

	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
						<p>arthritis, tendonopathy, and gait abnormality) compared to non-fluoroquinolone-treated children</p> <ul style="list-style-type: none"> <li>Information on clinical studies, AE profile</li> </ul>				
152.	8/22/2007	Risperdal	risperidone	Schizophrenia; short-term treatment of acute manic or mixed Episodes associated with Bipolar I Disorder	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended schizophrenia indication from adults to adolescents 13–17 years; extended bipolar mania indication from adults to children and adolescents 10-17 years</li> <li>Safety and effectiveness in children &lt; 13 years of age with schizophrenia have not been established; safety and effectiveness in children &lt; 10 years of age with bipolar mania have not been established</li> <li>No additional benefit was seen above 3 mg/day in schizophrenia studies and 2.5 mg/day in the Bipolar mania study; higher doses were associated with more adverse events. Doses higher than 6 mg/day have not been studied.</li> <li>Information on dose, clinical studies, AE profile</li> </ul>	B	Johnson & Johnson	2/28/2007	
153.	8/17/2007	Provigil	modafinil	Narcolepsy	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Modafinil is not approved for use in pediatric patients for any indication</li> <li>Safety and effectiveness were not demonstrated in a controlled 6-week study in 165 pediatric patients 5-17 years with narcolepsy</li> <li>Serious rash, including Stevens-Johnson Syndrome, requiring hospitalization and discontinuation of treatment has been reported in adults and children in association with the use of modafinil</li> <li>In the controlled and open-label clinical studies, treatment emergent adverse events of the psychiatric and nervous system included Tourettes' syndrome, insomnia, hostility, increased cataplexy, increased hypnagogic hallucinations and suicidal ideation</li> </ul>	B	Cephalon, Inc	3/21/2006	

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						<ul style="list-style-type: none"> <li>Information on safety, AEs and clinical study</li> </ul>				
154.	8/16/2007	Zingo	lidocaine	Topical local analgesia prior to venipuncture or peripheral intravenous cannulation in children 3-18 years of age		<ul style="list-style-type: none"> <li>Summary pending</li> </ul>	P	Anesiva	NA	
155.	7/18/2007	Toprol XL	metoprolol	Hypertension	<u>Labeling</u>	<ul style="list-style-type: none"> <li>A study in 144 pediatric hypertensive pediatric patients aged 6 - 16 years did not meet its primary endpoint. However, some study endpoints demonstrated effectiveness</li> <li>Adverse event profile similar to adults</li> <li>Safety and effectiveness have not been established in patients &lt; 6 years of age</li> <li>Information on PK parameters, clinical studies, and dose</li> </ul>	B	AstraZene ca	7/27/2006	
156.	6/14/2007	Lexiva Oral Suspension	fosamprenavir	Treatment of HIV infection in patients 2-18 years of age	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness and safety were established in two clinical studies of pediatric patients 2-18 years of age</li> <li>Adverse event profile is similar to that of adults with the exception of vomiting, which, regardless of causality, occurred more frequently among pediatric patients</li> <li>Dosing information provided</li> <li>Studies waived in children 0-1 month of age and deferred in children 1 month - 2 years of age</li> <li>New dosage form</li> </ul>	P	GlaxoSmit hKline	NA	
157.	6/12/2007	Extina Foam, 2%	ketoconazole	Topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness and safety were established in a clinical study that included 44 patients from 12-17 years of age</li> <li>Studies waived in children 0-12 years of age</li> </ul>	P	Stiefel Laboratori es	NA	

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				older		<ul style="list-style-type: none"> <li>• New dosage form</li> </ul>				
158.	6/8/2007	Betoptic S	betaxolol	Elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Extended indication from adults to pediatric patients</li> <li>• The adverse reaction profile was comparable to that seen in adults</li> </ul>	B	Alcon	2/28/2007	
159.	6/8/2007	Timolol GFS	timolol	Elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Extended indication from adults to pediatric patients</li> <li>• The adverse reaction profile was comparable to that seen in adults</li> </ul>	B	Falcon Pharmaceuticals	2/28/2007	
160.	5/30/2007	Zyflo CR Extended Release Tablets	zileuton	Prevention and chronic treatment of asthma in children 12 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Should not be used in children under 12 years of age</li> <li>• Effectiveness was established in clinical studies that included pediatric patients 12 years of age and older</li> <li>• Short-term and long-term safety were established in clinical studies that included pediatric patients 12 years of age and older</li> <li>• Studies waived in children 0-4 years of age and deferred in children 5-11 years of age</li> <li>• New dosage form</li> </ul>	P	Critical Therapeutics	NA	
161.	5/25/2007	Xyzal Tablets 5 mg	levocetirizine	Relief of symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis in adults and children 6 years of age or older, and for the treatment of the uncomplicated	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Summary pending</li> </ul>	P	UCB	NA	

