	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
				Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies		• Dosing should be based on the patient's body surface area. Maximum loading dose and daily maintenance dose should not exceed 70 mg • The safety profile in pediatrics is comparably to adults • Information on dose, AEs, PK parameters, clinical studies and infusion preparation instructions				
103.	7/24/2008	Navstel Intraocular Irrigating Solution Sterile#	balanced salt ophthalmic solution with hypromellose, dextrose and glutathione	Use as an intraocular irrigating solution during surgical procedures involving perfusion of the eye	Labeling	• Safety and efficacy have been demonstrated in pediatric patients • New active ingredient	P	Alcon	NA	✓
104.	7/1/2008	Flovent HFA	fluticasone propionate	Asthma in < 4 years	Labeling	• Flovent HFA should be administered by the orally inhaled route only in patients 4 years and older. • Clinical studies were conducted in children with asthma 6 months to less than 4 years • Information added to Pediatric Use	P	GlaxoSmithKline	NA	
105.	6/30/2008	Aciphex	rabeprazole	Gastroesophageal reflux in adolescent patients 12 years of age and above	Labeling	• Use in adolescent patients 12 years of age and older is supported by extrapolation of results from studies in adults and safety and PK studies performed in adolescent patients • Safety and effectiveness for GERD have not been established for pediatric patients <12 years of age • Safety and effectiveness for other uses have not been established in pediatric patients • Adverse events (AEs) similar to those seen in adults • Information on dose, AEs, clinical studies	B, P	Eisai Medical Research	NA	
106.	6/24/2008	KINRIX	Diphtheria and	*Active*	Package	See Package Insert for new information on	P	GlaxoSmit	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
			Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine•	*immunization against diphtheria, tetanus, pertussis, & poliomyelitis as the fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series when previous DTaP vaccine doses have been with INFANRIX and/or PEDIARIX and for the first three doses and INFANRIX for the fourth dose*	Insert	biologics		hKline Biologicals		
107.	6/24/2008	Viramune Tablets 200 mg Viramune Oral Suspension 10 mg/mL	nevirapine	Use in combination with other antiretroviral agents for the treatment of HIV-1 infection	Labeling	• Dosing information provided for children ages >15 days to <16 years old • Safety was evaluated in children 2 weeks and older in 5 clinical trials and important adverse events (all causality) include rash (21%), neutropenia (8.9%), anemia (7.3%) and hepatotoxicity (2.4%) • Safety, pharmacokinetics, and virologic and immunologic responses have been evaluated in HIV-infected pediatric patients age 3 months to 18 years • Safety and pharmacokinetics were evaluated in HIV-infected pediatric patients age 15 days to < 3 months • Efficacy was evaluated in one clinical study with children 3 months to 16 years of age	P	Boehringer Ingelheim	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
						• Post-marketing surveillance has shown anemia to be more commonly observed in children although development of anemia due to concomitant medication use cannot be ruled out • Potential drug interaction information is provided for children with respect to lopinavir/ritonavir • New dosing regimen				
108.	6/23/2008	Aptivus	tipranavir	Co-administered with ritonavir for combination antiretroviral in patients who are treatment-experienced and infected with HIV-1 strains resistant to more than one protease inhibitor	Labeling	• Extended indication from adults to children 2 years and older • The risk-benefit has not been established in patients <2 years of age • Dosing is based on body weight or body surface area not to exceed adult dose • AEs are generally similar to those seen in adults however, rash was more frequent in pediatric patients than in adults; The frequency of rash through 48 weeks of treatment was 21%. Most rashes were mild and 5% were moderate. Overall 3% interrupted treatment due to rash • Information on dose, AEs, PK parameters, lab abnormalities, and clinical study	B, P	Boehringer Ingelheim	3/7/2008	
109.	6/20/2008	Kaletra	lopinavir/ ritonavir	Use in combination with other antiretroviral agents for HIV-1 infection	Labeling	• Extended indication from 6 months - 12 years to 14 days - 18 years • The safety, efficacy, and pharmacokinetic profiles in pediatric patients < 14 days have not been established • Dose should be calculated based on body weight or body surface area not to exceed adult dose • Because no data exists for dosage when administered with efavirenz, nevirapine, (fos)amprenavir, or nelfinavir, it is recommended that lopinavir/ ritonavir not be administered in combination with these drugs in patients < 6 months of age • Infants <6 months of age generally had	B, P	Abbott	3/7/2008	

