	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	NNPS
39.	12/24/2009	Famvir	famciclovir	Treatment of children 1 month – 12 years of age w/ herpes simplex (HSV) & 1 – 12 years w/ varicella zoster (VSV)	Labeling	• Available data are insufficient to support the use of famciclovir for the treatment of children with chickenpox or infections due to HSV • The PK profile and safety were studied in 2 open-label studies: (1) a single-dose PK and safety study in infants 1 month to <1 year of age who had an active herpes simplex virus (HSV) infection or who were at risk for HSV infection and (2) a single-dose PK, multiple-dose safety study in children 1 to <12 years of age with clinically suspected HSV or varicella zoster virus (VZV) infection • Information added to Pediatric Use	B, P	Novartis	9/21/2009	
40.	12/22/2009	Flomax	tamsulosin	Treatment of elevated detrusor leak point pressure associated with neurological disorder	Labeling	• Efficacy and positive benefit/risk was not demonstrated in 2 studies (a randomized, double-blind, safety and efficacy study and an open label safety study) conducted in patients 2 -16 years • The most frequently reported adverse events from the 2 studies were urinary tract infection, vomiting, pyrexia, headache, nasopharyngitis, cough, pharyngitis, influenza, diarrhea, abdominal pain, and constipation. • Information added to Pediatric Use	B	Boehringer Ingelheim	9/17/2009	
41.	12/22/2009	Topamax	topiramate	Adjunctive Treatment for Partial Onset Epilepsy in Infants and Toddlers 1 to 24 months	Labeling	• Effectiveness was not demonstrated as adjunctive therapy in a randomized, double-blind trial in infants/toddlers 1 to 24 months of age with refractory partial onset seizures • Trials in infants/toddlers 1 to 24 months suggested some adverse reactions/toxicities not previously observed in older pediatric patients and adults; i.e, growth/length retardation, certain clinical laboratory abnormalities, and other adverse reactions/toxicities that occurred with a greater frequency and/or greater severity than had been recognized previously from studies in older pediatric patients or adults	B	Ortho-McNeil-Janssen	7/24/2008	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	NNPS
						for various indications. • Information added to Warnings and Precautions and Pediatric Use				
42.	12/22/2009	Topamax	topiramate	Migraine Prophylaxis	Labeling	• Safety and effectiveness for migraine prevention in pediatric patients have not been established • Dose-related increased shift in serum creatinine in adolescent patients occurred in a clinical study • Information added to Warnings and Precautions and Pediatric Use	P	Ortho-McNeil-Janssen	NA	
43.	12/14/2009	Daytrana	methylphenidate	Postmarketing safety study	Labeling	• Information added to Warnings and Adverse Reactions on skin reactions observed in a postmarketing dermal study in pediatric patients	P	Shire	NA	
44.	12/4/2009	Zyprexa	olanzapine	Treatment of manic or mixed episodes of bipolar I disorder and schizophrenia in adolescents ages 13-17	Labeling	• Extended schizophrenia and manic or mixed episodes of bipolar I disorder indications from adults to adolescents 13–17 years of age • Safety and effectiveness in children < 13 years of age have not been established • Recommended starting dose for adolescents is lower than that for adults • Compared to patients from adult clinical trials, adolescents were likely to gain more weight, experience increased sedation, and have greater increases in total cholesterol, triglycerides, LDL cholesterol, prolactin and hepatic transaminase levels • Information on dosing, adverse reactions, pharmacokinetics, clinical studies	B	Lilly	1/10/2007	✓

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
45.	12/2/2009	Seroquel	quetiapine	Treatment of schizophrenia in adolescents 13 to 17 years of age and the treatment of bipolar mania in children and adolescents 10 to 17 years of age	Labeling	• Extended schizophrenia indication from adults to adolescents 13–17 years of age; extended bipolar mania indication from adults to children and adolescents 10-17 years of age • Safety and effectiveness in children < 13 years of age with schizophrenia have not been established; safety and effectiveness in children < 10 years of age with bipolar mania have not been established • Most adverse reactions in pediatric clinical trials were similar to those observed in adults and included somnolence, dizziness, fatigue, increased appetite, nausea, vomiting, dry mouth, tachycardia, and weight increase. However, increases in blood pressure and potentially clinically significant increases in heart rate (> 110 bpm) occurred in children and adolescents and did not occur in adults. • Information on dosing, adverse reactions, pharmacokinetics, and clinical studies	B, P	AstraZeneca	1/23/2009	