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				skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age or older						
162.	5/18/2007	Locoid Lotion 0.1%	hydrocortisone butyrate	Treatment of mild to moderate atopic dermatitis in children 3 months of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness established in one study of 284 patients from 3 months to 18 years of age</li> <li>Information provided on HPA axis suppression from one safety study with Locoid Lotion of 84 pediatric patients from 3 months to 18 years of age with moderate to severe atopic dermatitis affecting at least 25% of body surface area</li> <li>Studies waived in children &lt; 3 months of age</li> <li>New dosage form</li> </ul>	P	Ferndale Labs	NA	
163.	4/27/2007	Azasite Ophthalmic Solution 1%	azithromycin	Treatment of bacterial conjunctivitis caused by certain microorganisms in patients down to 1 year of age	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness and safety were established in controlled clinical trials including patients down to 1 years of age</li> <li>Dosing information provided</li> <li>New dosage form</li> </ul>	P	InSite Vision	NA	
164.	4/19/2007	Valtropin	somatropin [rDNA origin]	Short stature in children with Turner Syndrome	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Summary pending</li> </ul>	P	LG Life	NA	
165.	4/12/2007	Altanax Ointment 1%	retapamulin	Treatment of impetigo in patients 9 months of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness established in studies that included 588 pediatric patients from 9 months of age to 17 years of age</li> <li>Studies waived in children 0-2 months of age and deferred in children 2-9 months of age</li> <li>New active ingredient</li> </ul>	P	GlaxoSmithKline	NA	
166.	3/28/2007	Ambien	zolpidem	Insomnia associated with ADHD	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness have not been established in pediatric patients with insomnia associated with ADHD</li> </ul>	B	Sanofi Aventis	11/20/2006	

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						<ul style="list-style-type: none"> <li>In an 8-week controlled study in 201 pediatric patients 6-17 years, psychiatric and nervous system disorders comprised &gt; 5% of treatment emergent adverse events, including dizziness (23.5%) headache (12.5%) and hallucinations (7.4%); treatment was discontinued due to an adverse event in 7.4%</li> </ul>				
167.	3/22/2007	Aldara	imiquimod	Molluscum contagiosum	Labeling	<ul style="list-style-type: none"> <li>Efficacy in patients 2 – 12 years for the treatment of molluscum contagiosum was not demonstrated in two clinical trials in 702 patients</li> <li>Information on clinical studies and AEs</li> </ul>	B	Graceway Pharmaceuticals	12/13/2006	
168.	3/19/2007	Keppra Tablets Keppra Oral Solution	levetiracetam*	Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in children 6 years of age and older with idiopathic generalized epilepsy	Labeling	<ul style="list-style-type: none"> <li>Safety and effectiveness established in study that included patients down to 4 years of age</li> <li>Pediatric dosing information added</li> <li>Studies waived in children 1 month to 2 years of age and deferred in children 2-6 years of age</li> <li>New indication</li> </ul>	P	UCB	NA	
169.	2/23/2007	Coreg	carvedilol	Heart failure	Labeling	<ul style="list-style-type: none"> <li>Effectiveness has not been established in patients &lt; 18 years</li> <li>In a double-blind trial of 161 children, 2 months to 17 years with chronic heart failure receiving standard background treatment, randomized to placebo or carvedilol, carvedilol demonstrated reduction of heart rate 4-6 beats per minute</li> <li>There was no significant effect of treatment on clinical outcomes after 8 months of follow-up</li> <li>AEs occurring in ≥ 10% of patients treated with carvedilol included chest pain (17%), dizziness (13%), and dyspnea (11%)</li> </ul>	B, P	GlaxoSmithKline	11/8/2006	

