	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	N N P S
						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	

	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
283.	1/08/2004	Norvasc	amlodipine	Hypertension	Labeling	• Information on dose, PK in pediatric patients 6-17 years of age • Adverse event profile in pediatric patients was similar to that seen in adults	B	Pfizer	11/27/2001	
284.	12/12/2003	Xenical	orlistat	Obesity management	Labeling	• Use in 12-16 year olds is supported by studies in adults with additional data from a 54 week safety and efficacy study in obese adolescent patients. • Since orlistat can reduce absorption of fat soluble vitamins, all patients should take a daily multivitamin supplement containing fat soluble vitamins. • Adverse event profile in adolescent patients was similar to that seen in adults	B	Roche	9/12/2003	
285.	12/10/2003	Ertaczo Cream	sertaconazole	Treatment of interdigital tinea pedis (athlete's foot) in children 12 years of age and older	Labeling	• Safety and effectiveness established in clinical trials involving adolescent patients • Studies in patients less than 12 years of age waived because there are too few children with the disease to study • New drug	P	Mylan	NA	
286.	12/2/2003	Malarone	atovaquone/ proguanil	Treatment of malaria	Labeling	• Safety and effectiveness established down to ≥ 11kg • Information on dose, efficacy, PK parameters and AE profile • Elimination half-life is shorter in pediatric patients (1 to 2 days) than in adults (2 to 3 days) • Attributable AE's occurring in ³ 5% of the pediatric patients were vomiting (10%) and pruritus (6%)	B	GlaxoSmithKline	8/6/2003	
287.	10/16/2003	Elestat Ophthalmic Solution	epinastine	Prevention of itching associated with allergic conjunctivitis in children 3 years of age and older	Labeling	• Based on effectiveness and safety studies that included children down to 10 years of age • Partial waiver for children < 3 years of age because the condition does not exist in the age group	P	Allergan	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 drug				
288.	10/10/2003	Denavir Cream	penciclovir	Treatment of recurrent herpes labialis (cold sores) in children 12 years of age and older	Labeling	• Extended indication down from 18 years of age to 12 years of age • Effectiveness extrapolated from adult studies • Safety study in patients 12-17 years of age • Pediatric submission	P	Novartis	NA	
289.	9/30/2003	Floxin Otic Solution	ofloxacin	Treatment of otitis externa (outer ear infection) in children 6 months of age and older	Labeling	• Dosing change from 2 times daily to 1 time daily for 7 days based on effectiveness and safety studies that included pediatric patients • New dosing regimen	P	Daiichi	NA	
290.	8/1/2003	Fludara	fludarabine	Refractory acute leukemia and solid tumors	Labeling	• Fludarabine was evaluated in 62 pediatric patients and the data were insufficient to establish efficacy in any childhood malignancy	B	Berlex	4/3/2003	
291.	12/28/2001; 7/29/2003	Rebetron; Rebetrol	ribavirin/intron a	Chronic hepatitis C	Labeling	• Labeling for 3 years to 16 years • There are no safety and efficacy data on treatment for longer than 48 weeks in pediatric patients • Pharmacokinetic information on patients 5 to 16 years with chronic hepatitis C virus infection • Increased incidence of suicidal ideation or attempts (2.4% versus 1%) among pediatric patients compared to adult patients • Decrease in rate of linear growth (mean percentile assignment decrease of 9%) and in rate of weight gain (mean percentile assignment decrease of 13%) during 48 weeks of treatment; a general reversal was noted during the 24 week post treatment period • Patients with viral genotype 1, had a lower response rate to combination therapy compared to patients with genotype non-1,	B	Schering	5/9/2001	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						36% versus 81% • In general, the adverse event profile in the pediatric population was similar to that observed in adults • New oral suspension developed				
292.	7/18/2003	Ciprodex Sterile Otic Suspension	ciprofloxacin*; dexamethasone	Treatment of acute otitis media in patients with tympanostomy tubes (inner ear infection) in children 6 months of age and older treatment of acute otitis externa (outer ear infection) in children 6 months of age and older	Labeling	• Over 700 pediatric patients in safety and effectiveness studies to support both indications • Pediatric dosing information added • New dosage form	P	Alcon	NA	
