
45.	Didanosine	8/13/01	Bristol-Myers	Treatment of HIV
46.	Docetaxel	3/17/10	Sanofi Aventis	Solid Tumors
47.	Dorzolamide	1/5/04	Merck	Reduction in intraocular pressure
48.	Duloxetine	7/2/12	Eli Lilly	Major depressive disorder (MDD)
49.	Emtricitabine	5/24/06	Gilead	Treatment of HIV-1
50.	Enalapril	2/2/00	Merck	Hypertension
51.	Eplerenone	10/24/07	Pfizer	Hypertension
52.	Ertapenem	2/11/05	Merck	Meningitis; hospital acquired pneumonia, intra-abdominal infection, or acute pelvic infection; CAP, cUTI, or skin and soft tissue infection
53.	Esmolol	8/22/03	Baxter	Hypertension
54.	Esomeprazole**	5/1/09	AstraZeneca	Treatment of gastroesophageal reflux disease (GERD)
55.	Eszopiclone	6/29/12	Sunovion	Insomnia in children with ADHD
56.	Etodolac	12/6/99	Wyeth Ayerst	Juvenile Rheum/Arthritis
57.	Everolimus	7/10/12	Novartis	Treatment of patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA)
58.	Ezetimibe	2/14/08	MSP Singapore	Heterozygous familial hypercholesterolemia
59.	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)
60.	Famotidine	11/21/00	Merck	Gastro-esophageal reflux
61.	Felodipine	8/30/01	Astra Zeneca	Hypertension
62.	Fentanyl	1/29/03	Alza	Chronic pain
63.	Fexofenadine	1/27/03	Aventis	Allergic rhinitis/urticaria
64.	Fluconazole	1/21/04	Pfizer	Tinea capitis

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65.	Fludarabine	4/3/03	Berlex	Refractory/relapse acute leukemia
66.	Fluoxetine	11/15/00	Lilly	Depression & Obsessive Compulsive Disorder
67.	Fluticasone	2/25/03	GSK	Asthma & atopic dermatitis
68.	Fluvastatin	12/15/05	Novartis	Familial Hypercholesterolemia
69.	Fluvoxamine	1/3/00	Solvay	Obsessive Compulsive Disorder
70.	Fosamprenavir	1/10/12	ViiV	HIV
71.	Fosinopril	1/27/03	Bristol-Myers Squibb	Hypertension
72.	Fulvestrant	2/1/11	AstraZeneca	Treatment of progressive precocious puberty in girls with McCune-Albright Syndrome
73.	Gabapentin	2/2/00	Parke Davis	Epilepsy
74.	Gatifloxacin	5/19/09	Allergan	Treatment of bacterial conjunctivitis in peds 0 - 1 month of age
75.	Gemcitabine	1/27/05	Lilly	Refractory or relapsed leukemia and non-Hodgkin's lymphoma
76.	Glimepiride	6/9/05	Aventis	Type II Diabetes
77.	Glyburide/ Metformin**	10/8/03	BMS	Diabetes Mellitus
78.	Ibuprofen	7/1/98	McNeil	Fever, aches/pains cold symptoms
79.	Ibuprofen**	7/1/98	Whitehall	Fever, aches/pains cold symptoms
80.	Ibuprofen/ pseudoephedrine	9/19/01	Whitehall	Cold, flu, sinus symptoms
81.	Imatinib Mesylate	6/9/06	Novartis	Philadelphia positive (Ph+) leukemia
82.	Imiquimod	12/13/06	3M	Molluscum contagiosum
83.	Insulin Aspart Recombinant	5/24/05	Novo Nordisk	Type I Diabetes
84.	Insulin Glargine	7/12/99	Aventis	Diabetes Mellitus
85.	Irbesartan	9/16/04	Sanofi-Synthelabo	Hypertension
86.	Irinotecan	3/10/04	Pharmacia & Upjohn	Refractory tumors
87.	Isotretinoin	6/12/01	Hoffman-La Roche	Severe recalcitrant nodular acne

