	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 efficacy have not been established in pediatric patients less than 13 years old or in pediatric renal transplant recipients considered at high immunologic risk • Information on PK parameters, adverse events and safety				
237.	3/11/2005	Xopenex HFA Inhalation Aerosol	levalbuterol	Treatment of bronchospasm in patients with reversible obstructive airway disease in children 4 years of age and older	Labeling	• Extended indication for use in children down from 6 years of age • Pediatric patients have a lower exposure to the drug than adults • Population PK model developed from patients down to 4 years of age • Effectiveness and safety established from studies in adults, adolescents (12 years of age and older) and children ages 4-11 years of age with asthma. • Deferred studies in patients < 4 years of age • New active ingredient	P	Sepracor	NA	
238.	3/3/2005	Clarinex D 24 Hour Extended Release Tablets	desloratadine*/ pseudoephedrine	Relief of nasal and non-nasal symptoms of seasonal allergic rhinitis, including nasal congestion, in patients 12 years of age and older	Labeling	• Two safety and effectiveness studies conducted in patients 12 years of age and older • PK study • Studies waived in children < 12 years of age • New active ingredient; new dosing regimen	P	Schering	NA	
239.	2/18/2005	Celexa	citalopram	Major Depressive Disorder	Labeling	• Safety and effectiveness in the pediatric population have not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Celexa or any other antidepressant in a	B	Forest	7/12/2002	

	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
						child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Celexa is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Two placebo-controlled trials in 407 pediatric patients with MDD have been conducted with Celexa, and the data were not sufficient to support a claim for use in pediatric patients				
240.	5/5/2004 and 2/18/2005	Effexor and Effexor XR	venlafaxine	Major Depressive Disorder	Labeling	• Effectiveness in pediatric patients has not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Effexor or any other antidepressant in a	B, P	Wyeth	12/2/2002	

	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
						child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Effexor is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials. • 18% of Effexor XR treated patients (6-17 years) versus 3.6 % of placebo treated patients experienced a weight loss of at least 3.5 % in both MDD and the GAD studies • In an open-label study increases in weight were less than expected based on data from age and sex matched peers. The difference between observed weight gain was larger for children less than 12 years than for adolescents older than 12 years • During an 8 week placebo controlled GAD trial, Effexor XR treated patients ages 6-17 years grew an average of 0.3 cm, while placebo treated patients grew an average of 1 cm. In a 6 month open-label study, height increases that were less than expected based on data from age and sex				

	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
						matched pairs. The difference between observed and expected growth rates were larger for children less than 12 years than for adolescents older than 12 years • Decreased appetite observed in 10% of patients ages 6-17 years old receiving Effexor XR • Occurrence of blood pressure and cholesterol increases considered clinically relevant in pediatric patients similar to that observed in adults				
241.	9/28/2000 and 2/18/2005	Luvox	fluvoxamine	Treatment of obsessions and compulsions in patients with OCD	Labeling	• Determined that a dose adjustment (increased dose) may be necessary in adolescents and girls 8-11 years of age may require lower doses • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of fluvoxamine or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Fluvoxamine is not approved for use in pediatric patients except for patients with obsessive compulsive disorder (OCD). (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a	B	Solvay	1/3/2000	

	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
						total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • The efficacy of fluvoxamine for the treatment of OCD was demonstrated in a 10-week multicenter placebo controlled study with 120 outpatients ages 8 to 17. In addition, 99 of these outpatients continued open-label fluvoxamine treatment for up to another one to three years, equivalent to 94 patient years				
242.	1/3/2003 and 2/18/2005	Prozac	fluoxetine	Major Depressive Disorder (MDD) & Obsessive Compulsive Disorder (OCD)	Labeling	• Effectiveness established in patients 7-17 years of age for OCD • Effectiveness established in patients 8-17 years of age for MDD • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Prozac or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Prozac is approved for use in pediatric patients with MDD and obsessive compulsive disorder (OCD). (See Warnings and Precautions: Pediatric	B	Lilly	11/15/2000	