293.	7/1/2003	Zestril	lisinopril	Hypertension	Labeling	• Labeling for 6-16 years of age • Not recommended for pediatric patients less than 6 years or with glomerular filtration rate < 30mL/min/1.73m2 • Information on dose, efficacy 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	AstraZeneca	11/19/2001	
294.	5/29/2003	Prinivil	lisinopril	Hypertension	Labeling	• Labeling for 6-16 years of age • Not recommended for pediatric patients with glomerular filtration rate < 30ml/min/1.73m2 • Information on dose, efficacy and pharmacokinetics • No relevant differences were identified between adverse experience profile for	B	Merck	11/19/2001	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						pediatric patients and that previously reported for adult patients • Information on preparation of a suspension				
295.	5/27/2003	Monopril	fosinopril	Hypertension	Labeling	• New data from a double-blind study in 252 patients 6-16 years of age • New recommended dose in children weighing more than 50kg • New Information on PK parameters • An appropriate dosage strength is not available for children weighing less than 50kg	B	Bristol-Myers Squibb	1/27/2003	
296.	5/23/2003	Duocaine Injection#	bupivacaine; lidocaine	Local regional anesthesia for ophthalmologic surgery by peripheral nerve block techniques in children 12 years of age and older	Labeling	• Safety and effectiveness extrapolated from existing clinical database • Safety and effectiveness not established in patients < 12 years of age • Partial waiver 0-12 years of age because general anesthesia is preferred in that population • New active ingredient	P	Amphastar	NA	
297.	5/20/2003	Duragesic	fentanyl	Management of chronic pain	Labeling	• Safety evaluated in three open-label trials in 291 patients 2 years through 18 years of age with chronic pain • New Warning: Duragesic should be administered to children only if they are opioid-tolerant and age 2 years or older • New information on pharmacokinetics, dosage and administration and patient information • Precaution to guard against accidental ingestions by children • Adverse Events: no apparent pediatric-specific risk associated with Duragesic use in children as young as 2 years old when used as directed. Most common adverse events were fever (35%), vomiting (33%), and nausea (24%)	B	Alza	1/29/2003	

	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
298.	5/12/2003	Allegra	fexofenadine	Allergic rhinitis	Labeling	• Three clinical safety studies in 845 children with allergic rhinitis are described in the label	B	Aventis	1/27/2003	
299.	4/15/2003	Ditropan & Ditropan XL	oxybutynin	Detrusor Overactivity Associated with a Neurological Condition	Labeling	Ditropan • Additional information on dose and PK parameters • Precautions section of label updated Ditropan XL • Safety and effectiveness established down to 6 years of age	B	Johnson & Johnson	2/8/2002	
300.	4/15/2003	Methylin Chewable Tablets#	methylphenidate	Treatment of Attention-Deficit Hyperactivity Disorder in children 6 years of age and older treatment of narcolepsy in children 6 years of age and older	Labeling	• Bioequivalence studies in adults • New dosage form	P	Mallinckrodt	NA	
301.	4/15/2003	Vigamox	moxifloxacin	Bacterial Conjunctivitis	Labeling	• Safety and effectiveness established down to 1 year of age	B	Alcon	1/10/2003	
302.	3/11/2003	Temodar	temozolomide	Recurrent CNS tumors	Labeling	• Temozolomide effectiveness in children has not been demonstrated • New data from 2 open-label Phase 2 studies in pediatric patients 3-18 years of age. In one study there were 29 patients with recurrent brain stem glioma and 34 patients with recurrent high grade astrocyoma. In a second study there were 122 patients enrolled with various types of tumors; 113 CNS tumors and 9 non-CNS tumors.	B	Schering	11/20/2002	

	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
						• The temozolomide toxicity profile in children is similar to adults				
