

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologicse) 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	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Information on dose, PK in pediatric patients 6-17 years of age</li> <li>Adverse event profile in pediatric patients was similar to that seen in adults</li> </ul>	B	Pfizer	11/27/2001	
284.	12/12/2003	Xenical	orlistat	Obesity management	<u>Labeling</u>	<ul style="list-style-type: none"> <li>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.</li> <li>Since orlistat can reduce absorption of fat soluble vitamins, all patients should take a daily multivitamin supplement containing fat soluble vitamins.</li> <li>Adverse event profile in adolescent patients was similar to that seen in adults</li> </ul>	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	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established in clinical trials involving adolescent patients</li> <li>Studies in patients less than 12 years of age waived because there are too few children with the disease to study</li> <li>New drug</li> </ul>	P	Mylan	NA	
286.	12/2/2003	Malarone	atovaquone/proguanil	Treatment of malaria	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established down to <math>\geq</math> 11 kg</li> <li>Information on dose, efficacy, PK parameters and AE profile</li> <li>Elimination half-life is shorter in pediatric patients (1 to 2 days) than in adults (2 to 3 days)</li> <li>Attributable AE's occurring in <sup>3</sup> 5% of the pediatric patients were vomiting (10%) and pruritus (6%)</li> </ul>	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	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Based on effectiveness and safety studies that included children down to 10 years of age</li> <li>Partial waiver for children &lt; 3 years of age because the condition does not exist in the age group</li> </ul>	P	Allergan	NA	

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288.	10/10/2003	Denavir Cream	penciclovir	Treatment of recurrent herpes labialis (cold sores) in children 12 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• New drug</li> <li>• Extended indication down from 18 years of age to 12 years of age</li> <li>• Effectiveness extrapolated from adult studies</li> <li>• Safety study in patients 12-17 years of age</li> <li>• Pediatric submission</li> </ul>	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	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Dosing change from 2 times daily to 1 time daily for 7 days based on effectiveness and safety studies that included pediatric patients</li> <li>• New dosing regimen</li> </ul>	P	Daiichi	NA	
290.	8/1/2003	Fludara	fludarabine	Refractory acute leukemia and solid tumors	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Fludarabine was evaluated in 62 pediatric patients and the data were insufficient to establish efficacy in any childhood malignancy</li> </ul>	B	Berlex	4/3/2003	
291.	12/28/2001; 7/29/2003	Rebetron; Rebetrol	ribavirin/intron a	Chronic hepatitis C	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Labeling for 3 years to 16 years</li> <li>• There are no safety and efficacy data on treatment for longer than 48 weeks in pediatric patients</li> <li>• Pharmacokinetic information on patients 5 to 16 years with chronic hepatitis C virus infection</li> <li>• Increased incidence of suicidal ideation or attempts (2.4% versus 1%) among pediatric patients compared to adult patients</li> <li>• 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</li> <li>• Patients with viral genotype 1, had a lower response rate to combination therapy compared to patients with genotype non-1.</li> </ul>	B	Schering	5/9/2001	

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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	<ul style="list-style-type: none"> <li>36% versus 81%</li> <li>In general, the adverse event profile in the pediatric population was similar to that observed in adults</li> <li>New oral suspension developed</li> <li>Over 700 pediatric patients in safety and effectiveness studies to support both indications</li> <li>Pediatric dosing information added</li> <li>New dosage form</li> </ul>	P	Alcon	NA	
293.	7/11/2003	Zestril	lisinopril	Hypertension	Labeling	<ul style="list-style-type: none"> <li>Labeling for 6-16 years of age</li> <li>Not recommended for pediatric patients less than 6 years or with glomerular filtration rate &lt; 30ml/min/1.73m<sup>2</sup></li> <li>Information on dose, efficacy and pharmacokinetics</li> <li>No relevant differences were identified between adverse experience profile for pediatric patients and that previously reported for adult patients</li> <li>Information on preparation of a suspension</li> </ul>	B	AstraZene ca	11/19/2001	
294.	5/29/2003	Prinivil	lisinopril	Hypertension	Labeling	<ul style="list-style-type: none"> <li>Labeling for 6-16 years of age</li> <li>Not recommended for pediatric patients with glomerular filtration rate &lt; 30ml/min/1.73m<sup>2</sup></li> <li>Information on dose, efficacy and pharmacokinetics</li> <li>No relevant differences were identified between adverse experience profile for</li> </ul>	B	Merck	11/19/2001	