	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
						Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Decreased weight gain has been observed in association with the use of fluoxetine, as with other SSRIs. In one 19-week clinical trial pediatric subjects treated with fluoxetine gained an average of 1.1cm less in height (p=0.004) and 1.1 kg less in weight (p=0.008) than those treated with placebo. Therefore, height and weight should be monitored periodically in pediatric patients treated with fluoxetine • Mania/hypomania led to discontinuation of 1.8% of fluoxetine treated patients vs. 0% of placebo controlled patients in the three placebo-controlled trials combined. Regular monitoring for the occurrence of mania/hypomania is recommended • Higher average steady state fluoxetine and norfluoxetine concentrations were observed in children than in adolescents. These differences were almost entirely explained by differences in weight • Separate dosing recommendations in lower weight children				
243.	2/18/2005	Zoloft	sertraline	Major Depressive Disorder and Obsessive	Labeling	• Safety and effectiveness in the pediatric population other than pediatric patients with OCD have not been established	B	Pfizer	2/1/2002	

	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
				Compulsive Disorder		• FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents • Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Zoloft or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Zoloft is not approved for use in pediatric patients except for patients with obsessive compulsive disorder (OCD). (See Warnings and Precautions: Pediatric Use) Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Two placebo controlled trials in 373 pediatric patients with MDD have been conducted with Zoloft, and the data were not sufficient to support a claim for use in pediatric patients				

	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
244.	1/12/2005	Paxil	paroxetine	Major Depressive Disorder	Labeling	• Safety and effectiveness in the pediatric population have not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Paxil or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Paxil is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Three placebo-controlled trials in 752 pediatric patients with MDD have been conducted with Paxil, and the data were not sufficient to support a claim for use in pediatric patients	B	Glaxo	6/27/2002	

	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
245.	1/12/2005	Remeron	mirtazapine	Major Depressive Disorder	Labeling	• Safety and effectiveness in the pediatric population have not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Remeron or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Remeron is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Two placebo-controlled trials in 258 pediatric patients with MDD have been conducted with Remeron and the data were not sufficient to support a claim for use in pediatric patients	B	Organon	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
246.	1/12/2005	Serzone	nefazodone	Major Depressive Disorder	Labeling	• Safety and effectiveness in the pediatric population have not been established • FDA required boxed warning for all antidepressants: Suicidality in Children and Adolescents - Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of Serzone or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Serzone is not approved for use in pediatric patients. (See Warnings and Precautions: Pediatric Use) Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events in patients receiving antidepressants was 4%, twice the placebo risk of 2%. No suicides occurred in these trials • Two placebo-controlled trials in 286 pediatric patients with MDD have been conducted with Serzone, and the data were not sufficient to support a claim for use in pediatric patients	B	Bristol-Myers Squibb	6/27/2002	

	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
247.	12/28/2004	Clolar	clofarabine	Relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens	Labeling	• Labeling for patients 1 to 21 years old. This use is based on the induction of complete responses • Randomized trials demonstrating increased survival or other clinical benefit have not been conducted • Information on dose, PK parameters, and AE profihe	B	Genzyme	7/14/2004	
248.	12/22/2004	Pataday Ophthalmic Solution	olopatadine	Treatment of ocular itching associated with allergic conjunctivitis (itchy eyes) in children 3 years of age and older	Labeling	• Based on clinical trials that included patients down to 3 years of age. • New indication	P	Alcon	NA	
249.	12/17/2004	Augmentin ES-600 Powder for Oral Suspension#	amoxicillin; clavulanate	Treatment of acute bacterial sinusitis (ABS) (sinus infection) in children 3 months of age and older	Labeling	• No new pediatric studies • Effectiveness extrapolated from adult studies for Augmentin XR for ABS and from studies in pediatric patients with otitis media and by similar pharmacokinetics in pediatric patients • New indication	P	GlaxoSmithKline	NA	✓
250.	12/16/2004	VisionBlue Ophthalmic Solution#	trypan blue	Aid in ophthalmic surgery by staining anterior capsule	Labeling	• Approved for use in all populations based on information from clinical trials in the literature • New drug	P	DORC International	NA	
251.	12/10/2004	Agrylin	anagrelide	Myeloproliferative disorders	Labeling	• An open-label study evaluated PK/PD but not efficacy. • Information on PK/PD profile, dosing, AEs, and safety in patients > 6 years to 17 years • No overall difference in dosing and safety were observed between pediatric and adult patients • Established recommended starting dose based on limited data. Dosage should be adjusted to the lowest effective dosage	B	Shire	5/25/2004	