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170.	2/23/2007	Vyvanse Capsules	lisdexamfetamine	Treatment of ADHD in children 6 to 12 years of age	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness established in two studies of patients 6-12 years of age</li> <li>Long-term effectiveness of more than 4 weeks has not been established</li> <li>Studies waived in children 0-5 years of age and deferred in children 13-17 years of age</li> <li>New active ingredient</li> </ul>	P	New River	NA	
171.	2/7/2007	Actiq	fentanyl	Treatment of breakthrough pain in opioid tolerant children	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and efficacy in patients below the age of 16 years was not established in a clinical trial of 15 patients 5 to 15 years</li> <li>Information on PK parameters and clinical studies</li> </ul>	B, P	Cephalon	NA	
172.	1/10/2007	Eloxatin	oxaliplatin	Solid tumors	<u>Labeling</u>	<ul style="list-style-type: none"> <li>The effectiveness of oxaliplatin in children has not been established</li> <li>No significant activity observed in 2 Phase I and 2 Phase II trials in 159 patients ages 7 months to 22 years with solid tumors</li> <li>Information on clinical studies and AEs</li> </ul>	B	Sanofi-Aventis	9/27/2006	
173.	12/22/2006	Emtriva	emtricitabine	HIV-1 infection in combination with other antiretroviral agents	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Efficacy in preventing or treating HIV in neonates to 3 month olds could not be determined after a PK study in 20 neonates born to HIV positive mothers</li> <li>Information on dose in 0-3 months, additional safety and PK parameters</li> </ul>	B	Gilead Sciences	5/24/2006	
174.	12/20/2006	Colazal	balsalazide	Mildly to moderately active ulcerative colitis in patients 5 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended indication from adults to patients 5 years and older</li> <li>Dosing can be initiated at either 6.75 or 2.25 g/day</li> <li>PK of balsalazide, and metabolites showed very large inter-patient variability similar to that seen in adults</li> <li>AEs were similar to those seen in adults</li> </ul>	B, P	Salix	8/23/2006	

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175.	12/15/2006	Celebrex	celecoxib	Relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA)	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• New indication in 2 years and older</li> <li>• Has not been studied in patients &lt; 2 years, in patients with body weight &lt; 10 kg, or in patients with active systemic features</li> <li>• Celecoxib should be used only with caution in patients with systemic onset JRA due to the risk for serious adverse reactions including the risk of disseminated intravascular coagulation</li> <li>• The long-term cardiovascular toxicity in children has not been evaluated; it is unknown if the long-term risk may be similar to that seen in adults</li> <li>• New 50 mg capsule developed</li> <li>• Information on adding contents of a capsule to applesauce. for patients with difficulty swallowing capsules</li> <li>• Information on dose, clinical studies, PK parameters, AEs</li> </ul>	B	Pfizer	8/23/2006	
176.	12/15/2006	Suprane	desflurane	Safety study of 2 agents used for maintenance of anesthesia in non-intubated patients	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Not indicated for maintenance of anesthesia in non-intubated pediatric patients</li> <li>• In a clinical safety trial in patients 2 - 16 years, desflurane and isoflurane were compared for maintenance of anesthesia in non-intubated patients to assess the incidence of respiratory adverse events. Desflurane was associated with higher rates of coughing, laryngospasm and secretions with an overall rate of respiratory events of 39%. 5% of pediatric patients 2-16 years old exposed to desflurane, experienced severe laryngospasm</li> <li>• The incidence of respiratory events was highest in children aged 2-6 years; therefore, similar studies in children under the age of 2 years were not initiated.</li> <li>• Additional information on clinical studies and AEs</li> </ul>	B	Baxter	9/13/2006	
177.	11/7/2006	Ziana Gel	clindamycin;	Treatment of	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Effectiveness and safety based on two</li> </ul>	P	Dow	NA	

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			tretinoin	acne vulgaris in patients 12 years of age and older		<p>studies in patients 12 years of age and older</p> <ul style="list-style-type: none"> <li>• New active ingredient</li> </ul>				
178.	11/1/2006	Humatrope for injection	somatropin [rDNA origin]	Treatment of short stature or growth failure in children with short stature homeobox-containing gene (SHOX) deficiency	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Effectiveness established from one 2-year study for SHOX in 52 pediatric patients</li> <li>• Information on adverse events provided</li> <li>• Dosing information provided</li> <li>• New indication</li> </ul>	P	Lilly	NA	
179.	10/20/2006	Desonate Gel	desonide	Treatment of mild to moderate atopic dermatitis in children 3 months of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Effectiveness established from two studies in patients 3 months to 18 years of age</li> <li>• Not recommended for use in patients under 3 months of age</li> <li>• Treatment should not exceed 4 consecutive weeks</li> <li>• HPA axis suppression studied in patients 6 months of age to 6 years of age</li> <li>• New dosage form</li> </ul>	P	Dow	NA	
180.	10/19/2006	Zaditor ophthalmic solution#	ketotifen	Temporary relief of itchy eyes in children 3 years of age and older  OTC	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• No new studies submitted</li> <li>• New indication</li> </ul>	P	Novartis	NA	✓
181.	10/16/2006	Allegra	fexofenadine	Seasonal allergic rhinitis (SAR) uncomplicated skin manifestations of chronic idiopathic urticaria (CIU)	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• New suspension developed</li> <li>• Suspension indicated for the treatment of SAR in 2 – 11 years based on the PK comparisons in adult and pediatric patients and an extrapolation of efficacy in adults; Suspension indicated for the treatment of CIU in 6 months – 11 years based on the PK comparisons in adults and children and an extrapolation of efficacy in adults</li> <li>• Safety and effectiveness of suspension in pediatric patients under 6 months of age have not been established</li> </ul>	B	Aventis	1/27/2003	