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295.	5/27/2003	Monopril	fosinopril	Hypertension	<u>Labeling</u>	<ul style="list-style-type: none"> <li>pediatric patients and that previously reported for adult patients</li> <li>Information on preparation of a suspension</li> </ul>	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	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness extrapolated from existing clinical database</li> <li>Safety and effectiveness not established in patients &lt; 12 years of age</li> <li>Partial waiver 0-12 years of age because general anesthesia is preferred in that population</li> <li>New active ingredient</li> </ul>	P	Amphastar	NA	
297.	5/20/2003	Duragesic	fentanyl	Management of chronic pain	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety evaluated in three open-label trials in 291 patients 2 years through 18 years of age with chronic pain</li> <li>New Warning: Duragesic should be administered to children only if they are opioid-tolerant and age 2 years or older</li> <li>New information on pharmacokinetics, dosage and administration and patient information</li> <li>Precaution to guard against accidental ingestions by children</li> <li>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%)</li> </ul>	B	Alza	1/29/2003	

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298.	5/12/2003	Allegra	fexofenadine	Allergic rhinitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Three clinical safety studies in 845 children with allergic rhinitis are described in the label</li> </ul>	B	Aventis	1/27/2003	
299.	4/15/2003	Ditropan & Ditropan XL	oxybutynin	Detrusor Overactivity Associated with a Neurological Condition	<u>Labeling</u>	<p>Ditropan</p> <ul style="list-style-type: none"> <li>Additional information on dose and PK parameters</li> <li>Precautions section of label updated</li> </ul> <p>Ditropan XL</p> <ul style="list-style-type: none"> <li>Safety and effectiveness established down to 6 years of age</li> </ul>	B	Johnson & Johnson	2/8/2002	
300.	4/15/2003	Methylphenidate 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	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Bioequivalence studies in adults</li> <li>New dosage form</li> </ul>	P	Mallinckrodt	NA	
301.	4/15/2003	Vigamox	moxifloxacin	Bacterial Conjunctivitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established down to 1 year of age</li> </ul>	B	Alcon	1/10/2003	
302.	3/11/2003	Temodar	temozolomide	Recurrent CNS tumors	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Temozolomide effectiveness in children has not been demonstrated</li> <li>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 astrocytoma. In a second study there were 122 patients enrolled with various types of tumors, 113 CNS tumors and 9 non-CNS tumors.</li> </ul>	B	Schering	11/20/2002	

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303.	2/26/2003	Pulmicort	budesonide	Maintenance and Prophylaxis of Asthma	<u>Labeling</u>	<ul style="list-style-type: none"> <li>The temozolomide toxicity profile in children is similar to adults</li> <li>Safety information in pediatric patients 6 to 12 months of age</li> <li>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</li> <li>Pneumonia was observed more frequently in patients treated with Pulmicort Respules than in patients treated with placebo</li> </ul>	B	AstraZeneca	11/12/2002	
304.	1/17/2003	Lamictal	lamotrigine	Adjunctive therapy for partial seizures	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended indication from adults to pediatric patients <math>\geq 2</math> years</li> <li>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</li> <li>Because of increased clearance in pediatrics, maintenance doses in patients weighing <math>&lt; 30</math> kg may need an increase of as much as 50% based upon clinical response</li> <li>Evidence shows that the inclusion of VPA in a multi-drug regimen increases the risk of serious, potentially life-threatening rash in pediatric patients</li> <li>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</li> </ul>	B	GlaxoSmithKline	2/14/2007	
305.	1/13/2003	Busulfex	busulfan	Part of a conditioning regimen	<u>Labeling</u>	<ul style="list-style-type: none"> <li>The population pharmacokinetic estimates of busulfan for clearance and volume of distribution were determined in an open-</li> </ul>	B	Orphan Medical	3/12/2002	