	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
						lower lopinavir AUC12 than children 6 months - 12 years of age • Information on dose, PK parameters, clinical studies, and AEs				
110.	6/20/2008	Pentacel	Diphtheria And Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus B Conjugate (Tetanus Toxoid Conjugate) Vaccine•	Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to *Haemophilus influenzae* type b	Package Insert	See Package Insert for new information on biologics	P	Sanofi Pasteur	NA	
111.	6/5/2008	Zetia and Vytorin	ezetimibe and ezetimibe/ simvastatin	Heterozygous familial hypercholesterolemia as an adjunct to diet	Labeling	• The effects of ezetimibe co-administered with simvastatin compared to simvastatin monotherapy have been evaluated in adolescent boys and girls with heterozygous familial hypercholesterolemia (HeFH)	B, P	MSP Singapore	2/14/2008	
112.	5/9/2008	OraVerse Injection 0.4 mg (0.235 mg/mL)	phentolamine mesylate	Reversal of soft-tissue anesthesia, i.e., anesthesia of the lip and tongue, and the associated functional deficits resulting from an intraoral submucosal injection of a local anesthetic containing a vasoconstrictor		• Use in children less than 6 years of age or weighing less than 15 kg (33 lbs) is not recommended • Dosing information provided for children weighing 15 to 30 kg (66 lbs) • Safety and efficacy were established in 2 clinical trials in children 12 to 17 years old, one trial in children ages 6 to 11 years, as well as adult studies • Safety has been evaluated in pediatric patients under the age of 6 years but not efficacy • Pharmacokinetics have been evaluated in children weighing 15 kg or more	P	Novalar Pharmaceuticals, Inc.	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
						• New indication				
113.	5/8/2008	Desmopressin acetate Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)		• Efficacy in RCCT was evaluated in a single trial with children 3 to 18 years old • Three studies evaluated efficacy in children 5 to 17 years old with PNE; an additional study evaluated efficacy in adolescents 12 to 17 years old • Fluid intake should be adjusted downward in children to decrease the potential occurrence of water intoxication and hyponatremia • Dosing information provided for children 3 to 18 years old for RCCT • Dosing information provided for pediatric patients 6 years of age and older with PNE • Tablet dosage and administration information provided for children with central diabetes insipidus • Pharmacokinetics and pharmacodynamics were evaluated in children • New indications and dosing regimen	P	Ferring	NA	
114.	5/5/2008	Levaquin Tablets, 250 mg, 500 mg, and 750 mg# Levaquin Oral Solution, 25 mg/mL# Levaquin Injection and Levaquin Injection, 5 mg/mL#	levofloxacin levofloxacin in 5% dextrose injection	Reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis (inhalational anthrax post-exposure)		• New indication • Dosing information provided for children less than and greater than 50 kg • Efficacy is based on plasma concentrations achieved in humans, a surrogate endpoint reasonably likely to predict clinical benefit, and animal studies were used to evaluate survival; the product has not been tested in humans for the post-exposure prevention of inhalation anthrax • Safety in pediatric patients treated for more than 14 days has not been studied • Long-term safety data, including effects on cartilage, following administration in pediatric patients is limited • Due to possible side effects, use is not recommended for pediatric patients except in the prevention of anthrax after	P	Ortho-McNeil-Janssen Pharmaceutical, Inc.	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
						inhalational exposure • Pharmacokinetics were investigated in pediatric patients 6 months to 16 years old				
115.	5/5/2008	Argatroban	argatroban	Heparin-Induced Thrombocytopenia (HIT) or HIT with Thrombosis	Labeling	• Safety and effectiveness, including the appropriate anticoagulation goals and duration of therapy, have not been established in pediatric patients • Population PK/PD analysis of sparse data in 15 seriously ill pediatric patients ages <6 months – 16 years diagnosed with HIT or suspected HIT requiring an alternative to heparin anticoagulation showed clearance in pediatric patients was 50% lower compared to healthy adults and led to dose recommendations • Information on dose, AEs and PK	B, P	Encysive	NA	
