	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
				skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age or older						
162.	5/18/2007	Locoid Lotion 0.1%	hydrocortisone butyrate	Treatment of mild to moderate atopic dermatitis in children 3 months of age and older	Labeling	• Effectiveness established in one study of 284 patients from 3 months to 18 years of age • Information provided on HPA axis suppression from one safety study with Locoid Lotion of 84 pediatric patients from 3 months to 18 years of age with moderate to severe atopic dermatitis affecting at least 25% of body surface area • Studies waived in children < 3 months of age • New dosage form	P	Ferndale Labs	NA	
163.	4/27/2007	Azasite Ophthalmic Solution 1%	azithromycin	Treatment of bacterial conjunctivitis caused by certain microorganisms in patients down to 1 year of age	Labeling	• Effectiveness and safety were established in controlled clinical trials including patients down to 1 years of age • Dosing information provided • New dosage form	P	InSite Vision	NA	
164.	4/19/2007	Valtropin	somatropin [rDNA origin]	Short stature in children with Turner Syndrome	Labeling	• Summary pending	P	LG Life	NA	
165.	4/12/2007	Altabax Ointment 1%	retapamulin	Treatment of impetigo in patients 9 months of age and older	Labeling	• Safety and effectiveness established in studies that included 588 pediatric patients from 9 months of age to 17 years of age • Studies waived in children 0-2 months of age and deferred in children 2-9 months of age • New active ingredient	P	GlaxoSmithKline	NA	
166.	3/28/2007	Ambien	zolpidem	Insomnia associated with ADHD	Labeling	• Safety and effectiveness have not been established in pediatric patients with insomnia associated with ADHD	B	Sanofi Aventis	11/20/2006	

	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
						• In an 8-week controlled study in 201 pediatric patients 6-17 years, psychiatric and nervous system disorders comprised > 5% of treatment emergent adverse events, including dizziness (23.5%) headache (12.5%) and hallucinations (7.4%); treatment was discontinued due to an adverse event in 7.4%				
167.	3/22/2007	Aldara	imiquimod	Molluscum contagiosum	Labeling	• Efficacy in patients 2 – 12 years for the treatment of molluscum contagiosum was not demonstrated in two clinical trials in 702 patients • Information on clinical studies and AEs	B	Graceway Pharmaceuticals	12/13/2006	
168.	3/19/2007	Keppra Tablets Keppra Oral Solution	levetiracetam*	Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in children 6 years of age and older with idiopathic generalized epilepsy	Labeling	• Safety and effectiveness established in study that included patients down to 4 years of age • Pediatric dosing information added • Studies waived in children 1 month to 2 years of age and deferred in children 2-6 years of age • New indication	P	UCB	NA	
169.	2/23/2007	Coreg	carvedilol	Heart failure	Labeling	• Effectiveness has not been established in patients < 18 years • In a double-blind trial of 161 children, 2 months to 17 years with chronic heart failure receiving standard background treatment, randomized to placebo or carvedilol, carvedilol demonstrated reduction of heart rate 4-6 beats per minute • There was no significant effect of treatment on clinical outcomes after 8 months of follow-up • AEs occurring in ≥ 10% of patients treated with carvedilol included chest pain (17%), dizziness (13%), and dyspnea (11%)	B, P	GlaxoSmithKline	11/8/2006	

	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
170.	2/23/2007	Vyvanse Capsules	lisdexamfetamine	Treatment of ADHD in children 6 to 12 years of age	Labeling	• Effectiveness established in two studies of patients 6-12 years of age • Long-term effectiveness of more than 4 weeks has not been established • Studies waived in children 0-5 years of age and deferred in children 13-17 years of age • New active ingredient	P	New River	NA	
171.	2/7/2007	Actiq	fentanyl	Treatment of breakthrough pain in opioid tolerant children	Labeling	• Safety and efficacy in patients below the age of 16 years was not established in a clinical trial of 15 patients 5 to 15 years • Information on PK parameters and clinical studies	B, P	Cephalon	NA	
172.	1/10/2007	Eloxatin	oxaliplatin	Solid tumors	Labeling	• The effectiveness of oxaliplatin in children has not been established • No significant activity observed in 2 Phase I and 2 Phase II trials in 159 patients ages 7 months to 22 years with solid tumors • Information on clinical studies and AEs	B	Sanofi-Aventis	9/27/2006	