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						<ul style="list-style-type: none"> <li>Additional information on dose, PK parameters, safety and AEs</li> </ul>				
182.	10/13/2006	Tirosint capsules#	levothyroxine	Replacement or supplemental therapy in hypothyroidism; treatment or prevention of euthyroid goiters	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Contraindicated in infants, small children, or any child who may be unable to swallow a capsule.</li> <li>Dosing information provided</li> <li>Information to monitor disease provided</li> <li>No clinical studies submitted</li> <li>New dosage form</li> </ul>	P	Institute Biochimique SA	NA	
183.	10/6/2006	Risperdal Tablets Risperdal Oral Solution Risperdal M-Tabs	risperidone*	Treatment of irritability associated with autistic disorder in children 5 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness and safety established based on two 8 week studies in patients 5-16 years of age and one long-term study of 4-6 months</li> <li>Studies waived in children under 2 years of age due to difficulty to diagnose and treat this population</li> <li>New indication</li> </ul>	P	Janssen	NA	
184.	10/5/2006	UV Protective Suncare#  Capital Soleil 20#  Anthelios 20#  UV Expert 20#	avobenzone; ecamsule; octocrylene; titanium	Prevention of sunburn and protection from UVA and UVB rays in children 6 months of age and older  OTC	<u>Labeling</u>	<ul style="list-style-type: none"> <li>No clinical studies submitted to support</li> <li>Age range based on monograph</li> <li>Studies deferred in children under 6 months of age</li> <li>New active ingredient</li> </ul>	P	L'Oreal	NA	
185.	9/29/2006	DuraPrep Surgical Solution#	iodine; isopropyl alcohol	Preoperative skin preparation for use in children 2 months of age and older  OTC		<ul style="list-style-type: none"> <li>Effectiveness based on determination that permeability of skin in children &gt; 2 months of age is essentially that of adult skin</li> <li>Studies waived in children under 2 months of age for safety reasons and includes the following statement in the label: Do not use in children under 2 months of age due to excessive skin irritation and transient hypothyroidism.</li> <li>New active ingredient</li> </ul>	P	3M Health	NA	
186.	9/29/2006	Fuzeon	enfuvirtide	HIV-1 infection in	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Additional safety and efficacy data and AE</li> </ul>	B, P	Hoffmann-	NA	

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				treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy		information from clinical study in 5-16 year olds <ul style="list-style-type: none"> <li>Insufficient data to provide dosing recommendations in patients &lt; 6 years</li> </ul>		La Roche		
187.	9/28/2006	Azopt ophthalmic suspension	brinzolamide	Elevated intraocular pressure	<u>Labeling</u>	<ul style="list-style-type: none"> <li>IOP-lowering efficacy was not demonstrated in a 3-month controlled clinical study in which brinzolamide was dosed only twice a day in pediatric patients 4 weeks to 5 years of age</li> </ul>	B	Alcon	6/28/2006	
188.	9/28/2006	Betaxon ophthalmic suspension	levobetaxolol	Elevated intraocular pressure	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended indication from adults to pediatric patients</li> <li>The adverse event profile was comparable to that seen in adults and elderly patients</li> </ul>	B, P	Alcon	6/28/2006	
189.	9/27/2006	Gleevec	imatinib mesylate	Treatment of newly diagnosed pediatric patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended age range for the treatment of newly diagnosed CML down to pediatric patients</li> <li>There are no data in children &lt; 2 years of age</li> <li>Follow-up in children with newly diagnosed Ph+ chronic phase CML is limited</li> <li>Information on hematologic toxicities, AE profile, clinical studies and dosing guidelines new for newly diagnosed pediatric patients</li> </ul>	B, P	Novartis	6/9/2006	
190.	9/22/2006	Lamictal Tablets Lamictal Chewable Dispersible Tablets	lamotrigine*	Adjunctive therapy for primary generalized tonic-clonic seizures in children 2 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness established in study with patients down to 2 years of age</li> <li>Revised boxed warning to remove restrictions on use in pediatric patients</li> <li>New indication</li> </ul>	P	GlaxoSmithKline	NA	
191.	9/19/2006	Verdeso Foam	desonide	Treatment of mild to moderate	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness established from studies in 581 pediatric patients 3 months to 17 years</li> </ul>	P	Connetics	NA	