116.	4/30/2008	Cardiolite	technetium tc99m sestamibi	Medical imaging in Kawasaki disease	Labeling	• Safety and effectiveness have not been established in the pediatric population • No evidence of diagnostic efficacy or clinical utility of scan was found in 3 clinical studies of children and adolescents with Kawasaki disease • A study of 445 pediatric patients failed to demonstrate the predictive value of Cardiolite rest and stress myocardial perfusion imaging to define children with Kawasaki disease at risk of developing cardiac events 6 months after receiving Cardiolite; only 3cardiac events were observed. In all 3 cases, the scan was negative • Adverse events similar to that of adults • Information on dose, PK, and clinical studies	B, P	Lantheus Medical Imaging	1/11/2008	
117.	4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR) in patients 12 years	Labeling	• Safety and effectiveness in children below the age of 12 years have not been established • Symptoms of antihistamine overdose in	P	Alcon Research, Ltd.	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
				of age and older		children may initially include agitation and restlessness followed by drowsiness • Efficacy and safety were evaluated in 3 clinical trials of 2 weeks duration in adult and adolescent patients, 12 years of age and older, with symptoms of SAR • Dosage and administration information provided for children 12 years and older • New indication, dosage form, dosing regimen, and route of administration				
118.	4/7/2008	Orencia	abatacept	Moderate to severe polyarticular juvenile idiopathic arthritis		• Indicated for reducing signs and symptoms in pediatric patients with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) ages 6 years and older. • The safety and effectiveness in pediatric patients < 6 years of age and in pediatric patients for uses other than JIA have not been established • Abatacept was studied in 190 patients 6 - 17 years with polyarticular JIA. • AEs were generally similar to those seen in adults. Overall frequency of adverse events in the 4-month, lead-in, open-label period of the study was 70%; infections occurred at a frequency of 36%. A total of 6 serious adverse events were reported during the initial 4 months of treatment with abatacept. • Information on dosing, PK, immunogenicity, immunization needs, AEs, and clinical study • New indication	P	Bristol-Myers Squibb	NA	
119.	4/3/2008	ROTARIX	Rotavirus Vaccine, Live, Oral•	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9)	Package Insert	See Package Insert for new information on biologics	P	GlaxoSmithKline Biolgocials	NA	
120.	3/31/2008	Lancôme UV	avobenzone,	Sunscreen		• Effectiveness extrapolated from adult	P	L'Oreal	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
		Expert 40 La Roche-Posay Anthelios 40 Vichy Capital Soleil 40	ecamsule, octocrylene, titanium dioxide cream	OTC		studies • Safety studies included pediatric patients 6 months of age and older • Age range based on standards established in over-the –counter monograph for sunscreens • New active ingredient •		USA		
121.	3/26/2008	Ventolin HFA	albuterol	Treatment of symptoms of bronchospasm associated with obstructive airway disease	Labeling	• Safety and effectiveness of albuterol administered with or without a spacer device in children < 4 years of age has not been demonstrated • 3 randomized, double-blind, placebo-controlled studies in 250 children < 4 years, in which efficacy was not demonstrated, suggest that either the optimal dose has not been defined in this age-group or the drug is not effective in this age-group • Information on clinical studies	B	GlaxoSmithKline	8/27/2008	
122.	3/25/2008	Reyataz	atazanavir	HIV in 6 years and older	Labeling	• Extended indication from adults to children 6 years and older • The safety, activity, and pharmacokinetic profiles in pediatric patients ages 3 months to < 6 years have not been established. Atazanavir should not be administered to pediatric patients below the age of 3 months due to the risk of kernicterus • Dosing is based on body weight or body surface area not to exceed adult dose • Adverse events (AEs) are generally similar to those seen in adults • Information on dose, AEs, PK parameters, lab abnormalities, and clinical study	B, P	Bristol-Myers Squibb	NA	
123.	3/24/2008	Depakote ER Depakote Sprinkles	divalproex disodium	Pediatric Bipolar Disorder; Prophylaxis of Migraine	Labeling	• Efficacy was not established in a double-blind, placebo controlled study of patients 10-17 years conducted to evaluate efficacy in the treatment of pediatric bipolar disorder • Efficacy was not established in a double-	B, P	Abbott	12/14/2007	

	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
						blind, placebo-controlled study of patients 12 – 17 years conducted to evaluate the efficacy in the prophylaxis of migraine • The safety and tolerability was similar to adults in 5 long-term safety studies • Additional information on clinical studies, AE profile in Depakote ER labeling				