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				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				
306.	12/31/2002	Singulair Oral Granules*, Tablets*, and Chewable Tablets*	montelukast	Seasonal allergic rhinitis in children 2 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>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</li> <li>New Indication</li> </ul>	P	Merck	NA	
307.	12/30/2002	Zovirax Cream	acyclovir	Treatment of herpes labialis (cold sores) in children 12 years and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Adolescents 12-17 years of age included in clinical safety studies.</li> <li>dosing regimen established waived in children &lt; 12 years of age because rarely seen in that population</li> <li>New dosage form</li> </ul>	P	GlaxoSmithKline	NA	
308.	12/26/2002	Relpax	eletriptan	Migraine	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Summary pending</li> </ul>	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-	<u>Labeling</u>	<ul style="list-style-type: none"> <li>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</li> <li>Extended age range down to 5 years of age for uncomplicated skin and skin structure infections based upon a comparator-</li> </ul>	B	Pfizer	2/11/2005	

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				resistant infections caused by susceptible strains		<ul style="list-style-type: none"> <li>controlled study in 5 to 17 year olds</li> <li>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</li> <li>Pediatric patients exhibit wider variability in clearance and systemic exposure (AUC) compared with adults</li> <li>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</li> <li>Information on PK parameters, AE profile, laboratory changes, dosing, and clinical studies</li> </ul>				
310.	12/4/2002	Centany Ointment 2%	mupirocin	Treatment of impetigo in children 2 months of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New dosage form: ointment that differed from already approved ointment with pediatric clinical trials to demonstrate equivalence</li> </ul>	P	Clay-Park Labs	NA	
311.	11/26/2002	Strattera	atomoxetine	Attention-Deficit Hyperactivity Disorder	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established down to 6 years of age</li> <li>It is unknown whether final adult height or weight is affected by treatment. Patients on long-term treatment should be monitored</li> <li>The effectiveness of atomoxetine beyond 9 weeks and safety beyond 1 year in pediatric patients, has not been systematically evaluated in controlled trials</li> </ul>	B	Lilly	12/18/2001	
312.	11/5/2002	Navelbine	vinorelbine	Malignant tumors	<u>Labeling</u>	<ul style="list-style-type: none"> <li>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</li> </ul>	B	GlaxoSmith hKline	8/15/2002	
313.	10/29/2002	Pravachol	pravastatin	Heterozygous	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication in boys and girls 8-18 years</li> </ul>	B	Bristol-	7/10/2002	