173.	12/22/2006	Emtriva	emtricitabine	HIV-1 infection in combination with other antiretroviral agents	Labeling	• Efficacy in preventing or treating HIV in neonates to 3 month olds could not be determined after a PK study in 20 neonates born to HIV positive mothers • Information on dose in 0-3 months, additional safety and PK parameters	B	Gilead Sciences	5/24/2006	
174.	12/20/2006	Colazal	balsalazide	Mildly to moderately active ulcerative colitis in patients 5 years of age and older	Labeling	• Extended indication from adults to patients 5 years and older • Dosing can be initiated at either 6.75 or 2.25 g/day • PK of balsalazide, and metabolites showed very large inter-patient variability similar to that seen in adults • AEs were similar to those seen in adults	B, P	Salix	8/23/2006	

	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
175.	12/15/2006	Celebrex	celecoxib	Relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA)	Labeling	• New indication in 2 years and older • Has not been studied in patients < 2 years, in patients with body weight < 10 kg, or in patients with active systemic features • Celecoxib should be used only with caution in patients with systemic onset JRA due to the risk for serious adverse reactions including the risk of disseminated intravascular coagulation • The long-term cardiovascular toxicity in children has not been evaluated; it is unknown if the long-term risk may be similar to that seen in adults • New 50 mg capsule developed • Information on adding contents of a capsule to applesauce. for patients with difficulty swallowing capsules • Information on dose, clinical studies, PK parameters, AEs	B	Pfizer	8/23/2006	
176.	12/15/2006	Suprane	desflurane	Safety study of 2 agents used for maintenance of anesthesia in non-intubated patients	Labeling	• Not indicated for maintenance of anesthesia in non-intubated pediatric patients • In a clinical safety trial in patients 2 - 16 years, desflurane and isoflurane were compared for maintenance of anesthesia in non-intubated patients to assess the incidence of respiratory adverse events. Desflurane was associated with higher rates of coughing, laryngospasm and secretions with an overall rate of respiratory events of 39%. 5% of pediatric patients 2-16 years old exposed to desflurane, experienced severe laryngospasm • The incidence of respiratory events was highest in children aged 2-6 years; therefore, similar studies in children under the age of 2 years were not initiated. • Additional information on clinical studies and AEs	B	Baxter	9/13/2006	
177.	11/7/2006	Ziana Gel	clindamycin;	Treatment of	Labeling	• Effectiveness and safety based on two	P	Dow	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
			tretinoin	acne vulgaris in patients 12 years of age and older		studies in patients 12 years of age and older • New active ingredient				
178.	11/1/2006	Humatrope for injection	somatropin [rDNA origin]	Treatment of short stature or growth failure in children with short stature homeobox-containing gene (SHOX) deficiency	Labeling	• Effectiveness established from one 2-year study for SHOX in 52 pediatric patients • Information on adverse events provided • Dosing information provided • New indication	P	Lilly	NA	
179.	10/20/2006	Desonate Gel	desonide	Treatment of mild to moderate atopic dermatitis in children 3 months of age and older	Labeling	• Effectiveness established from two studies in patients 3 months to 18 years of age • Not recommended for use in patients under 3 months of age • Treatment should not exceed 4 consecutive weeks • HPA axis suppression studied in patients 6 months of age to 6 years of age • New dosage form	P	Dow	NA	
180.	10/19/2006	Zaditor ophthalmic solution#	ketotifen	Temporary relief of itchy eyes in children 3 years of age and older OTC	Labeling	• No new studies submitted • New indication	P	Novartis	NA	✓
181.	10/16/2006	Allegra	fexofenadine	Seasonal allergic rhinitis (SAR) uncomplicated skin manifestations of chronic idiopathic urticaria (CIU)	Labeling	• New suspension developed • Suspension indicated for the treatment of SAR in 2 – 11 years based on the PK comparisons in adult and pediatric patients and an extrapolation of efficacy in adults; Suspension indicated for the treatment of CIU in 6 months – 11 years based on the PK comparisons in adults and children and an extrapolation of efficacy in adults • Safety and effectiveness of suspension in pediatric patients under 6 months of age have not been established	B	Aventis	1/27/2003	

	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
						• Additional information on dose, PK parameters, safety and AEs				