46.	12/1/2009	Patanase	olopatadine	Seasonal allergic rhinitis	Labeling	• Expanded age range down to 6 years; previously approved for use in 12 years and older • Safety and effectiveness have not been established in < 6 years of age • The incidence of epistaxis (nosebleed) was higher in children 6 -11 years of age compared to the adult and adolescent population • Information on clinical trials, adverse reactions, and new one spray per nostril twice daily dosing in 6-11 years	B, P	Alcon	8/12/2009	
47.	11/19/2009	Abilify	aripiprazole	Irritability associated with autistic disorder	Labeling	• Safety and effectiveness in pediatric patients demonstrating irritability associated with autistic disorder were established in two placebo-controlled clinical trials in pediatric patients 6 - 17 years of age • Most common adverse reactions observed	P	Otsuka	11/14/2007	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						in pediatric clinical trials in patients with autistic disorder included sedation, fatigue, vomiting, somnolence, tremor, pyrexia, drooling, decreased appetite, salivary hypersecretion, extrapyramidal disorder, and lethargy. Fatigue was a possible dose-response adverse reaction. • Information on dosing, adverse reactions, and clinical studies				
48.	11/12/2009	Protonix	pantoprazole	GERD	Labeling	• Extended indication from adults to pediatric patients 5 years of age and older • Use in pediatric patients 1 to 16 years of age is supported by extrapolation from studies in adults, and safety, efficacy and PK studies performed in pediatric patients • There is no age-appropriate formulation available for patients less than 5 years of age • Effectiveness was not demonstrated in a clinical trial of patients 1 month to 11 months of age with symptomatic GERD • Safety and effectiveness for pediatric uses other than EE have not been established • Information on adverse reactions, pharmacokinetics, and clinical studies	B, P	Wyeth	2/17/2009	
49.	11/10/2009	AFLURIA	Influenza Virus Vaccine•	Active immunization for the prevention of influenza disease caused by virus types A and B contained in the vaccine	Package Insert	See Package Insert for new information on biologics	P	CSL Limited	NA	
50.	11/6/2009	Retrovir	zidovudine	Treatment of HIV-1 infection in combination with other antiretroviral agents	Labeling	• Provided dosing recommendations for patients 4 weeks to < 6 weeks of age and weighing 4 kg to < 9 kg	P	GlaxoSmithKline	NA	✓

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
51.	10/23/2009	Focalin XR	dexmethylphenidate	ADHD	Labeling	• Revised maximum daily dosing due to dose-response studies. Doses above 30 mg/day in pediatrics and 40 mg/day in adults have not been studied and are not recommended • Dosing should be individualized to patient needs and response. • There was no clear benefit of the higher doses compared to the lower doses. Adverse events and discontinuations were dose-related. • New dosing regimen; new dosage strength (30 mg capsule)	P	Novartis	NA	
52.	10/22/2009	Atacand	candesartan	Hypertension	Labeling	• Expanded indication from adults to pediatric patients 1 to < 17 years of age. • Children < 1 year must not receive candesartan. Administering drugs that act directly on the renin-angiotensin system can have effects on the development of immature kidneys • Children with glomerular filtration rate < 30ml/min/1.73m2 should not receive candesartan. • In clinical trials, 4 of 233 children experienced worsening renal disease • Information on preparation of an oral suspension, dosing and administration, adverse events, pharmacokinetics, and clinical trials	B	AstraZeneca	7/20/2009	
53.	10/19/2009	Fluarix	Influenza Virus Vaccine•	Active immunization for the prevention of influenza disease caused by virus types A and B contained in the vaccine	Package Insert	See Package Insert for new information on biologics	P	GlaxoSmithKline	NA	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	NNPS