303.	2/26/2003	Pulmicort	budesonide	Maintenance and Prophylaxis of Asthma	Labeling	• Safety information in pediatric patients 6 to 12 months of age • A dose dependent effect on growth was observed in the 12-week trial which supports the finding that the use of Pulmicort Respules in infants 6 to 12 months of age may result in systemic effects and is consistent with the findings of growth suppression in other studies with inhaled corticosteroids • Pneumonia was observed more frequently in patients treated with Pulmicort Respules than in patients treated with placebo	B	AstraZeneca	11/12/2002	
304.	1/17/2003	Lamictal	lamotrigine	Adjunctive therapy for partial seizures	Labeling	• Extended indication from adults to pediatric patients ≥ 2 years • Patients aged 2 - 18 years had clearance influenced predominantly by total body weight and concurrent antiepileptic drug (AED) therapy. The oral clearance was higher, on a body weight basis, in pediatric patients than in adults • Because of increased clearance in pediatrics, maintenance doses in patients weighing < 30 kg may need an increase of as much as 50% based upon clinical response • Evidence shows that the inclusion of VPA in a multi-drug regimen increases the risk of serious, potentially life-threatening rash in pediatric patients • Approximately 11.5% of the 1,081 pediatric patients who received the drug as adjunctive therapy in clinical trials discontinued treatment because of an AE	B	GlaxoSmithKline	2/14/2007	
305.	1/13/2003	Busulfex	busulfan	Part of a conditioning regimen	Labeling	• The population pharmacokinetic estimates of busulfan for clearance and volume of distribution were determined in an open-	B	Orphan Medical	3/12/2002	

	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
				administered prior to hematopoietic progenitor cell transplantation for a variety of malignant hematologic or non-malignant diseases		label, uncontrolled PK study in 24 pediatric patients 5 months to 16 years who received busulfan as part of a conditioning regimen administered prior to hematopoietic progenitor cell transplantation for a variety of malignant hematologic or non-malignant diseases • Suggested dosing regimen				
306.	12/31/2002	Singulair Oral Granules*, Tablets*, and Chewable Tablets*	montelukast	Seasonal allergic rhinitis in children 2 years of age and older	Labeling	• Effectiveness extrapolated from studies in patients 15 years of age and older and supported with one pediatric safety trial in patients 2-14 years of age • New indication	P	Merck	NA	
307.	12/30/2002	Zovirax Cream	acyclovir	Treatment of herpes labialis (cold sores) in children 12 years and older	Labeling	• Adolescents 12-17 years of age included in clinical safety studies. • dosing regimen established waived in children < 12 years of age because rarely seen in that population • New dosage form	P	GlaxoSmithKline	NA	
308.	12/26/2002	Relpax	eletriptan	Migraine	Labeling	• Summary pending	R	Pfizer	21-016	
309.	12/19/2002	Zyvox	linezolid	Nosocomial pneumonia, community-acquired pneumonia, complicated and uncomplicated skin and skin structure infections, and vancomycin-	Labeling	• Extended age range down to birth for nosocomial pneumonia, community-acquired pneumonia, complicated skin and skin structure infections and vancomycin-resistant infections. Safety and efficacy extrapolated from studies in adults and supported by PK and comparator-controlled studies in patients from birth to 11 years • Extended age range down to 5 years of age for uncomplicated skin and skin structure infections based upon a comparator-	B	Pfizer	2/11/2005	

	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	N N P S
				resistant infections caused by susceptible strains		controlled study in 5 to 17 year olds • Clearance of linezolid varies as a function of age; As age of pediatric patients increases, clearance gradually decreases, and by adolescence mean clearance values approach those observed in adults • Pediatric patients exhibit wider variability in clearance and systemic exposure (AUC) compared with adults • New every 8 hours dosing regimen for pediatric patients birth to 11 years of age and every 12 hours dosing regimen for pediatric patients 12 years and older • Information on PK parameters, AE profile, laboratory changes, dosing, and clinical studies				
310.	12/4/2002	Centany Ointment 2%	mupirocin	Treatment of impetigo in children 2 months of age and older	Labeling	• New dosage form: ointment that differed from already approved ointment with pediatric clinical trials to demonstrate equivalence	P	Clay-Park Labs	NA	