182.	10/13/2006	Tirosint capsules#	levothyroxine	Replacement or supplemental therapy in hypothyroidism; treatment or prevention of euthyroid goiters	Labeling	• Contraindicated in infants, small children, or any child who may be unable to swallow a capsule. • Dosing information provided • Information to monitor disease provided • No clinical studies submitted • New dosage form	P	Institute Biochimique SA	NA	
183.	10/6/2006	Risperdal Tablets Risperdal Oral Solution Risperdal M-Tabs	risperidone*	Treatment of irritability associated with autistic disorder in children 5 years of age and older	Labeling	• Effectiveness and safety established based on two 8 week studies in patients 5-16 years of age and one long-term study of 4-6 months • Studies waived in children under 2 years of age due to difficulty to diagnose and treat this population • New indication	P	Janssen	NA	
184.	10/5/2006	UV Protective Suncare# Capital Soleil 20# Anthelios 20# UV Expert 20#	avobenzone; ecamsule; octocrylene; titanium	Prevention of sunburn and protection from UVA and UVB rays in children 6 months of age and older OTC	Labeling	• No clinical studies submitted to support • Age range based on monograph • Studies deferred in children under 6 months of age • New active ingredient	P	L'Oreal	NA	
185.	9/29/2006	DuraPrep Surgical Solution#	iodine; isopropyl alcohol	Preoperative skin preparation for use in children 2 months of age and older OTC	-	• Effectiveness based on determination that permeability of skin in children > 2 months of age is essentially that of adult skin • Studies waived in children under 2 months of age for safety reasons and includes the following statement in the label: Do not use in children under 2 months of age due to excessive skin irritation and transient hypothyroidism. • New active ingredient	P	3M Health	NA	
186.	9/29/2006	Fuzeon	enfuvirtide	HIV-1 infection in	Labeling	• Additional safety and efficacy data and AE	B, P	Hoffmann-	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
				treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy		information from clinical study in 5-16 year olds • Insufficient data to provide dosing recommendations in patients < 6 years		La Roche		
187.	9/28/2006	Azopt ophthalmic suspension	brinzolamide	Elevated intraocular pressure	Labeling	• IOP-lowering efficacy was not demonstrated in a 3-month controlled clinical study in which brinzolamide was dosed only twice a day in pediatric patients 4 weeks to 5 years of age	B	Alcon	6/28/2006	
188.	9/28/2006	Betaxon ophthalmic suspension	levobetaxolol	Elevated intraocular pressure	Labeling	• Extended indication from adults to pediatric patients • The adverse event profile was comparable to that seen in adults and elderly patients	B, P	Alcon	6/28/2006	
189.	9/27/2006	Gleevec	imatinib mesylate	Treatment of newly diagnosed pediatric patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase	Labeling	• Extended age range for the treatment of newly diagnosed CML down to pediatric patients • There are no data in children < 2 years of age • Follow-up in children with newly diagnosed Ph+ chronic phase CML is limited • Information on hematologic toxicities, AE profile, clinical studies and dosing guidelines new for newly diagnosed pediatric patients	B, P	Novartis	6/9/2006	
190.	9/22/2006	Lamictal Tablets Lamictal Chewable Dispersible Tablets	lamotrigine*	Adjunctive therapy for primary generalized tonic-clonic seizures in children 2 years of age and older	Labeling	• Effectiveness established in study with patients down to 2 years of age • Revised boxed warning to remove restrictions on use in pediatric patients • New indication	P	GlaxoSmithKline	NA	
191.	9/19/2006	Verdeso Foam	desonide	Treatment of mild to moderate	Labeling	• Effectiveness established from studies in 581 pediatric patients 3 months to 17 years	P	Connetics	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
				atopic dermatitis in patients 3 months of age and older		of age • Effect on HPA axis function was investigated in pediatric patients 6 months to 17 years of age in one study of 75 patients • Safety has not been evaluated in patients below 3 months of age • Use for the minimum amount of time necessary due to the potential to suppress HPA axis treatment should not exceed 4 consecutive weeks • New dosage form				