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				atopic dermatitis in patients 3 months of age and older		<p>of age</p> <ul style="list-style-type: none"> <li>Effect on HPA axis function was investigated in pediatric patients 6 months to 17 years of age in one study of 75 patients</li> <li>Safety has not been evaluated in patients below 3 months of age</li> <li>Use for the minimum amount of time necessary due to the potential to suppress HPA axis treatment should not exceed 4 consecutive weeks</li> <li>New dosage form</li> </ul>				
192.	9/15/2006	Noxafil Oral Suspension	posaconazole	Prevention of invasive Aspergillus and Candida infections in patients 13 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Information on PK and safety studies in patients 13-17 years of age</li> <li>Safety profile in patients 8-17 years of age similar to adults</li> <li>Safety and effectiveness in patients below 13 years of age have not been established</li> <li>Additional information on pharmacokinetics provided in patients down to 8 years of age</li> <li>Studies deferred in children 0-12 years of age</li> <li>New drug</li> </ul>	P	Schering	NA	
193.	7/28/2006	Xolegel Gel	ketoconazole	Treatment of seborrheic dermatitis in children 12 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness established from studies in patients 12 years of age and older</li> <li>Safety and effectiveness in pediatric patients below 12 years of age have not been established studies waived in children 0-12 years of age</li> <li>New dosage form</li> </ul>	P	Barrier Therapeutics	NA	
194.	7/27/2006	Sodium Chloride Injection#	sodium chloride	Use in flushing compatible contrast agents through IV administration sets into indwelling intravascular	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety of manual injection in pediatric patients is supported by reported clinical experience with IV infusion and flush safety and effectiveness of Sodium Chloride Injection, USP 0.9% administered by power injection in pediatric patients have not been established</li> <li>Administration to pediatric patients by</li> </ul>	P	Tyco Healthcare	NA	

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				access devices		<p>power injection is not recommended</p> <ul style="list-style-type: none"> <li>To minimize the risk of fluid overload, the smallest dose necessary for manually flushing contrast agent through the vascular access line should be used</li> <li>Manual injection to pediatric patients should take into account the patient's weight, fluid status, and concomitant medical conditions to determine if use is appropriate</li> <li>New indication</li> </ul>				
195.	7/21/2006	Anthelios SX Cream	avobenzone; ecamsule; octocrylene	Prevention of sunburn and protection from UVA and UVB rays in children 6 months of age and older  OTC	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness extrapolated from adult studies</li> <li>Safety studies included pediatric patients 6 months of age and older</li> <li>Age range based on monograph</li> <li>Deferred studies in children &lt; 6 months of age</li> <li>New active ingredient</li> </ul>	P	L'Oreal USA	NA	
196.	7/21/2006	Symbicort Inhalation Aerosol	Formoterol / budesonide*	Long-term maintenance treatment of asthma in children 12 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness and safety in patients 12 years of age and older established in studies up to 12 months long</li> <li>PK studies in patients 6-11 years of age</li> <li>Effectiveness in patients 6 to &lt; 12 years of age has not been established</li> <li>Overall safety profile in patients 6 to &lt; 12 years of age was similar to that observed in patients 12 years of age and older</li> <li>Studies waived in children 0-6 years of age; deferred in children 6-12 years of age</li> <li>New active ingredient</li> </ul>	P	AstraZeneca	NA	
197.	6/29/2006	Lidocaine and Tetracaine Cream	lidocaine; tetracaine	Topical local analgesia for superficial dermatological procedures	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Studies failed to show effectiveness over placebo in reducing the pain associated with venipuncture in pediatric patients 5-17 years of age</li> <li>New active ingredient</li> </ul>	P	ZARS	NA	

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198.	5/10/2006	Sandostatin LAR	octreotide	Weight loss due to hypothalamic obesity from cranial insult	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• A randomized double-blind, placebo-controlled study in 60 patients aged 6 –17 years with hypothalamic obesity from cranial insult did not demonstrate efficacy and safety of octreotide as a weight loss agent; Mean BMI increased 0.1 kg/m<sup>2</sup> in drug treated patients compared to 0.0 kg/m<sup>2</sup> in control-treated patients</li> <li>• No unexpected AEs were observed; However, the incidence of new cholelithiasis in this pediatric population (33%) was higher than that seen in adult indications</li> <li>• Information on PK parameters and AEs</li> </ul>	B	Novartis	1/12/2006	
199.	5/8/2006	Solodyn Extended-Release Tablets	minocycline	Treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in children 12 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Only used to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris</li> <li>• Safety and effectiveness established from studies in patients 12 years of age and older</li> <li>• Safety and effectiveness in pediatric patients below 12 years of age has not been established</li> <li>• Studies waived in children 0-11 years of age</li> <li>• New dosage form</li> </ul>	P	Medicis	NA	
200.	4/28/2006	Nexium	esomeprazole	Short-term treatment of GERD	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Use in adolescent patients 12 to 17 years of age is supported by extrapolation from studies in adults, and safety and PK studies performed in adolescent patients</li> <li>• Safety and effectiveness in patients &lt; 12 years has not been established</li> <li>• Safety and effectiveness for other pediatric uses have not been established</li> <li>• Information on dose, treatment related AEs, clinical study</li> </ul>	B	AstraZeneca	5/1/2009	
201.	4/27/2006	Genotropin Injection	somatropin	Long-term treatment of	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Indicated for use in pediatric patients with open epiphyses</li> </ul>	P	Pharmacia &	NA	