311.	11/26/2002	Strattera	atomoxetine	Attention-Deficit Hyperactivity Disorder	Labeling	• Safety and effectiveness established down to 6 years of age • It is unknown whether final adult height or weight is affected by treatment. Patients on long-term treatment should be monitored • The effectiveness of atomoxetine beyond 9 weeks and safety beyond 1 year in pediatric patients, has not been systematically evaluated in controlled trials	B	Lilly	12/18/2001	
312.	11/5/2002	Navelbine	vinorelbine	Malignant tumors	Labeling	• New data from a single-arm study in 46 patients with recurrent solid malignant tumors, including rhabdomyosarcoma /undifferentiated sarcoma, neuroblastoma, and CNS tumors, at doses similar to those used in adults showed no meaningful clinical activity	B	GlaxoSmithKline	8/15/2002	
313.	10/29/2002	Pravachol	pravastatin	Heterozygous	Labeling	• New indication in boys and girls 8-18 years	B	Bristol-	7/10/2002	

	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
				Familial Hypercholesterolemia		of age		Myers Squibb		
314.	10/21/2002	Zyrtec	cetirizine	Perennial Allergic Rhinitis & Chronic Urticaria	Labeling	• Extended the age range from 2 years to 6 months • Information on dose, PK parameters and AE profile	B	Pfizer	3/13/2002	
315.	10/18/2002	Lipitor	atorvastatin	Heterozygous Familial Hypercholesterolemia	Labeling	• New indication in adolescent boys and girls (post-menarche) 10-17 years of age	B	Pfizer	2/22/2002	
316.	10/18/2002	Zocor	simvastatin	Heterozygous Familial Hypercholesterolemia	Labeling	• New indication in adolescent boys and girls (at least one year post-menarche) 10-17 years of age	B	Merck	2/22/2002	
317.	10/8/2002	Epivir	lamivudine	HIV	Labeling	• Lamivudine clearance substantially reduced in 1-week-old neonates relative to pediatric patients >3 months of age	B	GlaxoSmithKline	9/22/2000	
318.	8/30/2002	Nolvadex	tamoxifen	McCune-Albright Syndrome	Labeling	• A study in 28 female patients aged 2-10 years with McCune-Albright Syndrome and precocious puberty did not demonstrate safety and effectiveness. Long term effects have not been established • Mean uterine volume increased after 6 months of therapy and doubled at end of 1-year study	B	AstraZeneca	5/16/2002	
319.	8/26/2002	DUAC Topical Gel	clindamycin 1%/benzoyl peroxide 5%	Acne	Labeling	• Added combination topical treatment for mild to moderate acne	R	Stiefel Laboratories	NA	
320.	7/26/2002	Singulair	montelukast	Prophylaxis and chronic treatment of asthma	Labeling	• Safety and effectiveness established in patients 12 months to 5 years of age • Information on dose, PK parameters and AE profile in patients 12-23 months and 2-5 years • New 4mg chewable tablet and 4mg oral granule formulations developed. The chewable tablets contain aspartame whereas the oral granule formulation does	B	Merck	12/10/2001	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics®) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	NNPS
						not				
321.	7/17/2002	Nasonex-nasal Elocon-topical	mometasone	Nasonex - Perennial and seasonal allergic rhinitis Elocon - Relief of inflammatory and pruritic manifestations of corticosteroid dermatose	Labeling - Nasonex Labeling - Elocon Cream Labeling - Elocon Ointment Labeling - Elocon Lotion	• Nasonex Nasal Spray • Extended age range from 3 years down to 2 years • In a clinical study in which pediatric patients 2-5 years were treated with mometasone nasal spray for up to 42 consecutive days, no significant effect on adrenal function was found • Upper respiratory tract infection was more common with Nasonex (2/28) compared to placebo (0/28) • Elocon Cream & Ointment • Evidence of HPA axis suppression in pediatric patients 6-23 months of age • Outlined local AE's as well as skin atrophy in pediatric patients 6-23 months of age • Approved down to 2 years of age as in previous labeling • Elocon Lotion • Safety and effectiveness have not been established in pediatric patients below 12 years of age and use <12 year old is not recommended • Should not be used for the treatment of diaper dermatitis	B	Schering	11/7/2001	
322.	7/12/2002	Prilosec	omeprazole	Gastroesophageal reflux and erosive esophagitis	Labeling	• Safety and effectiveness established in pediatric patients 2-16 years of age • Information on dose, PK parameters, exposure/response and AE profile	B	AstraZeneca	5/1/2001	