54.	10/16/2009	CERVARIX	Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant•	Prevention of genital warts caused by HPV 16 and 18	Package Insert	See Package Insert for new information on biologics	P	Merck	NA	
55.	10/16/2009	GARDASIL	Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant•	Prevention of vulvar and vaginal cancer caused by HPV types 16 and 18	Package Insert	See Package Insert for new information on biologics	P	Merck	NA	
56.	10/15/2009	Crestor	rosuvastatin	Heterozygous familial hypercholesterolemia	Labeling	• New indication in adolescent boys and girls (at least one year post-menarche) 10-17 years with heterozygous familial hypercholesterolemia • Has not been studied in children < 10 years or in pre-menarchal girls • Information on dose, adverse events and clinical studies	B, P	AstraZeneca	7/7/2009	
57.	10/2/2009	Welchol	colesevelam	Heterozygous familial hypercholesterolemia	Labeling	• New indication for use as monotherapy or with a statin in boys and postmenarchal girls 10-17 years with heterozygous familial hypercholesterolemia • Has not been studied in children < 10 years or in pre-menarchal girls • Information on dose, adverse events and clinical studies	B, P	Daiichi Sankyo	2/17/2009	
58.	10/1/2009	Mirena	levonorgestrel-releasing intrauterine system	Treatment of heavy menstrual bleeding for women using intrauterine contraception	Labeling	• New indication for the treatment of heavy menstrual bleeding for women who choose to use intrauterine contraception • Use before menarche is not indicated	P	Berlex	NA	✓
59.	9/18/2009	AndroGel	testosterone	Use in adolescent boys with delayed puberty	Labeling	• New safety information added to labeling including a Boxed Warning, and revisions to the Warnings and Precautions, Adverse Reactions, and Patient Counseling sections on the risk of virilization from secondary	B	Unimed	8/22/2007	✓

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						exposure of children to testosterone due to drug transfer from unwashed or uncovered application skin sites of adult males using testosterone gel products • Safety and efficacy have not been established in males < 18 years				
60.	9/8/2009	Bepreve Ophthalmic Solution	bepotastine besilate	Ocular itching associated with allergic conjunctivitis	Labeling	• Efficacy in pediatric patients 2 years to < 10 years based on clinical trials conducted in pediatric patients > 10 years and from adults • Safety and efficacy have not been established in pediatric patients < 2 years • New drug	P	Ista Pharmaceuticals	NA	
61.	9/2/2009	Intuniv	guanfacine	ADHD	Labeling	• Efficacy established in 2 controlled clinical trials in children 6-17 years • Safety and efficacy in pediatric patients< 6 years have not been established • In clinical trials, there were dose and exposure-related risks for adverse events (AEs) including hypotension, bradycardia, and sedative events. Somnolence and sedation were reported in 38% on guanfacine vs. 12% on placebo in children and adolescents with ADHD, especially during initial use • Information on dosing, clinical trials, and AEs • New dosage form	P	Shire	NA	
62.	8/31/2009	Astepro Nasal Spray	azelastine hydrochloride	Seasonal and perennial allergic rhinitis	Labeling	• Safety and efficacy for the treatment of seasonal and perennial allergic rhinitis were evaluated in 7 controlled clinical trials in patients 12 years and older • Information on clinical trials, dosing, and adverse events (AEs) • New indication (PAR) and dosing regimen	P	Meda	NA	
63.	8/28/2009	Valcyte	valganciclovir	Prevention of cytomegalovirus	Labeling	• Use in pediatric patients ≥ 4 months is based on efficacy data from a study in	B, P	Roche	7/24/2008	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
				(CMV) disease in pediatric kidney and heart transplant patients		adults and PK, safety, and efficacy data from an open-label trial in pediatric solid organ transplant recipients at risk for developing CMV disease • The efficacy and safety have not been established in children for: 1. Prevention of CMV disease in liver transplant patients 2. Prevention of CMV disease in solid organ transplants other than those indicated 3. Prevention of CMV disease in pediatric solid organ transplant patients < 4 months of age 4. Treatment of congenital CMV disease • Adverse events (AEs) similar to adult patients, however, certain AEs including upper respiratory tract infection, pyrexia, nasopharyngitis, anemia, and neutropenia were reported more frequently in pediatric patients • Information on dosing, PK, and clinical study • New dosage form				