192.	9/15/2006	Noxafil Oral Suspension	posaconazole	Prevention of invasive Aspergillis and Candida infections in patients 13 years of age and older	Labeling	• Information on PK and safety studies in patients 13-17 years of age • Safety profile in patients 8-17 years of age similar to adults • Safety and effectiveness in patients below 13 years of age have not been established • Additional information on pharmacokinetics provided in patients down to 8 years of age • Studies deferred in children 0-12 years of age • New drug	P	Schering	NA	
193.	7/28/2006	Xolegel Gel	ketoconazole	Treatment of seborrheic dermatitis in children 12 years of age and older	Labeling	• Effectiveness established from studies in patients 12 years of age and older • Safety and effectiveness in pediatric patients below 12 years of age have not been establishedstudies waived in children 0-12 years of age • New dosage form	P	Barrier Therapeutics	NA	
194.	7/27/2006	Sodium Chloride Injection#	sodium chloride	Use in flushing compatible contrast agents through IV administration sets into indwelling intravascular	Labeling	• Safety of manual injection in pediatric patients is supported by reported clinical experience with IV infusion and flush safety and effectiveness of Sodium Chloride Injection, USP 0.9% administered by power injection in pediatric patients have not been established • Administration to pediatric patients by	P	Tyco Healthcare	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
				access devices		power injection is not recommended • To minimize the risk of fluid overload, the smallest dose necessary for manually flushing contrast agent through the vascular access line should be used • Manual injection to pediatric patients should take into account the patient's weight, fluid status, and concomitant medical conditions to determine if use is appropriate • New indication				
195.	7/21/2006	Anthelios SX Cream	avobenzone; ecamsule; octocrylene	Prevention of sunburn and protection from UVA and UVB rays in children 6 months of age and older OTC	Labeling	• Effectiveness extrapolated from adult studies • Safety studies included pediatric patients 6 months of age and older • Age range based on monograph • Deferred studies in children < 6 months of age • New active ingredient	P	L'Oreal USA	NA	
196.	7/21/2006	Symbicort Inhalation Aerosol	Formoterol / budesonide*	Long-term maintenance treatment of asthma in children 12 years of age and older	Labeling	• Effectiveness and safety in patients 12 years of age and older established in studies up to 12 months long • PK studies in patients 6-11 years of age • Effectiveness in patients 6 to < 12 years of age has not been established • Overall safety profile in patients 6 to < 12 years of age was similar to that observed in patients 12 years of age and older • Studies waived in children 0-6 years of age; deferred in children 6-12 years of age • New active ingredient	P	AstraZeneca	NA	
197.	6/29/2006	Lidocaine and Tetracaine Cream	lidocaine; tetracaine	Topical local analgesia for superficial dermatological procedures	Labeling	• Studies failed to show effectiveness over placebo in reducing the pain associated with venipuncture in pediatric patients 5-17 years of age • New active ingredient	P	ZARS	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
198.	5/10/2006	Sandostatin LAR	octreotide	Weight loss due to hypothalamic obesity from cranial insult	Labeling	• A randomized double-blind, placebo-controlled study in 60 patients aged 6 –17 years with hypothalamic obesity from cranial insult did not demonstrate efficacy and safety of octreotide as a weight loss agent; Mean BMI increased 0.1 kg/m2 in drug treated patients compared to 0.0 kg/m2 in control-treated patients • No unexpected AEs were observed; However, the incidence of new cholelithiasis in this pediatric population (33%) was higher than that seen in adult indications • Information on PK parameters and AEs	B	Novartis	1/12/2006	
199.	5/8/2006	Solodyn Extended-Release Tablets	minocycline	Treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in children 12 years of age and older	Labeling	• Only used to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris • Safety and effectiveness established from studies in patients 12 years of age and older • Safety and effectiveness in pediatric patients below 12 years of age has not been established • Studies waived in children 0-11 years of age • New dosage form	P	Medicis	NA	
200.	4/28/2006	Nexium	esomeprazole	Short-term treatment of GERD	Labeling	• Use in adolescent patients 12 to 17 years of age is supported by extrapolation from studies in adults, and safety and PK studies performed in adolescent patients • Safety and effectiveness in patients < 12 years has not been established • Safety and effectiveness for other pediatric uses have not been established • Information on dose, treatment related AEs, clinical study	B	AstraZeneca	5/1/2009	