124.	3/20/2008	Prilosec	omeprazole	Maintenance healing of erosive esophagitis	Labeling	• Efficacy was extrapolated from adults and older children to 1 to 2 year olds and supported with an open-label trial • Unique adverse reactions in pediatric patients included increased respiratory system adverse events and fever. • Safety and effectiveness in children less than 1 year of age have not been established • Dosing and administration information provided for patients 1 year and older weighing at least 5 kg. • New dosage form	B, P	AstraZeneca	NA	
125.	3/20/2008	Zometa	zoledronic acid	Severe osteogenesis imperfecta	Labeling	• Zoledronic acid is not indicated for use in children • Safety and effectiveness was studied in 152 pediatric patients with severe osteogenesis imperfecta aged 1 - 17 years. At one year, increases in BMD were observed in the zoledronic acid treatment group but the changes did not necessarily correlate with the risk for fracture or the incidence or severity of chronic bone pain • Information on PK, clinical study, and AE profile	B	Novartis	12/21/2007	
126.	3/19/2008	ARTISS	Fibrin Sealant (Human)•	To adhere autologous skin grafts to surgically prepared wound beds resulting from burns	Package Insert	See Package Insert for new information on biologics	P	Baxter	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
127.	3/14/2008	NovoLog	insulin aspart [rDNA origin] injection	Insulin analog indicated to improve glycemic control	Labeling	• Efficacy was demonstrated in a clinical study with pediatric patients ages 4 to 18 years using an external insulin pump • New dosing regimen	P	Novo Nordisk	NA	
128.	3/12/2008	DAPTACEL	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed•	*Active immunization as a booster dose against diphtheria, tetanus & pertussis*	Package Insert	See Package Insert for new information on biologics	P	Sanofi Pasteur	NA	
129.	2/27/2008	Abilify	aripiprazole	Bipolar I Disorder	Labeling	• Extended treatment of acute Bipolar Disorder indication from adults to pediatrics 10–17 years • The efficacy for the maintenance treatment of Bipolar Disorder in the pediatric population has not been evaluated • The recommended target dose in Bipolar Disorder is 10 mg/day. • In the study of pediatric patients 10 – 17 years with Bipolar Mania, 4 common adverse reactions had a possible dose response relationship at 4 weeks; extrapyramidal disorder, somnolence, akathisia and salivary hypersecretion • Information on dose, AEs, clinical studies	B, P	Otsuka	11/14/2007	
130.	2/27/2008	Nexium	esomeprazole	Short-term treatment of GERD	Labeling	• Expanded age range to include pediatric patients 1-11 years. Previously approved in 12-17 years • Use in pediatric patients 1 to 17 years of age is supported by extrapolation from studies in adults, and safety and PK studies performed in pediatric and adolescent patients • Safety and effectiveness in pediatric patients <1 year of age have not been established • Safety and effectiveness for other pediatric uses have not been established • Information on dose, treatment related	B	AstraZeneca	5/1/2009	

	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
						adverse events (AEs), clinical study • New formulation				
131.	2/21/2008	Humira	adalimumab	Treatment of juvenile idiopathic arthritis	Labeling	• Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA)in patients 4 years of age and older • Has not been studied in children <4 years of age; there are limited data on treatment in children with weight <15 kg • Safety and efficacy in pediatric patients for uses other than JIA have not been established • Adalimumab was studied in 171 patients 4 - 17 years with polyarticular JIA. • AEs were generally similar to those seen in adults. 45% of children experienced an infection while receiving adalimumab with or without concomitant MTX in the first 16 weeks of treatment. Serious infections were observed in 4% of patients within approximately 2 years of initiation of treatment • Information on dose, AEs, lab abnormalities, PK parameters, immunogenicity, immunization needs and clinical study • New indication	P	Abbott	NA	
132.	2/1/2008	Asmanex Twisthaler 110mcg inhalation powder	mometasone furoate	Maintenance treatment of asthma as prophylactic therapy in children 4 years of age and older		• Not indicated for relief of acute bronchospasm or in children less than 4 years of age • Clinical studies, including 52 week safety trial conducted in children 4 – 11 years of age • Pediatric dosing information provided • Child may not get the most benefit for 1 to 2 weeks or longer after starting treatment • New dosage form	P	Schering Corporation	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
133.	1/31/2008	Inspra	eplerenone	Hypertension	Labeling	• Effectiveness was not established in a study of 304 hypertensive pediatric patients 4 - 17 years; eplerenone, at doses up to 100 mg/ day, did not lower blood pressure effectively • Therefore, it has not been studied in hypertensive patients <4 years old • Eplerenone has not been studied in hypertensive patients < 4 years or in pediatric patients with heart failure • Adverse events similar to that of adults	B, P	Pfizer	10/24/2007	