64.	8/27/2009	Zenpep	pancrelipase	Exocrine pancreatic insufficiency due to cystic fibrosis	Labeling	• Safety and efficacy assessed in 2 studies which included pediatric patients ages 1-17 years • Safety and efficacy for use in all pediatric age groups based on information from the literature and clinical experience with different formulations of pancrelipase with the same active ingredient. • High doses of pancreatic enzyme products have been associated with fibrosing colonopathy and colonic strictures in children <12 years of age • AEs similar to adults • Capsule should be swallowed whole. For	P	Eurand	NA	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						infants or patients unable to swallow intact capsules, the contents may be sprinkled on soft acidic food such as applesauce • Information on dosing, and clinical studies • Not interchangeable with other pancrelipase products • New drug				
65.	8/21/2009	Xyzal	levocetirizine dihydrochloride	Seasonal allergic rhinitis (SAR) in children 2 years of age and older; perennial allergic rhinitis (PAR) and chronic idiopathic urticaria (CIU) for children 6 months of age and older	Labeling	• Expanded age range for CIU down to 6 months; previously approved for use in 12 years and older • Expanded age range for PAR down to 6 months; previously approved for use in 6 years and older • Expanded age range for SAR down to 2 years; previously approved for use in 6 years and older • Pediatric use is supported by evidence from studies in adults with additional safety and PK data in pediatrics • Patient population altered	B, P	UCB	8/25/2009	
66.	8/19/2009	HIBERIX	*Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)* •	Active immunization as a booster dose for the prevention of invasive disease caused by *Haemophilus influenzae* type b	Package Insert	See Package Insert for new information on biologics	P	GlaxoSmithKline	NA	
67.	7/31/2009	Acyclovir/ Hydrocortisone	acyclovir/ hydrocortisone	Recurrent herpes labialis (cold sores) in 12 years of age and older	Labeling	• Use in adolescents ≥12 years is supported by evidence from studies in adults with additional safety data in adolescents ≥12 years • Safety and effectiveness in pediatric patients < 12 years have not been established • Information on clinical studies, and adverse events • New drug	P	Medivir	NA	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
68.	7/23/2009	Actonel	risedronate	Osteogenesis imperfecta	Labeling	• Safety and effectiveness have not been established in pediatric patients • In a 1 year double-blind, placebo controlled study of pediatric patients with osteogenesis imperfecta (OI), treatment with risedronate did not result in a reduction in the risk of fracture • Adverse events similar to those observed in adults except for an increased incidence in vomiting • Information on clinical study	B	Procter & Gamble	4/24/2009	
69.	7/10/2009	Plan B One Step	levonorgestrel	Emergency contraception - OTC in women 17 years and older; RX for women younger than age 17 years	Labeling	• New single dose 1.5 mg tablet • New dosage regimen	P	Duramed	NA	✓
70.	6/18/2009	Nexium	esomperazole	Short-term treatment of GERD	Labeling	• Effectiveness was not demonstrated in a randomized, placebo-controlled study in neonates to < 1 year • Information on clinical study, PK/PD parameters	B, P	AstraZeneca	5/1/2009	
71.	5/29/2009	Lamictal XR	lamotrigine*	Adjunctive therapy for partial onset seizures with or without secondary generalization in patients ≥13 years of age	Labeling	• Extended release tablets are indicated as adjunctive therapy for partial onset seizures with or without secondary generalization in patients ≥13 years • Safety and effectiveness of extended release tablets for any use in patients below the age of 13 have not been established • Information on adverse event profile, and clinical studies • New dosage form	P	GlaxoSmithKline	NA	
72.	5/28/2009	Besivance	besifloxacin ophthalmic suspension	Treatment of bacterial conjunctivitis	Labeling	• Efficacy in pediatric patients 1 year and older has been demonstrated in controlled clinical trials	P	Bausch & Lomb	NA	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						• Safety and effectiveness in infants < 1 year of age have not been established • There is no evidence that the ophthalmic administration of quinolones has any effect on weight bearing joints • Information on AE profile and clinical study • New drug				