201.	4/27/2006	Genotropin Injection	somatropin	Long-term treatment of	Labeling	• Indicated for use in pediatric patients with open epiphyses	P	Pharmacia &	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
				growth failure associated with Turner syndrome		• Effectiveness and safety based on studies in pediatric patients • New indication		Upjohn		
202.	4/10/2006	Lescol and Lescol XL	fluvastatin	Heterozygous familial hypercholesterolemia as an adjunct to diet	Labeling	• New indication in adolescent boys and girls (at least one year post-menarche) 10-16 years of age, with heterozygous familial hypercholesterolemia • Information on dose, AE profile and clinical studies	B, P	Novartis	12/15/2005	
203.	4/6/2006	Daytrana	methylphenidate	ADHD	Labeling	• Summary pending	P	Shire	NA	
204.	3/29/2006	Relenza	zanamivir	Prevention of influenza in children 5 years of age and older	Labeling	• Safety and effectiveness for prophylaxis based on 4 clinical studies in patients 5-16 years of age • No differences in safety and effectiveness were observed between pediatric and adult subjects. • Dosing information provided • Studies waived in children <5 years of age • New indication	P	GlaxoSmithKline	NA	
205.	3/16/2006	Avapro	irbesartan	Hypertension	Labeling	• In a study at a dose up to 4.5 mg/kg once daily, irbesartan did not appear to lower blood pressure effectively in pediatric patients ages 6 to 16 years	B	Sanofi-Synthelabo	9/16/2004	
206.	3/2/2006	Vanos Cream	fluocinonide	Relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in children 12 years of age and older	Labeling	• Use in pediatric patients younger than 12 years of age is not recommended • Effectiveness extrapolated from adult studies • Safety in patients 12 to 17 years of age was similar to that observed in adults • Information provided on HPA axis suppression from safety studies with Vanos Cream in 4 cohorts of pediatric patients (3 months - 18 years of age) with atopic dermatitis • Studies waived in children 0-11 years of	P	Medicis	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
						age • New indication				
207.	2/28/2006	Flovent HFA	fluticasone propionate	Asthma in 4 - 11 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	
208.	2/16/2006	Vusion Ointment	miconazole	Adjunctive treatment of diaper dermatitis in children 4 weeks of age and older	Labeling	• Indicated for use in immunocompetent children • Presence of candidal infection should be established by microscopic evaluation prior to initiating treatment • Effectiveness based on three clinical studies in infants and toddlers • Safety when used for more than 7 days is not known • New active ingredient	P	Barrier Therapeutics	NA	
209.	2/3/2006	ProAir HFA Inhalation Aerosol	albuterol	Prevention of exercise-induced bronchospasm in children 12 years of age and older	Labeling	• Expands use from previously approved bronchospasm with reversible obstructive airway disease • Effectiveness based on study in adults and adolescents • Safety and effectiveness in pediatric patients below 12 years of age have not been established • New indication	P	IVAX	NA	
210.	2/1/2006	Clarinex-D 12 Hour Extended Release Tablets	desloratadine*/ pseudoephedrine	Relief of nasal and non-nasal symptoms of seasonal allergic rhinitis in children 12 years of age and older	Labeling	• Approval based on two safety and effectiveness studies in patients down to 12 years of age • Not an appropriate dosage form for use in pediatric patients below 12 years of age. • Studies waived in children < 12 years of age	P	Schering	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 dosing regimen				
211.	12/21/2005	Fosamax	alendronate	Severe osteogenesis imperfecta	Labeling	• Alendronate is not indicated for use in children • The efficacy and safety were examined in a randomized, double-blind, placebo-controlled two-year study of 139 patients, 4-18 years old, with severe osteogenesis imperfecta • Treatment with alendronate did not reduce the risk of fracture • There were no statistically significant differences between the alendronate and placebo groups in reduction of bone pain • Information on PK parameters, AE profile, and clinical studies	B	Merck	4/28/2003	
212.	12/21/2005	TamiFlu	oseltamivir	Prophylaxis in pediatric patients 1 year to <13 years of age	Labeling	• Information on postmarketing clinical study in patients 1 to 12 years	P	Roche	NA	