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88.	Ixabepilone	4/5/11	BMS	Solid Tumors
89.	Ketorolac	9/6/01	Allergan	Itching associated with allergic conjunctivitis
90.	Lamivudine	9/22/00	Glaxo	HIV
91.	Lamivudine**	7/25/01	Glaxo/SK	Hepatitis B
92.	Lamotrigine	2/14/07	GSK	Partial seizures
93.	Lansoprazole	7/15/08	Tap Pharmaceutica l Products, Inc.	Treatment of Gastroesophageal Reflux Disease (GERD)
94.	Leflunomide	11/10/03	Aventis	JRA
95.	Levetiracetam	6/3/08	UCB Inc.	Partial seizures
96.	Levobetaxolol	6/28/06	Alcon	Treatment of elevated intraocular pressure
97.	Levocetirizine	8/25/09	UCB	Treatment of allergic rhinitis and urticaria in children 6 months to < 6 years of age
98.	Levofloxacin	3/14/07	Ortho McNeil	Community acquired pneumonia
99.	Linezolid	2/11/05	Pharmacia Upjohn	Skin and skin structure infections; suspected resistant gram positive infections; VRE infections; CSF shunts
100.	Lisinopril	11/19/01	Astra Zeneca	Hypertension
101.	Lisinopril	11/19/01	Merck	Hypertension
102.	Lopinavir/ Ritonavir§	3/7/08	Abbott	HIV
103.	Loratadine	8/14/00	Schering	Allergic rhinitis/urticaria
104.	Losartan	3/20/02	Merck	Hypertension
105.	Loteprednol/To bramycin	12/28/10	Bausch & Lomb	Treatment of superficial bacterial ocular infection
106.	Lovastatin	7/17/01	Merck	Hypercholesterolemia
107.	Meloxicam	4/15/05	Boehringer Ingelheim	JRA
108.	Metformin	3/15/00	Bristol-Myers	Diabetes Mellitus
109.	Methylphenidat e	12/4/03	McNeil	ADHD
110.	Metoprolol	7/27/06	AstraZeneca	Hypertension
111.	Midazolam	9/18/98	Roche	Sedation/anxiolysis Amnesia

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112.	Milrinone	9/24/01	Sanofi-Syhelabo	Prevent heart failure after cardiopulmonary bypass
113.	Modafinil	3/21/06	Cephalon	Narcolepsy
114.	Mometasone	11/7/01	Schering	Corticosteroid responsive dermatoses/ Allergic rhinitis
115.	Montelukast	12/10/01	Merck	Asthma
116.	Moxifloxacin Ophth	1/10/03	Alcon	Bacterial conjunctivitis
117.	Nabumetone	8/30/01	Glaxo/SK	Juvenile Rheum/Arthritis
118.	Nefazodone	6/27/02	Bristol-Myers	Depression
119.	Nelfinavir	9/4/03	Agouron	HIV
120.	Nevirapine	12/17/01	Boehringer Ingelheim	Perinatal transmission of HIV infection
121.	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
122.	Norgestimate/ ethinyl estradiol	12/18/03	Johnson & Johnson	Bone mineral density in anorexia nervosa patients
123.	Octreotide	1/12/06	Aventis	Hypothalamic obesity
124.	Ofloxacin	3/12/03	Allergan	Bacterial conjunctivitis
125.	Olanzapine	1/10/07	Lilly	Adolescent-Onset Bipolar disorder and Adolescent-Onset Schizophrenia
126.	Olmesartan	10/7/09	Daiichi Sankyo	Treatment of hypertension in pediatric patients 1 – 16 years of age
127.	Olopatadine	8/12/09	Alcon	Allergic rhinitis
128.	Omeprazole	5/1/01	Astra Zeneca	Gastro-esophageal reflux
129.	Ondansetron	12/1/04	Glaxo	Nausea
130.	Orlistat	9/12/03	Roche	Obesity
131.	Oseltamivir	3/22/04	Roche	Influenza A & B
132.	Oxaliplatin	9/27/06	Sanofi-Aventis	Refractory tumors
133.	Oxaprozin	12/6/99	Searle	Juvenile Rheum/Arthritis
134.	Oxcarbazepine	3/2/05	Novartis	Partial seizures