73.	5/8/2009	Lamictal	lamotrigine	Adjunctive treatment for partial seizures in pediatric patients 1 – 24 months	Labeling	• Safety and effectiveness as adjunctive treatment for partial seizures were not demonstrated in a small randomized, double-blind, placebo-controlled, withdrawal study in pediatric patients 1 - 24 months • Immediate release tablets were associated with an increased risk for infectious adverse reactions including bronchiolitis, bronchitis, ear infection, eye infection, otitis externa, pharyngitis, urinary tract infection, and viral infection (Lamictal 37%, Placebo 5%), and respiratory adverse reactions including nasal congestion, cough, and apnea. (Lamictal 26%, Placebo 5%)	B	GlaxoSmithKline	2/14/2007	
74.	5/1/2009	Cetraxal	ciprofloxacin otic solution	Treatment of acute otitis externa due to susceptible isolates of Pseudomonas aeruginosa or Staphylococcus aureus	Labeling	• Efficacy in pediatric patients 1 year and older has been demonstrated in controlled clinical trials • Safety and effectiveness in infants < 1 year have not been established • There is no evidence that the otic administration of quinolones has any effect on weight bearing joints • Information on AE profile and clinical study • New dosage form	P	Salvat	NA	
75.	4/30/2009	Axert	almotriptan	Acute treatment of pediatric migraine in adolescent patients age 12-17 years	Labeling	• Safety and effectiveness established in patients 12 – 17 years. Efficacy on migraine associated symptoms (nausea, photophobia and phonophobia) was not established. • Safety and effectiveness in pediatric	B	Ortho-McNeil	1/13/2009	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						patients < 12 years have not been established • The most common adverse events were dizziness, somnolence, headache, paresthesia, nausea and vomiting. Safety and tolerability similar to adults. • Information on dosing, adverse events, PK parameters, clinical study • Patient population altered				
76.	4/30/2009	Creon	pancrelipase	Exocrine pancreatic insufficiency due to cystic fibrosis or other conditions	Labeling	• Safety and efficacy assessed in a study that included patients 12-18 years • Safety and efficacy for use in all pediatric age groups based on information from the literature and clinical experience with different formulations of pancrelipase containing the same active ingredient. • High doses of pancreatic enzyme products have been associated with fibrosing colonopathy in children <12 years of age • AEs similar to adults • Capsule should be swallowed whole. For infants or patients unable to swallow intact capsules, the contents may be sprinkled on soft acidic food such as applesauce • Information on dosing and clinical study • Not interchangeable with other pancrelipase products • New drug	P	Solvey	NA	
77.	4/14/2009	Suprane	desflurane	Safety study of 2 agents used for maintenance of anesthesia in non-intubated patients	Labeling	• Postmarketing Reports subsection added to the Adverse Events section of labeling, including reports of cardiac disorders. • Postmarketing reports are voluntary; it is not possible to estimate frequency or causality to drug exposure.	B	Baxter	9/13/2006	✓
78.	4/9/2009	Ulesfia Lotion, 5%	benzyl alcohol	Treatment of head lice	Labeling	• Safety and effectiveness established in pediatric patients 6 months and older • Safety in pediatric patients < 6 months has not been established.	P	Sciele Pharma Inc	NA	

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						• Not recommended in pediatric patients < 6 months due to potential for increased systemic absorption • Neonates are at risk of gasping syndrome due to benzyl alcohol • Adverse events similar to those observed in adults • Information on dosing and administration, warnings and precautions, adverse events, PK parameters, and clinical studies • New drug				
79.	3/19/2009	Lexapro Tablets 5 mg, 10 mg, and 20 mg and Oral solution 5 mg/mL	escitalopram oxalate	Major depressive disorder in adolescents	Labeling	• Safety and effectiveness have been established in adolescents 12 to 17 years for the treatment of MDD. Maintenance efficacy is supported from extrapolation of data from adult studies along with comparisons with racemic citalopram pharmacokinetic parameters in adults and adolescents. • Safety and effectiveness have not been established in pediatric patients <12 years with MDD • Safety and effectiveness have not been established in pediatric patients less than 18 years of age with Generalized Anxiety Disorder • Adverse events generally similar to those observed in adults • Information on dosing, adverse events, PK parameters, and clinical studies • Patient population altered	B	Forest Laboratories	7/12/2002	