213.	12/8/2005	Meridia	sibutramine	Obesity	Labeling	• The data are inadequate to recommend the use of sibutramine for the treatment of obesity in pediatric patients • Efficacy in obese adolescents has not been adequately studied • Sibutramine's mechanism of action inhibiting the reuptake of serotonin and norepinephrine is similar to that of some antidepressants • It is unknown if sibutramine increases the risk of suicidal behavior or thinking in pediatric patients • In a study of adolescents with obesity in which 368 patients were treated with sibutramine and 130 patients with placebo, one patient in each group attempted suicide. Suicidal ideation was reported by 2 sibutramine-treated patients and none of the placebo patients	B	Abbott	10/6/2004	

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214.	12/1/2005	Effexor XR Extended-Release Capsules	venlafaxine*	Social anxiety disorder	Labeling	• Provided additional safety data for changes in weight, height, and appetite occurring in pediatric patient • Information based on a clinical study of patients with SAD • New indication (not approved in pediatric patients)	P	Wyeth	NA	
215.	11/28/2005	Amaryl	glimepiride	Type-2 Diabetes Mellitus	Labeling	• Data are insufficient to recommend pediatric use of glimepiride • In an active-controlled, single-blind, 24-week trial, 272 pediatric patients aged 8 to 17 years with Type 2 diabetes were randomized to treatment with glimepiride or metformin. Trial suggested differences favoring metformin • AE profile in the pediatric population was similar to that for adults • Information on PK parameters	B, P	Aventis	6/9/2005	
216.	11/9/2005	Fluocinolone Acetonide Oil	fluocinolone	Chronic eczematous external otitis (outer ear) in children 2 years of age and older	Labeling	• Effectiveness established in studies of patients 2 years of age and older • New indication	P	Hill Dermaceuticals	NA	
217.	10/28/2005	Trileptal	oxcarbazepine	Use as adjunctive therapy in children aged 2 years and above with epilepsy	Labeling	• Extended adjunctive therapy age range from 4 years down to 2 years • No evidence drug was effective as adjunctive therapy in patients < 2 years • In clinical studies as adjunctive therapy, apparent clearance (L/hr/kg) decreased when age increased such that children 2 to <4 years of age may require up to twice the dose per body weight compared to adults; and children 4 to ≤12 years of age may require a 50% higher dose per body weight compared to adults • Approximately 11% of pediatric patients < 4 years discontinued treatment because of adverse events including convulsions, status epilepticus and ataxia	B	Novartis	3/2/2005	

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						• Information on dose, PK parameters, AE profile and clinical studies				
218.	10/6/2005	Norvir	ritonavir	Treatment of HIV-infection in combination with other antiretroviral agents	Labeling	• Extended age range from 2 years down to 1 month • AE profile in the pediatric population was similar to that for adults • Information on dose and PK parameters	B	Abbott	6/14/2005	
219.	9/28/2005	Emtriva	emtricitabine	HIV-1 infection in combination with other antiretroviral agents	Labeling	• Safety and effectiveness in pediatric patients 3 months and older supported by data from 3 open-label, nonrandomized clinical studies • Safety and effectiveness in patients < 3 months have not been established • Relative bioavailability of Emtriva oral solution is approximately 80% of Emtriva capsules. Thus, maximum dosage is different for these 2 formulations: Solution max - 240 mg once daily; Capsules max - children weighing > 33 kg one 200 mg capsule once daily • The AE profile in pediatric patients was comparable to that observed in adults • Information on dose, PK parameters, AE profile and clinical studies •	B, P	Gilead Sciences	5/24/2006	
220.	9/13/2005	NovoLog	insulin aspart [rDNA origin] injection	Diabetes Mellitus	Labeling	• In clinical studies comparing NovoLog to regular human insulin in patients 2 to 18 years with type 1 diabetes, NovoLog achieved glycemic control comparable to regular human insulin • The incidence of hypoglycemia was similar for both treatment groups	B	Novo Nordisk	5/24/2005	
221.	8/11/2005	Mobic	meloxicam	Relief of signs and symptoms of pauciarticular or polyarticular course Juvenile	Labeling	• Safety and efficacy established in patients 2 years of age and older • Clinical studies evaluated doses ranging from 0.125 mg/kg/day to 0.375 mg/kg/day. There was no additional benefit	B, P	Boehringer Ingelheim	4/15/2005	

	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