	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
252.	11/16/2004	Zomig	zolmitriptan	Migraine	Labeling	• Clinical trial evaluating zolmitriptan in pediatric patients ages 12 -17 years did not establish the safety and effectiveness when compared to placebo • AEs observed in clinical trials were similar to those observed in clinical trials in adults.	B	AstraZeneca	12/18/2003	
253.	10/21/2004	Concerta	methylphenidate	ADHD	Labeling	• Expanded labeling for 13-17 year olds including information on dose, PK parameters, and AE profile • Increase in age resulted in increased apparent oral clearance • For patients new to methylphenidate: higher maximum recommended dosage for adolescents compared to children 6-12 years of age • Data are inadequate to determine whether chronic use of stimulants in children may cause suppression of growth. Therefore, growth should be monitored during treatment • Safety and efficacy in children <6 years have not been established	B	Alza	12/4/2003	
254.	10/13/2004	Imitrex Nasal Spray	sumatriptan	Migraine	Labeling	• Five clinical trials evaluating oral sumatriptan in pediatric patients ages 12 - 17 years did not establish the safety and effectiveness when compared to placebo • Postmarketing experience documents that serious AEs rarely reported in adults, including stroke, visual loss, and death have occurred in the pediatric population after use of subcutaneous, oral, and/ or nasal sumatriptan. • Since clinical data to determine the frequency of serious adverse events in pediatric patients who might receive injectable, oral, and/ or intranasal sumatriptan are not presently available, the use of sumatriptan in patients aged younger than 18 years is not recommended	B	Glaxo	2/18/2004	