80.	2/13/2009	TobraDex ST	tobramycin/ dexamethasone	Steroid-responsive inflammatory ocular conditions	Labeling	• Safety and effectiveness have been established in 2 years and older • Safety and effectiveness in pediatric patients < 2 years have not been established • New dosage form	P	Alcon	NA	✓
81.	12/19/2008	Ziagen	abacavir	HIV infection	Labeling	• Provided new scored tablet for use in	B, P	GlaxoSmit	12/14/1998	✓

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						pediatric patients weighing >14 kg who can swallow tablets • New dosing regimen		hKline		
82.	12/19/2008	Casodex	bicalutamide	Gonadotropin-independent precocious puberty in boys with familial male-limited precocious puberty (testotoxicosis)	Labeling	• Safety and effectiveness have not been established in pediatric patients • Bicalutamide was studied in combination with anastrozole in an open-label, non-comparative, multi-center study that assessed the efficacy and safety of this combination regimen over 12 months in the treatment of testotoxicosis in patients ≥2 years • Of the 14 patients exposed to study treatment, 13 had at least one adverse event. Adverse reactions considered possibly related to bicalutamide included gynecomastia (43%), central precocious puberty (14%), breast tenderness (14%), breast pain (7%), asthenia (7%), increased alanine aminotransferase (7%), increased aspartate aminotransferase (7%), and musculoskeletal chest pain (7%). Headache was the only adverse reaction considered possibly related to anastrozole • Information on clinical studies, AEs, and PK parameters	B	AstraZeneca	9/19/2008	
83.	12/18/2008	Prezista	darunavir	Treatment of HIV infection in pediatric patients 6 years and older when co-administered with ritonavir (Prezista/rtv), and with other antiretroviral agents	Labeling	• Extended indication from adults to pediatric patients 6 years and older • Safety and effectiveness in pediatric patients 3 to < 6 years of age have not been established • Do not administer in pediatric patients below 3 years of age • Do not administer Prezista/rtv once daily in pediatric patients • Dosing for patients 6 to < 18 years and weighing at least 44 lbs (20 kg) is based on body weight not to exceed adult dose • AE similar to those seen in adults • Information on dose, AEs, PK parameters,	B, P	Tibotec	NA	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						lab abnormalities, and clinical study				
84.	12/17/2008	Epiduo	adapalene and benzoyl peroxide	Topical treatment of acne vulgaris in patients 12 years of age and older	Labeling	• Safety and effectiveness established in patients 12 years of age and older • Safety and effectiveness in pediatric patients under the age of 12 have not been established • New drug	P	Galderma	NA	
85.	12/11/2008	PegIntron	Peginterferon alfa-2b	Co-administered with ritonavir to treat chronic hepatitis C in patients 3 years of age and older with compensated liver disease previously untreated with interferon alpha	Labeling	• Safety and efficacy established in pediatric patients 3–17 years of age • Safety and effectiveness in patients < 3 years have not been established. • Dosing for pediatric patients is determined by body surface area for peginterferon alfa-2b and by body weight for ritonavir • An open-label study in patients 3 - 17 years showed weight and height gain of pediatric patients treated with combination therapy lags behind that predicted by population data while on treatment. • Adverse events similar to those observed in adults. Most common pediatric adverse events were pyrexia, headache, neutropenia, fatigue, anorexia, injection site erythema, vomiting • Information on PK parameters, and clinical study • New indication	P	Schering	NA	
86.	12/5/2008	Arimidex	anastrozole	Male pubertal patients with gynecomastia and female pediatric patients with McCune-Albright syndrome with progressive precocious	Labeling	• Efficacy has not been demonstrated in clinical studies of anastrozole in the treatment of pubertal gynecomastia in adolescent boys 11-18 years and in the treatment of precocious puberty in girls with McCune-Albright Syndrome 2 to < 10 years • Information on clinical studies, AEs, and PK parameters	B	AstraZeneca	11/14/2007	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	NNPS