				Rheumatoid Arthritis		demonstrated by doses above 0.125 mg/kg/day in the clinical trials. The lowest effective dose should be used • Adverse events in children were similar to those in adults including skin reactions and gastrointestinal bleed risk • Information on dose, PK parameters, AE profile and clinical studies				
222.	8/4/2005	Loperamide Hydrochloride Soft Gelatin Capsules#	loperamide	Control symptoms of diarrhea in children 12 years of age and older	Labeling	• New dosage form; new dosing regimen • No new clinical studies • Bioequivalence study in adults compared the current OTC drug (Imodium caplet) and this drug • Studies waived in children 0-2 years of age	P	Banner Pharmacaps	NA	✓
223.	7/29/2005	Avandia	rosiglitazone	Type 2 Diabetes Mellitus	Labeling	• Data are insufficient to recommend pediatric use of rosiglitazone • In a 24 week double-blind controlled trial in children with type 2 diabetes mellitus, aged 10 to 17 years, with a baseline BMI of 33 kg/m2 were randomized to treatment with rosiglitazone or metformin • Mean change from baseline in HbA1c was -0.14% with rosiglitazone and -0.49% with metformin • There was an insufficient number of patients to establish statistically whether these observed mean treatment effects were similar or different • Weight gain similar to that in adults • Information on PK parameters, and AE profile	B	SB Pharmco	12/09/2004	
224.	7/27/2005	Singulair Oral Granules#, Tablets#, and Chewable Tablets#	montelukast	Relief of symptoms of perennial allergic rhinitis in children 6 months of age and older	Labeling	• Effectiveness was extrapolated from a allergic rhinitis study in patients 15 years of age and older • Safety in patients 6 to 23 months is supported by data from PK and safety and efficacy studies in asthma in this pediatric population and from adult PK studies	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
						• Studies waived in children < 6 months of age • New indication				
225.	7/21/2005	Adderall XR	amphetamines , mixed salts	ADHD	Labeling	• Expanded labeling for 13-17 year olds • On a mg/kg body weight basis children 6-12 years have a higher clearance than adolescents or adults. Body weight is the primary determinant • There was not adequate evidence that doses greater than 20 mg/day conferred additional benefit in a placebo-controlled study conducted in adolescents aged 13-17 with ADHD • In a single-dose PK study in adolescents, isolated increases in systolic blood pressure (SBP) were observed in patients receiving 10 mg and 20 mg Adderall XR. Higher single doses were associated with a greater increase in SBP • Sustained increases in blood pressure should be treated with dose reduction and/or appropriate medication • Information on dose, PK parameters, and AE profile	B, P	Shire	10/28/2004	
226.	6/29/2005	Topamax Tablets and Sprinkle Capsules	topiramate*	Initial monotherapy for partial onset or primary generalized tonic-clonic seizures in children 10 years of age and older	Labeling	• Effectiveness established in studies of patients down to 6 years of age • Use in patients who were converted to monotherapy from a previous regimen of other anticonvulsant drugs have not been established in controlled trials • Provides information regarding treatment-emergent decrease in serum bicarbonate and adverse events • Some patients in the study discontinued therapy due to adverse events; however, adverse events associated with discontinuing therapy included difficulty with concentration/attention • Studies waived in children 0-2 years of age;	P	Johnson & Johnson	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
						deferred in children 2-10 years of age • New indication				
227.	6/21/2005	Keppra	levetiracetam	Adjunctive therapy in the treatment of partial onset seizures in patients with epilepsy	Labeling	• Extended indication from adults to patients 4 years and older • Safety and effectiveness have not been established in patients less than 4 years of age • PK analysis showed that clearance increased with an increase in body weight • Approximately 22% increase of apparent total body clearance of levetiracetam when co-administered with enzyme-inducing Anti-Epileptic Drugs (AEDs). Dose adjustment not necessary • 37.6% of pediatric patients reported behavioral symptoms compared to 13.3% in adults • Somnolence occurred in 22.8% in pediatric patients compared to 14.8% in adults • Information on dose, PK parameters, AE profile and clinical studies	B	UCB Pharma	6/3/2008	