	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
255.	9/29/2004	Amlexanox Mucoadhesive Patch	amlexanox	Treatment of apthous ulcers in children 12 years of age and older	Labeling	• Approval based on monograph and previous studies for other indication • No new studies submitted • Studies in children birth – 12 years of age waived • New indication	P	Access Pharmaceuticals	NA	✓
256.	9/1/2004	Clarinex	desloratadine	Seasonal and perennial allergic rhinitis, and the symptomatic relief of pruritus, and hives	Labeling	• Indicated for seasonal allergic rhinitis down to 2 years of age. Extended age range down to 6 months for perennial allergic rhinitis and chronic idiopathic urticaria • Safety and effectiveness of tablets or syrup has not been established in pediatric patients less than 6 months of age • Information on dose, PK parameters, and AE profile in pediatric patients 6 months - 11 years of age	B	Schering	2/12/2003	
257.	8/19/2004	Vioxx	rofecoxib	Pauciarticular or polyarticular course Juvenile Rheumatoid Arthritis	Labeling	• Merck announced a voluntary worldwide withdrawal of Vioxx (rofecoxib) due to safety concerns on September 30, 2004. http://www.fda.gov/cder/drug/infopage/vioxx/PHA_vioxx.htm	B	Merck	2/18/2004	
258.	8/13/2004	Ferrlecit	sodium ferric gluconate complex	Iron deficiency anemia in chronic hemodialysis patients receiving supplemental erythropoietin therapy	Labeling	• Safety and effectiveness established in pediatric patients 6 -15 years old • Patients <6 years of age not studied • Information on dose, PK parameters and AE profile	B, P	Watson	3/24/2004	
259.	7/30/2004	Claritin-D 12 Hour Extended-Release Tablets# Claritin-D 24 Hour Extended-Release	loratadine*; pseudoephedrine	Temporary relief of nasal congestion due to the common cold in children 12 years of age and older OTC	Labeling	• Approval based on monograph and previous studies for other indication • No new studies submitted • Studies in children birth - 12 years of age waived • New indication	P	Schering-Plough	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
		Tablets#								
260.	6/24/2004	Camptosar	irinotecan	Refractory solid tumors	Labeling	• Effectiveness in pediatric patients has not been established • Adverse event profile from a Phase 2 trial with 170 children with refractory solid tumors comparable to that seen in adults; Grade 3-4 neutropenia experienced by 54 (31.8%) patients, neutropenia complicated by fever in 15 (8.8%) patients, Grade 3-4 diarrhea observed in 35 (20.6%) patients. • Accrual for phase 2 study with 21 children with previously untreated rhabdomyosarcoma halted due to high rate (23.6%) of progressive disease and early deaths (14%) • Adverse event profile seen in the 21 children different than that observed in adults; most significant Grade 3 or 4 adverse events were dehydration experienced by 6 patients (28.6%) associated with severe hypokalemia in 5 patients (23.8%) and hyponatremia in 3 patients (14.3%); in addition Grade 3-4 infection was reported in 5 patients (23.8%)(across all courses of therapy and irrespective of causal relationship) • PK parameters comparable to adults • Minimal accumulation of irinotecan and SN-38 (active metabolite) observed in children on daily dosing	B	Pfizer	3/10/2004	
261.	6/24/2004	TamiFlu	oseltamivir	Treatment of uncomplicated acute illness due to influenza infection in patients 1 year and older	Labeling	• Not recommended in pediatric patients less than 1 year of age because of uncertainties regarding the rate of development of the human blood-brain barrier and the unknown clinical significance of animal toxicology data for human infants	B	Roche	3/22/2004	
262.	6/21/2004	Codeprex Extended-Release Suspension#	chlorpheniramine; codeine	Temporary relief of cough associated with the common cold	Labeling	• Approval and age range based on monograph for antitussives and antihistamine • No clinical studies submitted	P	Celltech 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
				or inhaled irritants; temporary relief of symptoms of hay fever, other upper respiratory allergies, or allergic rhinitis in children 6 years of age and older OTC		• Studies in children < 6 years of age deferred • New dosage form; new dosing regimen				
263.	6/17/2004	Prevacid	lansoprazole	Short-term treatment of symptomatic GERD and erosive Esophagitis	Labeling	• Effectiveness was not established in a 4 week multicenter, double-blind, placebo-controlled study of patients 1 month and < 12 months of age • AE profile similar to that observed in adults • Information on PK parameters in neonates to < 1 year, and clinical studies	B	Tap	7/15/2008	
264.	6/2/2004	Humalog Injection	insulin lispro	Treatment of patients with diabetes mellitus for the control of hyperglycemia (high blood sugar) in children 3-11 years of age	Labeling	• Safety and effectiveness established from studies in patients 3-11 years of age • Dosing information added for external insulin pumps • New route of administration	P	Lilly	NA	
265.	5/25/2004	Axid	nizatidine	Esophagitis, and heartburn due to GERD	Labeling	• Indicated in pediatric patients 12 years and older • Information on dose, PK parameters, and AE profile	B	Reliant Pharms	NA	
266.	5/6/2004	Lidosite Topical System Kit	epinephrine; lidocaine	Topical local analgesia for superficial dermatological procedures in children 5 years of age and older	Labeling	• 505(b)(2) with clinical studies • Safety and effectiveness established in studies of pediatric patients 5-18 years of age • PK study in pediatric patients 6-15 years of age dosing regimen established in clinical trials • Studies in patients 0-5 years of age deferred	P	Vyteris	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; new route of administration				
267.	4/29/2004	Mucinex DM Extended-release Tablet#	guaifenesin; dextromethorphan	Expectorant and cough suppressant in children 12 years of age and older	Labeling	• 505(b)(2) approved with no pediatric information • Age range based on monograph • Do not use in children under 12 years of age • studies waived in children < 12 years of age due to safety concerns • New dosage form	P	Adams Respiratory Therapeutics	NA	
268.	4/21/2004	Advair Diskus	fluticasone/ salmeterol	Asthma	Labeling	• Extended indication from 12 years down to 4 years of age	P	GlaxoSmithKline	NA	
269.	4/14/2004	Detrol LA	tolterodine	Urinary frequency and urge incontinence in neurologically normal children and improvement of urodynamic parameters in children with neurologic disease	Labeling	• Efficacy in pediatric population has not been demonstrated • The dose-plasma concentration relationship is linear in patients from 11 to 15 years • Parent/ metabolite ratios differed according to CYP2D6 metabolizer status • 710 pediatric patients ages 5 -10 years with urinary frequency and urge incontinence were studied in 2 randomized placebo controlled trials. Urinary tract infections were higher in patients treated with Detrol LA (6.6%) compared to placebo (4.5%) • Aggressive, abnormal and hyperactive behavior and attention disorders occurred in 2.9% of children treated with Detrol LA compared to 0.9% treated with placebo	B	Pfizer	1/5/2004	
270.	4/14/2004	Trusopt	dorzolamide	Reduction in intraocular pressure	Labeling	• Safety and IOP-lowering effects have been demonstrated in pediatric patients • Adverse event profile was comparable to that seen in adults	B	Merck	1/5/2004	
271.	4/1/2004	Corlopam	fenoldopam	Indicated for the in-hospital, short-term reduction in	Labeling	• Indicated for the in-hospital, short-term (up to 4 hours) reduction in blood pressure in pediatric patients <1 month (at least 2 kg)	B	Hospira	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
				blood pressure		to 12 years of age • Information on PK, dose and AE profile • Clinical studies did not include patients 12 – 16 years of age				
272.	3/31/2004	Zemplar	paricalcitol	Secondary hyperparathyroidism associated with end stage renal disease	Labeling	• Safety and effectiveness were examined in a 12 week randomized, double-blind, placebo-controlled study of 29 pediatric patients aged 5-19 years old with end stage renal disease on hemodialysis; information • Primary efficacy analysis revealed 9 of 15 patients in Zemplar group had 2 consecutive 30 % decreases from baseline intact PTH compared with 3 of 14 patients in placebo group • No patients in either group developed hypercalcemia (defined as at least one calcium value >11.2 mg/dL) during study	B	Abbott	12/8/2003	
273.	3/25/2004	Cipro	ciprofloxacin	Complicated UTI and pyelonephritis	Labeling	• Indicated for the treatment of complicated urinary tract infections (cUTIs) and pyelonephritis in pediatric patients 1 – 17 years of age • Not drug of first choice due to increased adverse events compared to controls including events related to joints and/or surrounding tissues • Information on PK and dose in pediatric patients 1 – 17 years of age • The most frequent adverse events observed within 6 weeks of treatment initiation during the cUTI clinical trial were gastrointestinal 15% compared to 9% and musculoskeletal 9.3% compared to 6% in ciprofloxacin-treated compared to control-treated patients, respectively	B	Bayer	12/18/2003	
274.	3/19/2004	Viracept	nelfinavir	HIV-1	Labeling	• Safety and effectiveness established in patients 2 – 13 years of age • New twice daily dosing regimen and modified three times daily dosing for	B, P	Pfizer	9/4/2003	