323.	6/26/2002	Clarinex RediTabs Orally Disintegrating Tablets	desloratadine	Allergic rhinitis and chronic ideopathic urticaria	Labeling	• Approved for use down to 12 years of age; new formulation	R	Schering	NA	
324.	6/6/2002	Pepcid	famotidine	Gastroesophageal reflux	Labeling	• Labeling for patients less than 1 year of age including information on dose, PK/PD parameters and AE profile	B	Merck	11/21/2000	

	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
						• Lower dose recommended in patients <3 months of age • Pediatric patients 0-3 months of age had clearance values 2 to 4-fold less than those in older patients and adults • In a clinical study of 35 pediatric patients <1 year of age, agitation was observed in 5 patients on famotidine and resolved upon discontinuation of the drug				
325.	6/5/2002	Ritalin LA Capsules	methylphenidate	Attention Deficit Hyperactivity Disorder	Labeling	• Approved for use in 6-12 years of age; once a day dose in the morning	R	Novartis	NA	
326.	5/2/2002	Accutane	isotretinoin	Severe recalcitrant nodular acne	Labeling	• Safety and effectiveness information on pediatric patients 12-17 years of age • Identified an increased incidence of back pain, arthralgia and myalgia in pediatric patients • New General Precautions subsection-caution when prescribing Accutane to pediatric patients with disorders of bone metabolism, such as osteoporosis and osteomalacia • Adolescents who participate in sports with a repetitive impact may be at increased risk for bone related injuries • In an open-label study of pediatric patients (n=217) given a single course of therapy, 16 (7.9%) had decreases in lumbar spine bone mineral density (BMD) >4% (adjusted for body mass index); 21 (10.6%) patients had decreases in total hip BMD >5% (adjusted for body mass index)	B	Hoffman La-Roche	6/12/2001	
327.	4/18/2002	Advil Suspension	ibuprofen / pseudoephedrine	Temporary relief of nasal and sinus congestion, headache, stuffy nose, sore throat, minor aches and pains, and fever	Labeling	• Information on the over-the-counter use in pediatric patients 2 to 11 years of age	B	Whitehall	9/19/2001	
328.	4/1/2002	Videx	didanosine	HIV infection	Labeling	• Safety and effectiveness established down	B	Bristol-	8/13/2001	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics●) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						to 2 weeks		Myers Squibb		
329.	3/29/2002	Zerit	stavudine	HIV infection	Labeling	• Safety and effectiveness established down to birth • Established a dose for newborns from birth to 13 days	B	Bristol-Myers Squibb	8/13/2001	
330.	2/14/2002	Mevacor	lovastatin	Heterozygous Familial Hypercholesterolemia	Labeling	• New indication in adolescent boys and girls (at least one year post-menarche) 10-17 years of age	B	Merck	7/17/2001	
331.	2/8/2002	Acular & Acular PF	ketorolac	Relief of ocular itching due to seasonal allergic rhinitis and postoperative inflammation after cataract extraction	Labeling	• Safety and effectiveness established down to 3 years; previously approved down to 12 years	B	Allergan	9/6/2001	
332.	2/8/2002	Clarinex Tablets	desloratadine	Relief of pruritis/hives in patients with chronic idiopathic urticaria	Labeling	• Approved down to 12 years of age	R	Schering	NA	
333.	2/8/2002	Clarinex Tablets	desloratadine	Perennial allergic rhinitis	Labeling	• Approved down to 12 years of age	R	Schering	NA	
334.	1/30/2002	Xopenex Inhalation Solution	levalbuterol	Treatment and prevention of bronchspasm	Labeling	• Approved down to 6 years of age; recommended dose is 0.31mg TID for patients 6-11 years of age	R	Sepracor	NA	
335.	1/25/2002	Daypro	oxaprozin	Relief of signs and symptoms of Juvenile Rheumatoid Arthritis	Labeling	• New indication in 6 years -16 years	B	Searle	12/6/1999	
336.	5/1/2003 & 1/18/2002	Flonase Nasal Spray & Cutivate Ointment	fluticasone	Flonase - nasal symptoms of seasonal and perennial allergic and nonallergic rhinitis	Labeling - Flonase Labeling - Cutivate	• Flonase • New data from 1-year placebo-controlled clinical growth study in pediatric patients 3-9 years of age; no statistically significant effect on growth was noted compared to placebo. No evidence of clinically relevant	B	GlaxoSmithKline	2/25/2003	

	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