134.	1/28/2008	Xyzal 0.5 mg/mL Oral Solution#	levocetirizine dihydrochloride	Relief of symptoms associated with seasonal and perennial allergic rhinitis (SAR and PAR) and treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (CIU)	Labeling	• Dosing information provided • Studies waived in children less than 6 months of age with PAR and CIU • Waived in children less than 2 years of age with SAR • New dosage form pediatric	P	UCB	NA	✓
135.	1/23/2008	Moxatag	amoxicillin	Use for tonsillitis and/or pharyngitis secondary to Streptococcus pyogenes patients 12 years of age and older	Labeling	• Safety and effectiveness in pediatric patients younger than 12 years have not been established • One clinical study evaluated safety and effectiveness in pediatric patients 12 years of age and older with no significant differences in treatment response or adverse reactions between adults and children • A prospective study of 51 children suggested that overdosages of less than 250 mg/kg are not associated with significant clinical symptoms and do not require gastric emptying • Waiver of studies in children ages 0 to less than two years because too few children have the disease	P	Middlebrook Pharmaceuticals	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
						• New dosage form				
136.	1/17/2008	TamiFlu	oseltamivir	Safety information resulting from studies that established treatment of uncomplicated acute illness due to influenza infection in patients 1 year and older	Labeling	• Influenza can be associated with a variety of neurologic and behavioral symptoms which can include events such as hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease. • These events have been reported in patients receiving oseltamivir, primarily among pediatric patients, appear to be uncommon, and often had an abrupt onset and rapid resolution • If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient	B	Roche	3/22/2004	✓
137.	1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma in patients 12 years of age and older.	Labeling	• Not indicated for children under the age of 12 years • Five clinical studies evaluated safety in children 12 years of age and older • Safety and effectiveness have not been established in children under 12 years of age • Waiver of studies in children 0 to less than 6 months of age due to too few patients with the disease • New dosage form	P	Nycomed US Inc.	NA	
138.	1/2/2008	EVICEL	Fibrin Sealant (Human)•	Adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques is ineffective or	Package Insert	See Package Insert for new information on biologics	P	Johnson/Johnson Wound Management	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
				impractical						
139.	12/27/2007	AndroGel	testosterone	Use in adolescent boys with delayed puberty	Labeling	• Safety and efficacy in males < 18 years old have not been established • Improper use may result in acceleration of bone age and premature closure of epiphyses	B	Unimed	8/22/2007	
140.	12/27/2007	Voluven	6% Hydroxyethyl Starch 130/0.4 In 0.9% Sodium Chloride Injection•	Plasma volume substitute for treatment and prophylaxis of hypovolemia	Package Insert	See Package Insert for new information on biologics	P	Fresenius Kabi Norge AS	NA	
141.	12/19/2007	Hepsera	adefovir dipivoxil	Chronic hepatitis B virus infection	Labeling	• Extended indication from adults to pediatric patients 12 years and older • Not recommended for children <12 years of age. Efficacy was not significantly different from placebo in a clinical study in children <12 years • Safety ≥12 – < 18 years was similar to that observed in adults • Information on PK, AEs, clinical study, clinical resistance	B, P	Gilead	NA	
142.	12/12/2007	Derma-Smoothe/FS Topical Oil	fluocinolone	Treatment of atopic dermatitis in pediatric patients 3 months and older for up to 4 weeks.		• Extended age range down to 3 months • Effectiveness and safety are not established in children less than 3 months old • Safety was evaluated in two pediatric clinical studies (including facial use) • Pediatric dosing and administration information provided • Studies waived in children under 3 months of age due to safety concerns of adrenal suppression • New indication	P	Hill	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
143.	11/29/2007	Triesence 40mg/mL	triamcinolone acetonide injectable suspension	Visualization during vitrectomy	Labeling	• Efficacy and safety of corticosteroids in the pediatric population are based on the well-established course of effect of corticosteroids, which is similar in pediatric and adult populations • Adverse effects of corticosteroids in pediatric patients are similar to those in adults • New indication	P	Alcon Research, Ltd.	NA	✓