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				Familial Hypercholesterolemia		of age		Myers Squibb		
314.	10/21/2002	Zyrtec	cetirizine	Perennial Allergic Rhinitis & Chronic Urticaria	Labeling	<ul style="list-style-type: none"> <li>Extended the age range from 2 years to 6 months</li> <li>Information on dose, PK parameters and AE profile</li> </ul>	B	Pfizer	3/13/2002	
315.	10/18/2002	Lipitor	atorvastatin	Heterozygous Familial Hypercholesterolemia	Labeling	<ul style="list-style-type: none"> <li>New indication in adolescent boys and girls (post-menarche) 10-17 years of age</li> </ul>	B	Pfizer	2/22/2002	
316.	10/18/2002	Zocor	simvastatin	Heterozygous Familial Hypercholesterolemia	Labeling	<ul style="list-style-type: none"> <li>New indication in adolescent boys and girls (at least one year post-menarche) 10-17 years of age</li> </ul>	B	Merck	2/22/2002	
317.	10/8/2002	Epivir	lamivudine	HIV	Labeling	<ul style="list-style-type: none"> <li>Lamivudine clearance substantially reduced in 1-week-old neonates relative to pediatric patients &gt;3 months of age</li> </ul>	B	GlaxoSmithKline	9/22/2000	
318.	8/30/2002	Nolvadex	tamoxifen	McCune-Albright Syndrome	Labeling	<ul style="list-style-type: none"> <li>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</li> <li>Mean uterine volume increased after 6 months of therapy and doubled at end of 1-year study</li> </ul>	B	AstraZeneca	5/16/2002	
319.	8/26/2002	DUAC Topical Gel	clindamycin 1%/benzoyl peroxide 5%	Acne	Labeling	<ul style="list-style-type: none"> <li>Added combination topical treatment for mild to moderate acne</li> </ul>	R	Stiefel Laboratories	NA	
320.	7/26/2002	Singulair	montelukast	Prophylaxis and chronic treatment of asthma	Labeling	<ul style="list-style-type: none"> <li>Safety and effectiveness established in patients 12 months to 5 years of age</li> <li>Information on dose, PK parameters and AE profile in patients 12-23 months and 2-5 years</li> <li>New 4mg chewable tablet and 4mg oral granule formulations developed. The chewable tablets contain aspartame whereas the oral granule formulation does</li> </ul>	B	Merck	12/10/2001	

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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	<u>Labeling - Nasonex</u> <u>Labeling - Elocon Cream</u> <u>Labeling - Elocon Ointment</u> <u>Labeling - Elocon Lotion</u>	<p>not</p> <ul style="list-style-type: none"> <li>Nasonex Nasal Spray</li> <li>Extended age range from 3 years down to 2 years</li> <li>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</li> <li>Upper respiratory tract infection was more common with Nasonex (2/28) compared to placebo (0/28)</li> <li>Elocon Cream &amp; Ointment</li> <li>Evidence of HPA axis suppression in pediatric patients 6-23 months of age</li> <li>Outlined local AE's as well as skin atrophy in pediatric patients 6-23 months of age</li> <li>Approved down to 2 years of age as in previous labeling</li> <li>Elocon Lotion</li> <li>Safety and effectiveness have not been established in pediatric patients below 12 years of age and use &lt;12 year old is not recommended</li> <li>Should not be used for the treatment of diaper dermatitis</li> </ul>	B	Schering	11/7/2001	
322.	7/12/2002	PriLOSEC	omeprazole	Gastroesophageal reflux and erosive esophagitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established in pediatric patients 2-16 years of age</li> <li>Information on dose, PK parameters, exposure/response and AE profile</li> </ul>	B	AstraZeneca	5/1/2001	
323.	6/26/2002	Clarinet RediTabs Orally Disintegrating Tablets	desloratadine	Allergic rhinitis and chronic idiopathic urticaria	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved for use down to 12 years of age; new formulation</li> </ul>	R	Schering	NA	
324.	6/6/2002	Pepcid	famotidine	Gastroesophageal reflux	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Labeling for patients less than 1 year of age including information on dose, PK/PPD parameters and AE profile</li> </ul>	B	Merck	11/21/2000	