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				growth failure associated with Turner syndrome		<ul style="list-style-type: none"> <li>Effectiveness and safety based on studies in pediatric patients</li> <li>New indication</li> </ul>		Upjohn		
202.	4/10/2006	Lescol and Lescol XL	fluvastatin	Heterozygous familial hypercholesterolemia as an adjunct to diet	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication in adolescent boys and girls (at least one year post-menarche) 10-16 years of age, with heterozygous familial hypercholesterolemia</li> <li>Information on dose, AE profile and clinical studies</li> </ul>	B, P	Novartis	12/15/2005	
203.	4/6/2006	Daytrana	methylphenidate	ADHD	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Summary pending</li> </ul>	P	Shire	NA	
204.	3/29/2006	Relenza	zanamivir	Prevention of influenza in children 5 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness for prophylaxis based on 4 clinical studies in patients 5-16 years of age</li> <li>No differences in safety and effectiveness were observed between pediatric and adult subjects.</li> <li>Dosing information provided</li> <li>Studies waived in children &lt;5 years of age</li> <li>New indication</li> </ul>	P	GlaxoSmithKline	NA	
205.	3/16/2006	Avapro	irbesartan	Hypertension	<u>Labeling</u>	<ul style="list-style-type: none"> <li>In a study at a dose up to 4.5 mg/kg once daily, irbesartan did not appear to lower blood pressure effectively in pediatric patients ages 6 to 16 years</li> </ul>	B	Sanofi-Synthelabo	9/16/2004	
206.	3/2/2006	Vanos Cream	fluocinonide	Relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in children 12 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Use in pediatric patients younger than 12 years of age is not recommended</li> <li>Effectiveness extrapolated from adult studies</li> <li>Safety in patients 12 to 17 years of age was similar to that observed in adults</li> <li>Information provided on HPA axis suppression from safety studies with Vanos Cream in 4 cohorts of pediatric patients (3 months - 18 years of age) with atopic dermatitis</li> <li>Studies waived in children 0-11 years of</li> </ul>	P	Medicis	NA	

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						age <ul style="list-style-type: none"> <li>• New indication</li> </ul>				
207.	2/28/2006	Flovent HFA	fluticasone propionate	Asthma in 4 - 11 years	Labeling	<ul style="list-style-type: none"> <li>• Flovent HFA should be administered by the orally inhaled route only in patients 4 years and older.</li> <li>• Clinical studies were conducted in children with asthma 6 months to less than 4 years</li> <li>• Information added to Pediatric Use</li> </ul>	P	GlaxoSmit hKline	NA	
208.	2/16/2006	Vusion Ointment	miconazole	Adjunctive treatment of diaper dermatitis in children 4 weeks of age and older	Labeling	<ul style="list-style-type: none"> <li>• Indicated for use in immunocompetent children</li> <li>• Presence of candidal infection should be established by microscopic evaluation prior to initiating treatment</li> <li>• Effectiveness based on three clinical studies in infants and toddlers</li> <li>• Safety when used for more than 7 days is not known</li> <li>• New active ingredient</li> </ul>	P	Barrier Therapeutics	NA	
209.	2/3/2006	ProAir HFA Inhalation Aerosol	albuterol	Prevention of exercise-induced bronchospasm in children 12 years of age and older	Labeling	<ul style="list-style-type: none"> <li>• Expands use from previously approved bronchospasm with reversible obstructive airway disease</li> <li>• Effectiveness based on study in adults and adolescents</li> <li>• Safety and effectiveness in pediatric patients below 12 years of age have not been established</li> <li>• New indication</li> </ul>	P	IVAX	NA	
210.	2/1/2006	Clarinet-D 12 Hour Extended Release Tablets	desloratadine*/ pseudoephedrine	Relief of nasal and non-nasal symptoms of seasonal allergic rhinitis in children 12 years of age and older	Labeling	<ul style="list-style-type: none"> <li>• Approval based on two safety and effectiveness studies in patients down to 12 years of age</li> <li>• Not an appropriate dosage form for use in pediatric patients below 12 years of age.</li> <li>• Studies waived in children &lt; 12 years of age</li> </ul>	P	Schering	NA	