				Cutivate Ointment - corticosteroid-responsive dermatoses		changes in HPA axis function or bone mineral density was observed as assessed by 12-hour urinary cortisol excretion and dual-energy x-ray absorptiometry, respectively. • Cutivate • Indicated for use only in adult patients • In a study of 35 pediatric patients treated for atopic dermatitis, subnormal adrenal function was observed with cosyntropin stimulation testing				
337.	12/21/2001	Clarinex Tablets	desloratadine	Seasonal allergic rhinitis	Labeling	• Approved down to 12 years of age	R	Schering	NA	
338.	12/20/2001	Alphagan	brimonidine	Prevention of post-operative IOP elevations	Labeling	• Safety and effectiveness established down to 2 years • Somnolence in patients 2 to 6 years (50-83%) versus patients 7 years of age or older (25%)	B	Allergan	10/10/2001	
339.	12/13/2001	Elidel	pimecrolimus	Treatment of mild/moderate atopic dermatitis	Labeling	• Indicated for short-term and intermittent long-term therapy for mild to moderate atopic dermatitis in non-immunocompromised patients 2 years and older • Not recommended for use in pediatric patients less than 2 years of age. Infants on Elidel Cream had an increased incidence of some adverse events compared to vehicle which included pyrexia, URI, nasopharyngitis, gastroenteritis, otitis media, and diarrhea.	B	Novartis	9/24/2001	
340.	11/16/2001	Calcijex	calcitriol	Management of hypocalcemia in patients undergoing chronic renal dialysis	Labeling	• The safety and effectiveness of calcitriol was examined in a double-blind placebo-controlled trial of 35 pediatric patients (13-18 years of age) with end-stage renal disease and on dialysis. • The primary efficacy endpoint favored the calcitriol-treated versus the placebo-treated	B	Abbott	2/16/2001	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics•) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
						patients • Transient hypercalcemia was seen in 1 of 16 calcitriol-treated patients; 6 of 16 (38%) calcitriol-treated patients and 2 of 19 (11%) placebo-treated patients had Ca x P >75				
341.	10/10/2001	Derma-Smoothe/FS Topical Oil	fluocinolone	Atopic dermatitis	Labeling	• Approved down to 2 years of age	R	Hill	NA	
342.	10/3/2001	Diprolene AF, Diprosone, Lotrisone	betamethasone	Diprolene AF and Diprosone - Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses Lotrisone- Treatment of symptomatic inflammatory tinea pedis, tinea cruris and tinea corporis	Labeling	• Diprolene AF Cream • In an open-label study for the treatment of atopic dermatitis, 19 of 60 (32%) evaluable patients (ages 3 mo-12 years) showed HPA axis suppression. The younger the age group, the greater the proportion of patients with adrenal suppression. • Indicated in patients 13 years and older. Not recommended in pediatric patients 12 years and younger • Strengthened labeling in Clinical Pharmacology, Precautions- General and Pediatric Use subsections • Local adverse reactions including signs of skin atrophy (telengiectasia, bruising, shininess) occurred in 10% of pediatric patients (3mo-12 years) • Diprosone Cream, Ointment, Lotion • A separate open-label study was performed in pediatric patients with atopic dermatitis for each Diprosone formulation • Testing for HPA axis suppression was positive with each formulation in the age groups studied: Cream - 23% (ages 2yr-12yr); Ointment - 28% (ages 6mo-12yr); and Lotion - 73% (ages 6yr-12yr) • Indicated in patients 13 years and older. Not recommended in pediatric patients 12 years and younger • Strengthened labeling in Clinical Pharmacology, Precautions- General and Pediatric Use subsections	B	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
						• Local adverse reactions including signs of skin atrophy (telengiectasia, bruising, shininess) occurred in the cream and ointment studies • Lotrisone • Not recommended for patients under the age of 17 years and not recommended for diaper dermatitis; previously not recommended for patients under the age of 12 years • In an open-label study of Lotrisone cream for the treatment of tinea pedis, 17 of 43 (39.5%) evaluable patients (ages 12-16 years) demonstrated adrenal suppression as determined by cosyntropin testing • In an open-label study of Lotrisone cream for the treatment of tinea cruris, 8 of 17 (47.1%) evaluable patients (ages 12-16 years) demonstrated adrenal suppression by cosyntropin testing • Indicated in patients 17 years and older				