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						<ul style="list-style-type: none"> <li>Lower dose recommended in patients &lt;3 months of age</li> <li>Pediatric patients 0-3 months of age had clearance values 2 to 4-fold less than those in older patients and adults</li> <li>In a clinical study of 35 pediatric patients &lt;1 year of age, agitation was observed in 5 patients on famotidine and resolved upon discontinuation of the drug</li> </ul>				
325.	6/5/2002	Ritalin LA Capsules	methylphenidate	Attention Deficit Hyperactivity Disorder	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved for use in 6-12 years of age; once a day dose in the morning</li> </ul>	R	Novartis	NA	
326.	5/2/2002	Accutane	isotretinoin	Severe recalcitrant nodular acne	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness information on pediatric patients 12-17 years of age</li> <li>Identified an increased incidence of back pain, arthralgia and myalgia in pediatric patients</li> <li>New General Precautions subsection-caution when prescribing Accutane to pediatric patients with disorders of bone metabolism, such as osteoporosis and osteomalacia</li> <li>Adolescents who participate in sports with a repetitive impact may be at increased risk for bone related injuries</li> <li>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) &gt;4% (adjusted for body mass index); 21 (10.6%) patients had decreases in total hip BMD &gt;5% (adjusted for body mass index)</li> </ul>	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 HIV infection	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Information on the over-the-counter use in pediatric patients 2 to 11 years of age</li> </ul>	B	Whitehall	9/19/2001	
328.	4/1/2002	Videx	didanosine		<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established down</li> </ul>	B	Bristol-	8/13/2001	

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329.	3/29/2002	Zerit	stavudine	HIV infection	<u>Labeling</u>	<ul style="list-style-type: none"> <li>to 2 weeks</li> <li>Safety and effectiveness established down to birth</li> <li>Established a dose for newborns from birth to 13 days</li> </ul>	B	Myers Squibb	8/13/2001	
330.	2/14/2002	Mevacor	lovastatin	Heterozygous Familial Hypercholesterolemia	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication in adolescent boys and girls (at least one year post-menarche) 10-17 years of age</li> </ul>	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	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established down to 3 years; previously approved down to 12 years</li> </ul>	B	Allergan	9/6/2001	
332.	2/8/2002	Clarinet Tablets	desloratadine	Relief of pruritis/hives in patients with chronic idiopathic urticaria	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 12 years of age</li> </ul>	R	Schering	NA	
333.	2/8/2002	Clarinet Tablets	desloratadine	Perennial allergic rhinitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 12 years of age</li> </ul>	R	Schering	NA	
334.	1/30/2002	Xopenex Inhalation Solution	levalbuterol	Treatment and prevention of bronchospasm	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 6 years of age; recommended dose is 0.31mg TID for patients 6-11 years of age</li> </ul>	R	Sepracor	NA	
335.	1/25/2002	Daypro	oxaprozin	Relief of signs and symptoms of Juvenile Rheumatoid Arthritis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication in 6 years -16 years</li> </ul>	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	<u>Labeling - Flonase</u> <u>Labeling - Cutivate</u>	<ul style="list-style-type: none"> <li>Flonase</li> <li>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</li> </ul>	B	GlaxoSmithKline	2/25/2003	