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135.	Oxybutynin	2/8/02	Alza	Detrusor hyperreflexia
136.	Paliperidone	1/5/11	Ortho-McNeil-Janssen	Treatment of adolescent schizophrenia
137.	Pantoprazole	2/17/09	Wyeth	Short-term treatment of Symptomatic GERD in pediatric patients
138.	Paricalcitol	12/8/03	Abbott	End Stage Renal Disease
139.	Paroxetine	6/27/02	GlaxoSK	Depression & OCD
140.	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
141.	Pemirolast	8/11/99	Santen	Allergic conjunctivitis
142.	Pimecrolimus	9/24/01	Novartis	Atopic dermatitis
143.	Pravastatin	7/10/02	Bristol-Myers	Hypercholesterolemia
144.	Propofol	8/11/99	Zeneca	Anesthetic
145.	Quetiapine	1/23/09	AstraZeneca	Treatment of schizophrenia and bipolar mania in pediatric patients
146.	Quinapril	6/7/02	Parke-Davis	Hypertension
147.	Ranitidine	1/19/99	Glaxo	Gastro-esophageal reflux
148.	Remifentanyl	3/15/00	Abbott	Anesthetic
149.	Ribavirin/Intron A	5/9/01	Schering	Chronic Hepatitis C
150.	Risedronate	4/24/09	Procter & Gamble	Prevent vertebral and non-vertebral fractures in children with moderate-to-severe osteogenesis imperfecta (OI)
151.	Risperidone	2/28/07	Janssen	Adolescent-Onset Schizophrenia; Bipolar Disorder
152.	Ritonavir	6/14/05	Abbott	HIV
153.	Rizatriptan	9/20/11	Merck	Migraine headaches
154.	Rocuronium	4/3/08	Organon	Anesthesia
155.	Rofecoxib	2/18/04	Merck	JRA
156.	Rosiglitazone	12/9/04	SB Pharmco	Type II Diabetes

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157.	Rosuvastatin	7/7/09	AstraZeneca	Adjunct to diet to reduce cholesterol and ApoB levels in children 10-17 years of age
158.	Salmeterol	3/9/06	GSK	Asthma
159.	Saquinavir	10/26/10	Hoffman-La Roche Inc.	Treatment of HIV infection in pediatric patients in combination with other antiretroviral agents
160.	Sertraline	2/1/02	Pfizer	Depression
161.	Sevoflurane	8/2/00	Abbott	Anesthetic
162.	Sibutramine	10/6/04	Abbott	Pediatric Obesity
163.	Sildenafil	2/9/12	Pfizer	Treatment of pulmonary arterial hypertension (PAH)
164.	Simvastatin	2/22/02	Merck	Hypercholesterolemia
165.	Sirolimus	11/17/04	Wyeth	Prevention of organ rejection following renal transplantation
166.	Sodium ferric gluconate complex	3/24/04	Watson	Iron deficiency due to chronic hemodialysis
167.	Sotalol	1/6/00	Berlex Lab	Arrhythmias
168.	Stavudine	8/13/01	Bristol-Myers	HIV
169.	Sumatriptan	2/18/04	GSK	Migraine
170.	Tamoxifen	5/16/02	AstraZeneca	McCune-Albright Syndrome
171.	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)
172.	Technetium Tc99 sestamibi	1/11/08	BMS	Kawasaki's disease
173.	Temozolomide	11/20/02	Schering	Refractory/relapse malignancies
174.	Temsirolimus	2/28/12	Pfizer	Treatment of relapsed/refractory solid tumors
175.	Tenofovir	9/6/11	Gilead	HIV
176.	Terbinafine	12/4/06	Novartis	Tinea capitis
177.	Testosterone	8/22/07	Unimed Pharmaceuticals,	Delayed onset of puberty in boys
178.	Timolol	2/28/07	Alcon	Treatment of elevated intraocular pressure
179.	Tipranavir	3/7/08	Boehringer Ingelheim	HIV

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180.	Tolterodine	1/5/04	Pfizer	Detrusor hyperreflexia/ overactive bladder
181.	Topiramate	7/24/08	Ortho-McNeil-Janssen Pharmaceutica ls, Inc.	- Mono- and adjunctive therapy for partial onset or primary generalized tonic-clonic seizures (epilepsy) - Adjunctive therapy for seizures associated w/ Lennox-Gastaut syndrome
182.	Topotecan	11/20/02	GlaxoSK	Refractory/relapse malignancies
183.	Tramadol	4/19/00	R.W. Johnson	Post-surgical pain
184.	Valacyclovir	2/26/08	GSK	Herpes simplex virus infection
185.	Valganciclovir	7/24/08	Hoffman-La Roche Inc.	Treatment & prevention of Cytomegalovirus (CMV) Disease
186.	Valproic acid	12/14/07	Abbott	Migraine, Bipolar disorder, Epilepsy
187.	Valsartan	8/8/07	Novartis	Hypertension
188.	Venlafaxine	12/2/02	Wyeth-Ayerst	Depression/ OCD
189.	Vinorelbine	8/15/02	GSK	Leukemia/lymphoma
190.	Zoledronic acid	12/21/07	Novartis	Severe osteogenesis imperfecta
191.	Zolmitriptan	12/18/03	AstraZeneca	Migraine
192.	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.