144.	11/29/2007	Diovan	valsartan	Hypertension	Labeling	• Labeling for 6-16 years of age • Not recommended for pediatric patients less than 6 years due to safety findings possibly related to treatment or with glomerular filtration rate < 30mL/min/1.73m2 • Information on dose, clinical studies in 1-16 years and pharmacokinetics • No relevant differences were identified between adverse experience profile for pediatric patients and that previously reported for adult patients • Information on preparation of a suspension	B	Novartis	8/8/2007	
145.	11/21/2007	Omnaris Nasal Spray	ciclesonide	Treatment of seasonal allergic rhinitis (SAR) in patients 6 through less than 12 years of age	Labeling	• Indication extended down to 6 years of age • Pediatric dosing information provided • Two clinical studies evaluated safety in children 6 to 11 years of age and the overall incidence of adverse events was comparable to those treated with placebo • Efficacy in children 2 to 5 years of age was not established in clinical trials conducted in this age group. • Waiver of studies in children ages 0 to less than 2 years of age for SAR because of local and systemic safety concerns as well as lack of disease and/or diagnosis difficulties in children • New indication	P	Nycomed US Inc.	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
146.	11/9/2007	Kaletra Oral Solution, 80 mg/20 mg & Kaletra (1opinavir/ritonavir) Tablets, 200 mg/50 mg	lopinavir/ ritonavir	HIV -1 protease inibitor indicated in combination with other antiretroviral agents for the treatment of HIV -1 infection.	Labeling	• Dosing and administration information provided for children • Use of a lower strength tablet in a twice daily dosing regimen for pediatric patients weighing greater than 15 kg • New dosing regimen	P	Abbott Laboratories	NA	✓
147.	10/30/2007	Combigan 0.2%/0.5% ophthalmic solution	brimonidine tartrate/timolol maleate	Reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension	Labeling	• Safety and effectiveness supported by evidence from clinical studies in adults with additional data from a study in children with glaucoma ages 2 – 7 years old • Not recommended for use in children under the age of 2 years due to safety concerns based on reports of apnea, bradycardia, hypotension, hypothermia, hypotonia, and somnolence in infants • Safety and effectiveness have not been studied in children below the age of two years • New active ingredient	P	Allergan	NA	✓
148.	10/29/2007	Abilify	aripiprazole	Schizophrenia	Labeling	• Extended schizophrenia indication from adults to adolescents 13–17 years • Safety and effectiveness in pediatric patients with bipolar mania or agitation associated with schizophrenia or bipolar mania have not been established • Efficacy for the maintenance treatment of schizophrenia in the pediatric population has not been evaluated • In 6-week placebo controlled efficacy trial in patients 13 – 17 years with Schizophrenia 30 mg/day was not shown to be more efficacious than 10 mg/day • Common adverse events observed were extrapyramidal disorder, somnolence, and tremor; these 3 AEs appear to have a possible dose response relationship • Information on dose, AEs, clinical studies	B	Otsuka)	11/14/2007	
149.	9/28/2007	Lamisil	terbinafine	Tinea capitis	Labeling	• New indication in 4 years and older	B	Novartis	12/4/2006	

	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
		Oral Granules				• Two randomized safety and efficacy trials were conducted in patients 4 to 12 years old with tinea capitis. Terbinafine was dosed on a mg/kg basis and treated for 6 weeks • Although no hepatotoxicity was seen during trials, pre-treatment serum transaminases tests are advised. • The most common adverse events observed in the trials were nasopharyngitis, headache, pyrexia, cough, vomiting, and upper respiratory tract infection • New 125 mg and 187.5 mg oral granule formulations developed; take with food • Information on dose, PK parameters, AE profile, and instructions for use				
150.	9/20/2007	Norditropin Cartridges	somatropin [rDNA origin]	Treatment of short stature in children with Turner syndrome	Labeling	• Safety and effectiveness based on studies in pediatric patients • New Warning: Patients with Turner syndrome should be evaluated carefully for otitis media and other ear disorders since these patients have an increased risk of ear and hearing disorders. Somatropin treatment may increase the occurrence of otitis media in patients with Turner syndrome. In addition, patients with Turner syndrome should be monitored closely for cardiovascular disorders (e.g., stroke, aortic aneurysm/dissection, hypertension) as these patients are also at risk for these conditions • Information on recommended dosing, adverse events (AEs) and clinical studies • New indication	P	Novo Nordisk	NA	