	Pediatric Labeling Date	Trade Name	Generic or Proper Name (Biologics●)	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. <ul style="list-style-type: none"> <li>Cutivate</li> <li>Indicated for use only in adult patients</li> <li>In a study of 35 pediatric patients treated for atopic dermatitis, subnormal adrenal function was observed with cosyntropin stimulation testing</li> </ul>				
337.	12/21/2001	Clarinex Tablets	desloratadine	Seasonal allergic rhinitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 12 years of age</li> </ul>	R	Schering	NA	
338.	12/20/2001	Alphagan	brimonidine	Prevention of post-operative IOP elevations	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established down to 2 years</li> <li>Somnolence in patients 2 to 6 years (50-83%) versus patients 7 years of age or older (25%)</li> </ul>	B	Allergan	10/10/2001	
339.	12/13/2001	Elidel	pimecrolimus	Treatment of mild/moderate atopic dermatitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Indicated for short-term and intermittent long-term therapy for mild to moderate atopic dermatitis in non-immunocompromised patients 2 years and older</li> <li>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.</li> </ul>	B	Novartis	9/24/2001	
340.	11/16/2001	Calcijex	calcitriol	Management of hypocalcemia in patients undergoing chronic renal dialysis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>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.</li> <li>The primary efficacy endpoint favored the calcitriol-treated versus the placebo-treated</li> </ul>	B	Abbott	2/16/2001	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics●) Name	Indications Studied	Product Labeling	Labeling Changes	BPAA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
341.	10/10/2001	Derma-Smoothie/FS Topical Oil	flucinolone	Atopic dermatitis	<u>Labeling</u>	<p>patients</p> <ul style="list-style-type: none"> <li>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 &gt;75</li> <li>Approved down to 2 years of age</li> </ul>	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	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Diprolene AF Cream</li> <li>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.</li> <li>Indicated in patients 13 years and older. Not recommended in pediatric patients 12 years and younger</li> <li>Strengthened labeling in Clinical Pharmacology, Precautions- General and Pediatric Use subsections</li> <li>Local adverse reactions including signs of skin atrophy (telangiectasia, bruising, shininess) occurred in 10% of pediatric patients (3mo-12 years)</li> <li>Diprosone Cream, Ointment, Lotion</li> <li>A separate open-label study was performed in pediatric patients with atopic dermatitis for each Diprosone formulation</li> <li>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)</li> <li>Indicated in patients 13 years and older. Not recommended in pediatric patients 12 years and younger</li> <li>Strengthened labeling in Clinical Pharmacology, Precautions- General and Pediatric Use subsections</li> </ul>	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	N N P S
343.	10/1/2001	Betapace	sotalol	Arrhythmia	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Local adverse reactions including signs of skin atrophy (telangiectasia, bruising, shininess) occurred in the cream and ointment studies</li> <li>Lotrisone</li> <li>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</li> <li>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</li> <li>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</li> <li>Indicated in patients 17 years and older</li> </ul>	B	Berlex	1/6/2000	
344.	8/28/2001	Topamax Tablets & Sprinkle Capsule	topiramate	Seizures associated with Lennox-Gastaut syndrome	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Information on dose, pharmacokinetics and AE's</li> <li>Pharmacokinetics: BSA most important covariate and more relevant than age</li> <li>Smaller children (BSA &lt; 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</li> <li>Individualized dosing on a mg/m2 basis</li> <li>Information on preparation of a suspension</li> </ul>	R	R. W. Johnson	NA	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics●) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PRA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N N P S
345.	8/16/2001	Epivir-HBV	lamivudine	Treatment of Chronic Hepatitis B	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established down to 2 years</li> <li>Established a dose of 3mg/kg/day up to a maximum of 100mg/day (adult dose)</li> </ul>	B	GlaxoSmit hKline	7/25/2001	
346.	7/19/2001	Buspar	buspirone	General Anxiety Disorder	<u>Labeling</u>	<ul style="list-style-type: none"> <li>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</li> <li>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</li> </ul>	B	Bristol-Myers Squibb	5/22/2000	
347.	6/25/2001	Valtrex Caplets	valacyclovir	Treatment of cold sores	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication approved for use down to 12 years of age</li> </ul>	R	GlaxoSmit hKline	NA	
348.	6/6/2001	Mentax Cream	butenafine	Tinea versicolor	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 12 years of age; previously approved in adults only</li> </ul>	R	Bertek	NA	
349.	5/11/2001	Agenerase Capsules and Oral Solution	amprenavir	HIV	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved for use in combination with other antiretroviral agents; new labeling provides information about the effects of drug-drug interaction</li> </ul>	R	GlaxoSmit hKline	NA	
350.	3/30/2001	Ultane	sevoflurane	Induction and maintenance of general anesthesia	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New study in pediatric patients 9 days-12 years comparing sevoflurane and halothane</li> <li>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</li> <li>Pediatric information consolidated into new</li> </ul>	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	Nasalbrom	cromolyn	Prevention and relief of nasal symptoms of hay fever and other nasal allergies	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Established proper dose in 2 year - 6 year olds and provided additional safety and compliance data for this age group</li> </ul>	B	Pharmacia & UpJohn	11/2/1999	
352.	2/23/2001	Diprivan	propofol	Induction and/or maintenance of anesthesia	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Maintenance of anesthesia- age decreased down to 2 months from 3 years</li> <li>Induction of anesthesia remains the same- 3 years of age and above</li> <li>Concomitant administration with fentanyl may result in serious bradycardia</li> <li>Abrupt discontinuation following prolonged infusion may result in flushing of hands and feet, agitation, tremulousness and hyperirritability</li> <li>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</li> </ul>	B	AstraZeneca	8/11/1999	
353.	2/21/2001	Infuvite Pediatric	Multivitamin infusion	Daily multivitamin maintenance	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved for infants down to newborn</li> </ul>	R	Sabex, Inc.	NA	
354.	2/13/2001	Vasotec	enalapril	Hypertension	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Labeling for 1 month-16 years of age</li> <li>Information on dose, efficacy and pharmacokinetics</li> <li>Information on preparation of a suspension</li> </ul>	B	Merck	2/2/2000	
355.	12/21/2000	Benzaclin	benzoyl peroxide; clindamycin phosphate	Acne vulgaris	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 12 years of age</li> </ul>	R	Sanofi Aventis	NA	
356.	12/20/2000	CellCept IV,	mycophenylate	Prophylaxis of	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved for use down to 3 months of age</li> </ul>	R	Hoffman-	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
		Suspension, Capsules		organ rejection in renal transplant patients		as a combination regimen with cyclosporine and corticosteroids		LaRoche		
357.	12/15/2000	Glucophage (immediate release)	metformin	Diabetes Mellitus	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness as monotherapy established in patients 10-16 years of age</li> </ul>	B	Bristol-Myers Squibb	3/15/2000	
358.	12/14/2000	Tamiflu	oseltamivir	Treatment of uncomplicated acute illness due to influenza	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established for treatment in patients 1-12 years of age</li> <li>The safety and effectiveness in pediatric patients younger than 1 year of age have not been established</li> <li>Safety and effectiveness for prophylaxis in pediatric patients younger than 13 years of age have not been established (Note: labeled for prophylaxis down to 1 year due to PREA on 12/21/2005)</li> <li>The adverse event profile in adolescents is similar to that for adults and pediatric patients aged 1 to 12 years</li> <li>Information on dosing, PK parameters, AE profile, and clinical studies</li> </ul>	B	Roche	3/22/2004	
359.	12/11/2000	Maxalt and Maxalt-MLT	rizatriptan	Migraine		Summary pending	R	Merck	20-864/002; 20-865/004	
360.	12/8/2000	Protopic Ointment	tacrolimus	Atopic dermatitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 2 years of age; lower dose of 0.03% twice daily recommended for patients 2-15 years of age</li> </ul>	R	Fujisawa	NA	
361.	12/4/2000	Claritin	loratadine	Allergic rhinitis/Urticaria	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Labeling for 2 - 5 year olds including information on dose, PK parameters and AE profile</li> <li>PK parameter in 2-5 year olds given a 5mg dose was comparable to the 10mg dose in children 6 years to adolescence</li> </ul>	B	Schering	8/14/2000	