228.	5/26/2005	Focalin XR Extended-Release Capsules	dexmethylphenidate	Treatment of Attention-Deficit Hyperactivity Disorder in children 6 years of age and older	Labeling	• Should not be used in children under 6 years of age • Effectiveness in patients age 6 years of age and older was established in clinical studies • PK studies also conducted • Long-term effects in children have not been established • New dosage form	P	Novartis	NA	
229.	5/25/2005	Merrem I.V.	meropenem	Treatment of complicated skin and skin structure infections in children 3 months of age and older	Labeling	• Supported by extrapolating safety and effectiveness from an adequate and well-controlled adult study and additional data from pediatric PK studies • Studies waived for children < 3 months of age • New indication	P	AstraZeneca	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
230.	5/18/2005	Invanz	ertapenem	Complicated Intra-abdominal Infections; Complicated Skin and Skin Structure Infections; Community Acquired Pneumonia; Complicated Urinary Tract Infections; Acute Pelvic Infections	Labeling	• Approved for use down to 3 months of age. Efficacy extrapolated from studies in adults and supported by PK and safety studies in pediatric patients • Not recommended in infants under 3 months of age as no data are available • Not recommended in the treatment of meningitis in the pediatric population due to lack of sufficient CSF penetration • Information on dose, PK parameters, AE profile and clinical studies	B	Merck	2/11/2005	
231.	5/13/2005	Ortho Tri-Cyclen	norgestimate/ ethinyl estradiol	Evaluation of total hip bone mineral density in adolescent females with anorexia nervosa	Labeling	• No significant difference between Ortho Tri-Cyclen and placebo in mean change in total lumbar spine (L1-L4) and total hip bone mineral density in 123 adolescent females with anorexia nervosa in a double-blind, placebo-controlled, multicenter, one-year clinical trial	B	Ortho McNeil	12/18/2003	
232.	5/12/2005	Zyvox	linezolid	Central nervous system infections	Labeling	• PK data in pediatric patients with ventriculoperitoneal shunts showed variable cerebrospinal fluid (CSF) concentrations; therapeutic concentrations were not consistently achieved or maintained in the CSF • Use of linezolid for the empiric treatment of pediatric patients with central nervous system infections is not recommended • Additional information on efficacy in pediatric patients with infectious vancomycin-resistant Enterococcus faecium	B	Pfizer	2/11/2005	
233.	5/6/2005	Doryx Delayed-Release Tablets#	doxycycline	Treatment of infections	Labeling	• No new clinical studies submitted • PK data • Dosing information for new dosage form (to decrease esophagitis seen from capsules) • New dosage form	P	Warner Chilcott	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
234.	4/26/2005	Gemzar	gemcitabine	Refractory leukemia	Labeling	• Effectiveness in pediatric patients has not been demonstrated • Phase 1 trial in pediatric patients with refractory leukemia demonstrated a maximum tolerated dose; however, no meaningful clinical activity observed in a Phase 2 trial of gemcitabine in 22 patients with relapsed acute lymphoblastic leukemia and 10 patients with acute myelogenous leukemia • Toxicities observed were similar to those reported in adults	B	Lilly	1/27/2005	
235.	3/25/2005	Zofran	ondansetron	Prevention of chemotherapy-induced and postoperative induced nausea and vomiting	Labeling	• Established dosing for surgical patients down to 1 month from 2 years of age • Established dosing for cancer patients down to 6 months from 4 years of age • Surgical and cancer patients < 18 years tend to have a higher ondansetron clearance compared to adults leading to a shorter half-life in most pediatric patients • The clearance of ondansetron in patients 1-4 months of age is slower and the half-life is approximately 2.5 fold longer than patients who are > 4 – 24 months of age • Patients < 4 months of age receiving this drug should be closely monitored • Additional information on dose, PK parameters, AE profile and safety	B	GlaxoSmithKline	12/1/2004	
236.	3/11/2005	Rapamune	sirolimus	Prophylaxis of organ rejection in patients undergoing renal transplants	Labeling	• Safety and efficacy established in children 13 years or older judged to be at low to moderate immunologic risk • Safety was assessed in a controlled clinical trial in pediatric (<18 years of age) renal transplant recipients considered high immunologic risk. The use of Rapamune in combination with calcineurin inhibitors and corticosteroids was associated with an increased risk of deterioration of renal function, lipid abnormalities, and urinary tract infections	B	Wyeth	11/17/2004	