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						<ul style="list-style-type: none"> <li>• New dosing regimen</li> </ul>				
211.	12/21/2005	Fosamax	alendronate	Severe osteogenesis imperfecta	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Alendronate is not indicated for use in children</li> <li>• The efficacy and safety were examined in a randomized, double-blind, placebo-controlled two-year study of 139 patients, 4-18 years old, with severe osteogenesis imperfecta</li> <li>• Treatment with alendronate did not reduce the risk of fracture</li> <li>• There were no statistically significant differences between the alendronate and placebo groups in reduction of bone pain</li> <li>• Information on PK parameters, AE profile, and clinical studies</li> </ul>	B	Merck	4/28/2003	
212.	12/21/2005	TamiFlu	oseltamivir	Prophylaxis in pediatric patients 1 year to <13 years of age	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Information on postmarketing clinical study in patients 1 to 12 years</li> </ul>	P	Roche	NA	
213.	12/8/2005	Meridia	sibutramine	Obesity	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• The data are inadequate to recommend the use of sibutramine for the treatment of obesity in pediatric patients</li> <li>• Efficacy in obese adolescents has not been adequately studied</li> <li>• Sibutramine's mechanism of action inhibiting the reuptake of serotonin and norepinephrine is similar to that of some antidepressants</li> <li>• It is unknown if sibutramine increases the risk of suicidal behavior or thinking in pediatric patients</li> <li>• In a study of adolescents with obesity in which 368 patients were treated with sibutramine and 130 patients with placebo, one patient in each group attempted suicide. Suicidal ideation was reported by 2 sibutramine-treated patients and none of the placebo patients</li> </ul>	B	Abbott	10/6/2004	



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214.	12/1/2005	Effexor XR Extended-Release Capsules	venlafaxine*	Social anxiety disorder	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Provided additional safety data for changes in weight, height, and appetite occurring in pediatric patient</li> <li>• Information based on a clinical study of patients with SAD</li> <li>• New indication (not approved in pediatric patients)</li> </ul>	P	Wyeth	NA	
215.	11/28/2005	Amaryl	glimepiride	Type-2 Diabetes Mellitus	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Data are insufficient to recommend pediatric use of glimepiride</li> <li>• In an active-controlled, single-blind, 24-week trial, 272 pediatric patients aged 8 to 17 years with Type 2 diabetes were randomized to treatment with glimepiride or metformin. Trial suggested differences favoring metformin</li> <li>• AE profile in the pediatric population was similar to that for adults</li> <li>• Information on PK parameters</li> </ul>	B, P	Aventis	6/9/2005	
216.	11/9/2005	Fluocinolone Acetonide Oil	fluocinolone	Chronic eczematous external otitis (outer ear) in children 2 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Effectiveness established in studies of patients 2 years of age and older</li> <li>• New indication</li> </ul>	P	Hill Dermaceuticals	NA	
217.	10/28/2005	Trileptal	oxcarbazepine	Use as adjunctive therapy in children aged 2 years and above with epilepsy	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Extended adjunctive therapy age range from 4 years down to 2 years</li> <li>• No evidence drug was effective as adjunctive therapy in patients &lt; 2 years</li> <li>• In clinical studies as adjunctive therapy, apparent clearance (L/hr/kg) decreased when age increased such that children 2 to &lt;4 years of age may require up to twice the dose per body weight compared to adults; and children 4 to ≤12 years of age may require a 50% higher dose per body weight compared to adults</li> <li>• Approximately 11% of pediatric patients &lt; 4 years discontinued treatment because of adverse events including convulsions, status epilepticus and ataxia</li> </ul>	B	Novartis	3/2/2005	

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						<ul style="list-style-type: none"> <li>Information on dose, PK parameters, AE profile and clinical studies</li> </ul>				
218.	10/6/2005	Norvir	ritonavir	Treatment of HIV-infection in combination with other antiretroviral agents	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended age range from 2 years down to 1 month</li> <li>AE profile in the pediatric population was similar to that for adults</li> <li>Information on dose and PK parameters</li> </ul>	B	Abbott	6/14/2005	
219.	9/28/2005	Emtriva	emtricitabine	HIV-1 infection in combination with other antiretroviral agents	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness in pediatric patients 3 months and older supported by data from 3 open-label, nonrandomized clinical studies</li> <li>Safety and effectiveness in patients &lt; 3 months have not been established</li> <li>Relative bioavailability of Emtriva oral solution is approximately 80% of Emtriva capsules. Thus, maximum dosage is different for these 2 formulations: Solution max - 240 mg once daily; Capsules max - children weighing &gt; 33 kg one 200 mg capsule once daily</li> <li>The AE profile in pediatric patients was comparable to that observed in adults</li> <li>Information on dose, PK parameters, AE profile and clinical studies</li> <li></li> </ul>	B, P	Gilead Sciences	5/24/2006	
220.	9/13/2005	NovoLog	insulin aspart [rDNA origin] injection	Diabetes Mellitus	<u>Labeling</u>	<ul style="list-style-type: none"> <li>In clinical studies comparing NovoLog to regular human insulin in patients 2 to 18 years with type 1 diabetes, NovoLog achieved glycemic control comparable to regular human insulin</li> <li>The incidence of hypoglycemia was similar for both treatment groups</li> </ul>	B	Novo Nordisk	5/24/2005	
221.	8/11/2005	Mobic	meloxicam	Relief of signs and symptoms of pauciarticular or polyarticular course Juvenile	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and efficacy established in patients 2 years of age and older</li> <li>Clinical studies evaluated doses ranging from 0.125 mg/kg/day to 0.375 mg/kg/day. There was no additional benefit</li> </ul>	B, P	Boehringer Ingelheim	4/15/2005	