	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
362.	11/27/2000	Benzamycin Pak	erythromycin-benzoyl peroxide	Acne vulgaris		<ul style="list-style-type: none"> <li>Approved down to 12 years of age</li> </ul>	R	Dermik Laboratories, Inc.	NA	
363.	11/27/2000	Clindagel	clindamycin topical gel	Acne vulgaris	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 12 years of age</li> </ul>	R	Target Research Associates	NA	
364.	11/17/2000	Tamiflu Capsule	oseltamivir	Prophylaxis of influenza A and B	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved for prophylactic use down to 13 years of age</li> </ul>	R	Roche	NA	
365.	11/14/2000	Trizivir Tablets	abacavir, lamivudine, zidovudine	HIV	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved in adults and adolescents weighing <math>\geq</math> 40kg</li> </ul>	R	GlaxoSmithKline	NA	
366.	10/27/2000	Atrovent Nasal Spray	ipratropium	Rhinorrhea		<ul style="list-style-type: none"> <li>Approved down to 5 years of age</li> </ul>	R	Boehringer Ingelheim	NA	
367.	10/12/2000	Neurontin	gabapentin	Adjunctive therapy in the treatment of partial seizures	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established down to 3 years</li> <li>Neuropsychiatric AE's identified in 3-12 year olds</li> <li>Oral clearance normalized per body weight increased in children &lt;5 years</li> <li>Higher doses of gabapentin required in children &lt;5 years</li> </ul>	B	Parke-Davis	2/2/2000	
368.	9/29/2000	Flovent Diskus Inhalation Powder	fluticasone	Asthma		<ul style="list-style-type: none"> <li>Approved down to 4 years of age; new delivery system</li> </ul>	R	GlaxoSmithKline	NA	
369.	9/24/2000	Alamast	pemirolast	Allergic Conjunctivitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established down to 3 years</li> </ul>	B	Santen	8/11/1999	
370.	8/25/2000	Lac-Hydrin	ammonium lactate	Xerosis, ichthyosis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established in patients 2 – 11 years of age; previously approved <sup>3</sup>12 years of age</li> </ul>	B	Westwood-Squibb	10/1/1999	
371.	8/24/2000	Advair Diskus	fluticasone/salmeterol	Asthma		<ul style="list-style-type: none"> <li>Approved down to 12 years of age</li> </ul>	R	GlaxoSmithKline	NA	
372.	8/21/2000	Unithroid Tablets	levothyroxine	Hypothyroidism	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to the newborn</li> </ul>	R	Jerome Stevens	NA	