	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
						pediatric patients > 2 years • A reliably effective dose not established in patients <2 years of age • PK information in pediatric patients from birth to 13 years of age • Highly variable drug exposure is a significant problem in pediatric patients • Adverse event profile was similar to that for adults				
275.	3/15/2004	Glucovance	glyburide / metformin	Type 2 Diabetes Mellitus	Labeling	• As studied in active-controlled, double blind trial in pediatric patients (9 – 16 years of age), Glucovance was not statistically superior to either metformin or glyburide in reducing HbA1C from baseline • No unexpected safety findings	B	Bristol-Myers Squibb	10/8/2003	
276.	3/11/2004	Cozaar	losartan	Hypertension	Labeling	• Antihypertensive effects established in hypertensive patients 6-16 years of age • Not recommended for pediatric patients less than 6 years or with glomerular filtration rate < 30mL/ min/1.73 m2 due to no data • Information on PK and dose in pediatric patients 6-16 years of age. • No relevant differences between the AE profile for pediatric patients compared to reported AEs for adults • Information on preparation of a suspension	B	Merck	3/20/2002	
277.	3/8/2004	Ultiva	remifentanil	Maintenance of anesthesia	Labeling	• Safety and efficacy for the maintenance of anesthesia established from birth to 1 year of age • Recommended dosing guidelines for maintenance of anesthesia for patients from birth to 2 months • The clearance rate observed in neonates was highly variable – approximately 2 times higher than young healthy adults • Individual doses for each patient should be	B, P	Abbott	3/15/2000	