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				Rheumatoid Arthritis		<p>demonstrated by doses above 0.125 mg/kg/day in the clinical trials. The lowest effective dose should be used</p> <ul style="list-style-type: none"> <li>• Adverse events in children were similar to those in adults including skin reactions and gastrointestinal bleed risk</li> <li>• Information on dose, PK parameters, AE profile and clinical studies</li> </ul>				
222.	8/4/2005	Loperamide Hydrochloride Soft Gelatin Capsules#	loperamide	Control symptoms of diarrhea in children 12 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• New dosage form; new dosing regimen</li> <li>• No new clinical studies</li> <li>• Bioequivalence study in adults compared the current OTC drug (Imodium caplet) and this drug</li> <li>• Studies waived in children 0-2 years of age</li> </ul>	P	Banner Pharmaceuticals	NA	✓
223.	7/29/2005	Avandia	rosiglitazone	Type 2 Diabetes Mellitus	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Data are insufficient to recommend pediatric use of rosiglitazone</li> <li>• In a 24 week double-blind controlled trial in children with type 2 diabetes mellitus, aged 10 to 17 years, with a baseline BMI of 33 kg/m<sup>2</sup> were randomized to treatment with rosiglitazone or metformin</li> <li>• Mean change from baseline in HbA1c was -0.14% with rosiglitazone and -0.49% with metformin</li> <li>• There was an insufficient number of patients to establish statistically whether these observed mean treatment effects were similar or different</li> <li>• Weight gain similar to that in adults</li> <li>• Information on PK parameters, and AE profile</li> </ul>	B	SB Pharmco	12/09/2004	
224.	7/27/2005	Singulair Oral Granules#, Tablets#, and Chewable Tablets#	montelukast	Relief of symptoms of perennial allergic rhinitis in children 6 months of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Effectiveness was extrapolated from a allergic rhinitis study in patients 15 years of age and older</li> <li>• Safety in patients 6 to 23 months is supported by data from PK and safety and efficacy studies in asthma in this pediatric population and from adult PK studies</li> </ul>	P	Merck	NA	

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						<ul style="list-style-type: none"> <li>• Studies waived in children &lt; 6 months of age</li> <li>• New indication</li> </ul>				
225.	7/21/2005	Adderall XR	amphetamines , mixed salts	ADHD	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Expanded labeling for 13-17 year olds</li> <li>• On a mg/kg body weight basis children 6-12 years have a higher clearance than adolescents or adults. Body weight is the primary determinant</li> <li>• There was not adequate evidence that doses greater than 20 mg/day conferred additional benefit in a placebo-controlled study conducted in adolescents aged 13-17 with ADHD</li> <li>• In a single-dose PK study in adolescents, isolated increases in systolic blood pressure (SBP) were observed in patients receiving 10 mg and 20 mg Adderall XR. Higher single doses were associated with a greater increase in SBP</li> <li>• Sustained increases in blood pressure should be treated with dose reduction and/or appropriate medication</li> <li>• Information on dose, PK parameters, and AE profile</li> </ul>	B, P	Shire	10/28/2004	
226.	6/29/2005	Topamax Tablets and Sprinkle Capsules	topiramate*	Initial monotherapy for partial onset or primary generalized tonic-clonic seizures in children 10 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Effectiveness established in studies of patients down to 6 years of age</li> <li>• Use in patients who were converted to monotherapy from a previous regimen of other anticonvulsant drugs have not been established in controlled trials</li> <li>• Provides information regarding treatment-emergent decrease in serum bicarbonate and adverse events</li> <li>• Some patients in the study discontinued therapy due to adverse events; however, adverse events associated with discontinuing therapy included difficulty with concentration/attention</li> <li>• Studies waived in children 0-2 years of age;</li> </ul>	P	Johnson & Johnson	NA	