343.	10/1/2001	Betapace	sotalol	Arrhythmia	Labeling	• Analysis of 2 trials provided information on PK and PD in children 3 days – 12 years; safety and efficacy have not been established • Information on dose, pharmacokinetics and AE's • Pharmacokinetics: BSA most important covariate and more relevant than age • Smaller children (BSA < 0.33 m2) showed tendency for larger change in QTc and increased frequency of prolongation of the QTc interval as well as greater beta-blocking effects • Individualized dosing on a mg/m2 basis • Information on preparation of a suspension	B	Berlex	1/6/2000	
344.	8/28/2001	Topamax Tablets & Sprinkle Capsule	topiramate	Seizures associated with Lennox-Gastaut syndrome	Labeling	• Approved for treatment down to 2 years of age	R	R.W. 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	NNPS
						•				
345.	8/16/2001	Epivir-HBV	lamivudine	Treatment of Chronic Hepatitis B	Labeling	• Safety and effectiveness established down to 2 years • Established a dose of 3mg/kg/day up to a maximum of 100mg/day (adult dose)	B	GlaxoSmithKline	7/25/2001	
346.	7/19/2001	Buspar	buspirone	General Anxiety Disorder	Labeling	• Safety and effectiveness were not established in patients 6 to 17 years of age for treatment of General Anxiety Disorder at doses recommended for use in adults • PK parameters (AUC and Cmax) of buspirone and its active metabolite were found to be equal to or higher in children and adolescents than that of adults	B	Bristol-Myers Squibb	5/22/2000	
347.	6/25/2001	Valtrex Caplets	valacyclovir	Treatment of cold sores	Labeling	• New indication approved for use down to 12 years of age	R	GlaxoSmithKline	NA	
348.	6/6/2001	Mentax Cream	butenafine	Tinea versicolor	Labeling	• Approved down to 12 years of age; previously approved in adults only	R	Bertek	NA	
349.	5/11/2001	Agenerase Capusles and Oral Solution	amprenavir	HIV	Labeling	• Approved for use in combination with other antiretroviral agents; new labeling provides information about the effects of drug-drug interaction	R	GlaxoSmithKline	NA	
350.	3/30/2001	Ultane	sevoflurane	Induction and maintenance of general anesthesia	Labeling	• New study in pediatric patients 9 days-12 years comparing sevoflurane and halothane • Precautions section and Adverse Events During Post-Marketing subsection updated to add information on the rare cases of seizures that have been reported in pediatric patients in association with sevoflurane use. The majority of cases were in children and young adults, most of whom had no medical history of seizures • Pediatric information consolidated into new	B	Abbott	8/2/2000	

	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
						Pediatric Use subsection				
351.	3/27/2001	Nasalcrom	cromolyn	Prevention and relief of nasal symptoms of hay fever and other nasal allergies	Labeling	• Established proper dose in 2 year - 6 year olds and provided additional safety and compliance data for this age group	B	Pharmacia & UpJohn	11/2/1999	
352.	2/23/2001	Diprivan	propofol	Induction and/or maintenance of anesthesia	Labeling	• Maintenance of anesthesia- age decreased down to 2 months from 3 years • Induction of anesthesia remains the same- 3 years of age and above • Concomitant administration with fentanyl may result in serious bradycardia • Abrupt discontinuation following prolonged infusion may result in flushing of hands and feet, agitation, tremulousness and hyperirritability • Propofol is not indicated for pediatric ICU sedation as safety has not been established. In a single multicenter trial of ICU sedation in critically ill pediatric patients (patients with upper respiratory tract infections excluded), the incidence of mortality (causality not established) was 9% in the propofol arm versus 4% in the standard sedative agents arm	B	AstraZeneca	8/11/1999	
353.	2/21/2001	Infuvite Pediatric	Multivitamin infusion	Daily multivitamin maintenance	Labeling	• Approved for infants down to newborn	R	Sabex, Inc.	NA	
354.	2/13/2001	Vasotec	enalapril	Hypertension	Labeling	• Labeling for 1 month-16 years of age • Information on dose, efficacy and pharmacokinetics • Information on preparation of a suspension	B	Merck	2/2/2000	
355.	12/21/2000	Benzaclin	benzoyl peroxide; clindamycin phosphate	Acne vulgaris	Labeling	• Approved down to 12 years of age	R	Sanofi Aventis	NA	
356.	12/20/2000	CellCept IV,	mycophenylate	Prophylaxis of	Labeling	• Approved for use down to 3 months of age	R	Hoffman-	NA	