				puberty						
87.	11/14/2008	Neulasta	Pefilgrastim	Sarcoma		• Safety and effectiveness in pediatric patients have not been established • Safety and PK were studied in 37 pediatric patients with sarcoma • Information added to Pediatric Use	P	Amgen	NA	
88.	10/28/2008	Prevacid	lansoprazole	Symptomatic GERD in infants	Labeling	• Expanded age range to include patients 12 -17 years of age; previously labeled only in pediatric patients 1-11 years of age • Safety and effectiveness in pediatric patients <1 year of age have not been established • Information on dose, PK parameters, and AE profile	B, P	Takeda	7/15/2008	
89.	10/24/2008	Apidra	insulin glulisine recombinant	Diabetes Mellitus	Labeling	• Extended indication from adults to pediatric patients 4 years and older with type 1 diabetes • Has not been studied in pediatric patients less than 4 years with type 1 diabetes and in pediatric patients with type 2 diabetes • Pediatric patients had a higher incidence of severe symptomatic hypoglycemia compared to adults in the clinical study • New indication	P	Sanofi-Aventis	NA	
90.	10/21/2008	Acanya Gel	clindamycin/ benzoyl peroxide combination	Acne vulgaris in patients 12 years of age and older	Labeling	• Safety and effectiveness established in 2 clinical studies in patients 12 years of age and older • Safety and effectiveness in pediatric patients under the age of 12 have not been evaluated • New drug	P	Dow	NA	
91.	10/14/2008	Zomig Nasal Spray	zolmitriptan	Migraine	Labeling	• Safety and effectiveness have not been established in pediatric patients less than18 years of age. • A single, multi-center, double-blind randomized placebo-controlled study failed	B, P	AstraZeneca	12/18/2003	✓

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						to demonstrate efficacy in pediatric patients ages 12 -17 years for the acute treatment of migraine headaches • Adverse events similar to those observed in adults.				
92.	10/10/2008	Kogenate FS	Antihemophilic Factor (Recombinant) •	Routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no pre-existing joint damage	Package Insert	See Package Insert for new information on biologics	P	Bayer	NA	
93.	10/8/2008	Zmax Oral Susp	azithromycin	Community-Acquired Pneumonia	Labeling	• Safety and effectiveness established in pediatric patients 6 months of age or older with community-acquired pneumonia. Use is supported by evidence from studies in adults with additional safety and PK data in pediatric patients • Safety and effectiveness in the treatment of pediatric patients < 6 months of age have not been established. • Safety and effectiveness in the treatment of pediatric patients with acute bacterial sinusitis have not been established • Information on dose, PK parameters, AE profile, lab abnormalities, and clinical studies • New indication	P	Pfizer	NA	✓
94.	10/07/2008	Akten Ophthalmic gel 3.5%	lidocaine hydrochloride	Ocular surface anesthesia during ophthalmologic procedures	Labeling	• Safety and efficacy extrapolated from studies in adults and older pediatric patients using different ophthalmic formulations of lidocaine. • New dosage form	P	Akorn	NA	✓
95.	9/29/2008	Videx EC	didanosine	HIV infection in	Labeling	• Extended indication from adults to children	B, P	Bristol-	8/13/2001	✓

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
				>20 kg		weighing ≥20kg who can swallow capsules • Dosing is based on body weight not to exceed adult dose • Adverse events (AEs) are generally similar to those seen in adults • Information on dose, AEs, population PK analysis, lab abnormalities, and historical clinical studies		Myers Squibb		
96.	9/19/2008	Retrovir syrup, capsules and tablets#	zidovudine	Used in combination with 18 other antiretroviral agents for the treatment of HIV-1 infection	Labeling	• Dosing and administration information provided to children 6 weeks to less than 18 years of age • Macrocytosis was reported in the majority of pediatric patients receiving Retrovir 180 mg/m2 every 6 hours in open-label studies • New dosing regimen	P	GlaxoSmithKline	NA	✓