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373.	8/11/2000	Lodine	etodolac	Relief of signs & symptoms of Juvenile Rheumatoid Arthritis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication in 6 years -16 years</li> <li>Higher dose (per kg basis) in younger children which is approximately 2 times the lower dose recommended for adults</li> </ul>	B	Wyeth Ayerst	12/6/1999	
374.	8/1/2000	Concerta Extended Release Tablets	methylphenidate	ADHD	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Efficacy established down to 6 years of age</li> </ul>	R	Alza	NA	
375.	8/1/2000	Motrin Suspension	ibuprofen / pseudoephedrine	Temporary relief of nasal and sinus congestion, minor body aches and pains, fever, stuffy nose, headache and sore throat	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Information on the over-the-counter use in pediatric patients 2 to 11 years of age</li> </ul>	B	McNeil	NA	
376.	7/27/2000	Vaniqa Cream	eflornithine	Reduction of facial hair in females	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved for female patients down to 12 years of age</li> </ul>	R	Bristol-Myers Squibb	NA	
377.	7/14/2000	ChlorPrep OneStep OTC	chlorhexidine/isopropyl alcohol	Skin preparation prior to surgery	-	<ul style="list-style-type: none"> <li>New indication approved down to 2 months of age; Warning: do not use in less than 2 months of age</li> </ul>	R	Medi-Flex Hospital Products	NA	
378.	7/14/2000	Malarone	atovaquone/proguanil	Prophylaxis and treatment of malaria	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and efficacy for treatment of malaria established down to 5 kg.</li> <li>Attributable AE occurring in ≥ 5% of the pediatric patients (5-&lt; 11 kg) was diarrhea (6%)</li> <li>Malarone tablets may be crushed and mixed with condensed milk just prior to administration for children who may have difficulty swallowing.</li> <li>The apparent clearance (CL/F) of both atovaquone and proguanil are related to body weight</li> </ul>	B	Glaxo Wellcome	8/6/2003	
379.	6/16/2000	AmBisome Injection	amphotericin B	Cryptococcal meningitis in HIV infected patients	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication approved down to 1 year of age; established a dose of 6mg/kg/day</li> </ul>	R	Fujisawa	NA	