151.	9/11/2007	Levaquin	levofloxacin	Community-acquired pneumonia	Labeling	• Levofloxacin is not indicated for pediatric patients < 18 years of age • In a prospective, long-term, surveillance study, levofloxacin treated children had a significantly higher incidence of musculoskeletal (MS) disorders (arthralgia,	B, P	Ortho-McNeil	3/14/2007	

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						arthritis, tendonopathy, and gait abnormality) compared to non-fluoroquinolone-treated children • Information on clinical studies, AE profile				
152.	8/22/2007	Risperdal	risperidone	Schizophrenia; short-term treatment of acute manic or mixed Episodes associated with Bipolar I Disorder	Labeling	• Extended schizophrenia indication from adults to adolescents 13–17 years; extended bipolar mania indication from adults to children and adolescents 10-17 years • 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 • No additional benefit was seen above 3 mg/day in schizophrenia studies and 2.5 mg/day in the Bipolar mania study; higher doses were associated with more adverse events. Doses higher than 6 mg/day have not been studied. • Information on dose, clinical studies, AE profile	B	Johnson & Johnson	2/28/2007	
153.	8/17/2007	Provigil	modafinil	Narcolepsy	Labeling	• Modafinil is not approved for use in pediatric patients for any indication • Safety and effectiveness were not demonstrated in a controlled 6-week study in 165 pediatric patients 5-17 years with narcolepsy • Serious rash, including Stevens-Johnson Syndrome, requiring hospitalization and discontinuation of treatment has been reported in adults and children in association with the use of modafinil • In the controlled and open-label clinical studies, treatment emergent adverse events of the psychiatric and nervous system included Tourettes' syndrome, insomnia, hostility, increased cataplexy, increased hypnagogic hallucinations and suicidal ideation	B	Cephalon, Inc	3/21/2006	

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						• Information on safety, AEs and clinical study				
154.	8/16/2007	Zingo	lidocaine	Topical local analgesia prior to venipuncture or peripheral intravenous cannulation in children 3-18 years of age		• Summary pending	P	Anesiva	NA	
155.	7/18/2007	Toprol XL	metoprolol	Hypertension	Labeling	• A study in 144 pediatric hypertensive pediatric patients aged 6 - 16 years did not meet its primary endpoint. However, some study endpoints demonstrated effectiveness • Adverse event profile similar to adults • Safety and effectiveness have not been established in patients < 6 years of age • Information on PK parameters, clinical studies, and dose	B	AstraZeneca	7/27/2006	
156.	6/14/2007	Lexiva Oral Suspension	fosamprenavir	Treatment of HIV infection in patients 2-18 years of age	Labeling	• Effectiveness and safety were established in two clinical studies of pediatric patients 2-18 years of age • Adverse event profile is similar to that of adults with the exception of vomiting, which, regardless of causality, occurred more frequently among pediatric patients • Dosing information provided • Studies waived in children 0-1 month of age and deferred in children 1 month - 2 years of age • New dosage form	P	GlaxoSmithKline	NA	
157.	6/12/2007	Extina Foam, 2%	ketoconazole	Topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and	Labeling	• Effectiveness and safety were established in a clinical study that included 44 patients from 12-17 years of age • Studies waived in children 0-12 years of age	P	Stiefel Laboratories	NA	

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				older		• New dosage form				
158.	6/8/2007	Betoptic S	betaxolol	Elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension	Labeling	• Extended indication from adults to pediatric patients • The adverse reaction profile was comparable to that seen in adults	B	Alcon	2/28/2007	
159.	6/8/2007	Timolol GFS	timolol	Elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension	Labeling	• Extended indication from adults to pediatric patients • The adverse reaction profile was comparable to that seen in adults	B	Falcon Pharmaceuticals	2/28/2007	
160.	5/30/2007	Zyflo CR Extended Release Tablets	zileuton	Prevention and chronic treatment of asthma in children 12 years of age and older	Labeling	• Should not be used in children under 12 years of age • Effectiveness was established in clinical studies that included pediatric patients 12 years of age and older • Short-term and long-term safety were established in clinical studies that included pediatric patients 12 years of age and older • Studies waived in children 0-4 years of age and deferred in children 5-11 years of age • New dosage form	P	Critical Therapeutics	NA	
161.	5/25/2007	Xyzal Tablets 5 mg	levocetirizine	Relief of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis in adults and children 6 years of age or older, and for the treatment of the uncomplicated	Labeling	• Summary pending	P	UCB	NA	