	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
						carefully titrated				
278.	3/5/2004	Arava	leflunomide	Polyarticular Juvenile Rheumatoid Arthritis	Labeling	• Safety and efficacy in pediatric patients with polyarticular JRA have not been fully evaluated • 94 patients with polyarticular JRA were studied in a double-blind active controlled trial (1:1 randomization); approximately 68% of pediatric patients receiving Arava versus 89% receiving active comparator demonstrated improvement on the primary endpoint by week 16 • Pediatric patients with a body weight ≤ 40 kg have a reduced clearance relative to adult rheumatoid arthritis patients • Information on PK of M1, the active metabolite responsible for in vivo activity in children 3-17 years old • Most common adverse events in 74 polyarticular JRA patients 3-17 years old included abdominal pain, diarrhea, nausea, vomiting, oral ulcers, upper respiratory tract infections, alopecia, rash, headache, and dizziness • 14 of the 74 patients experienced ALT and/or AST elevations; 5/14 were between 3 and 8 fold the upper limit of normal	B, P	Aventis	11/10/2003	
279.	3/2/2004	Lotensin	benazepril	Hypertension	Labeling	• Information on dose, PK in pediatric patients 6-16 years of age • Not recommended for pediatric patients less than 6 years or with glomerular filtration rate < 30mL/min/1.73 m2 due to insufficient data • Infants below the age of 1 year should not be given ACE inhibitors due to concerns over possible effects on kidney development • The clearance rate was substantially higher in hypertensive children and adolescents than that of healthy adults • The terminal half life (t1/2) in pediatric	B	Novartis	7/2/2003	

	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
						patients was one third of that observed in adults • Adverse event profile in pediatric patients was similar to that seen in adults • Information on preparation of a suspension				
280.	2/27/2004	Myfortic Delayed-Release Tablets	mycophenolic acid	Prevention of organ rejection in patients receiving allogeneic renal transplants in children 5-16 years of age with stable renal transplants	Labeling	• Approval based on extrapolation of safety and effectiveness in adult patients • One PK study with information down to 5 years of age • Waived studies in birth to 10 years because there are too few children to study. • New active ingredient	P	Novartis	NA	
281.	2/24/2004	Children's Advil Allergy Sinus Suspension	chlorpheniramine; ibuprofen*; pseudoephedrine*	Symptoms of allergic rhinitis (runny nose) and the common cold in children 6 years of age and older	Labeling	• Effectiveness extrapolated from adult studies • Bioequivalence studies in healthy adults • PK and safety studies in children 6 to 12 years of age • New dosage form	P	Wyeth Consumer Healthcare	NA	
282.	1/15/2004	Zithromax Tablets	azithromycin	Treatment of acute bacterial sinusitis (sinus infection) in patients 6 months of age and older	Labeling	• Effectiveness extrapolated from adult sinusitis studies and from pediatric acute otitis media studies • Clinical studies conducted in pediatric patients 3 years to 16 years of age to determine PK and safety for oral suspension • Safety and effectiveness in patients under 6 months of age have not been established • Side effects seen in pediatric patients were comparable to those seen in adults, with different incidence rates for the dosage regimens recommended in pediatric patients • Dosing regimen established • Partial waiver < 6 months of age because too few patients to study • New indication	P	Pfizer	NA	