97.	9/19/2008	Nasacort AQ	triamcinolone	Treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older	Labeling	• Expands pediatric use, or age range, to include patients 2 to 5 years of age • Dosing and administration information provided • Not recommended for children under 2 years of age • An effect on adrenal function in children 2 to 5 years of age cannot be ruled out • Pharmacokinetics were evaluated in children 2 to 5 years of age • Safety and efficacy were evaluated in one clinical study involving pediatric patients 2 to 5 years old • Studies in children >6 months and less than 2 years of age were not performed due to safety concerns since controlled clinical studies have shown that intranasal corticosteroids may cause a reduction in growth velocity in pediatric patients.	P	Sanofi-Aventis	NA	
98.	9/12/2008	GARDASIL	Human Papillomavirus Quadrivalent (Types 6, 11,	Prevention of vulvar and vaginal cancer caused by HPV	Package Insert	See Package Insert for new information on biologics	P	Merck	NA	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
			16, 18) Vaccine, Recombinant•	types 16 and 18						
99.	9/3/2008	Valtrex	valacyclovir	Chickenpox; active or at risk for herpes virus infection	Labeling	• New indication for treatment of chickenpox in pediatric patients 2 to <18 years based on single-dose pharmacokinetic and multiple-dose safety data from an open-label trial with valacyclovir and supported by safety and extrapolated efficacy data from 3 randomized, double-blind, placebo-controlled trials evaluating oral acyclovir in pediatric patients with chickenpox • The efficacy and safety of valacyclovir have not been established in pediatric patients: o <12 years of age with cold sores o <18 years of age with genital herpes o <18 years of age with herpes zoster o <2 years of age with chickenpox, o for suppressive therapy following neonatal HSV infection • Adverse events similar to that of adults • Information on PK parameters, AEs, clinical studies, and preparation of an extemporaneous formulation	B, P	GlaxoSmithKline	2/26/2008	
100.	8/28/2008	Zemuron	rocuronium	Adjunct to general anesthesia	Labeling	• Expanded pediatric indication to include 0-17 years. Previously approved in ages 3 months – 14 years • Not recommended for rapid sequence intubation in pediatric patients • In clinical studies of rocuronium, onset time and clinical duration varied with dose, the age of the patient, and anesthetic technique • The overall analysis of ECG data in pediatric patients indicates that the concomitant use of rocuronium with general anesthetic agents can prolong the QTc interval • The time to maximum block for an intubating dose was shortest in infants and	B, P	Organon USA	4/3/2008	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	NNPS
						longest in neonates. The duration of clinical relaxation following an intubating dose is shortest in children > 2 years to 11 years and longest in infants • Additional information on dose, clinical studies, and PK/PD parameters				
101.	8/14/2008	Zyprexa	olanzapine	schizophrenia; bipolar disorder	Labeling	• Safety and effectiveness have not been established for patients less than 18 years of age • In an analysis of placebo-controlled olanzapine monotherapy studies of adolescent patients, including those with schizophrenia or bipolar disorder, olanzapine was associated with: o Hyperglycemia - a statistically significantly greater mean change in fasting glucose levels compared to placebo o Hyperlipidemia – statistically significant increases compared to placebo in fasting triglycerides, fasting total cholesterol and fasting LDL cholesterol o Weight gain – olanzapine treated patients gained an average of 4.6 kg, compared to an average of 0.3 kg in placebo-treated patients with a median exposure of 3 weeks; Average weight gain during long-term therapy was 7.4 kg	B	Lilly	1/10/2007	
102.	7/29/2008	Cancidas	caspofungin	Empirical therapy for presumed fungal infections in febrile, neutropenic patients; Candidemia and certain *Candida* infections; Esophageal Candidiasis;	Labeling	• Extended indication from adults to children 3 months and older based upon evidence from adequate and well-controlled studies in adults and PK data in pediatric patients and additional data from pediatric studies • The efficacy and safety have not been adequately studied in infants < 3 months • The ability of caspofungin to penetrate the blood-brain barrier and to treat patients with meningitis and endocarditis is unknown	B, P	Merck	4/15/2008	