

	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
				>20 kg		<ul style="list-style-type: none"> <li>weighing <math>\geq 20</math>kg who can swallow capsules</li> <li>Dosing is based on body weight not to exceed adult dose</li> <li>Adverse events (AEs) are generally similar to those seen in adults</li> <li>Information on dose, AEs, population PK analysis, lab abnormalities, and historical clinical studies</li> </ul>		Myers Squibb		
96.	9/19/2008	Retrovir syrup, capsules and tablets#	zidovudine	Used in combination with 18 other antiretroviral agents for the treatment of HIV-1 infection	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Dosing and administration information provided to children 6 weeks to less than 18 years of age</li> <li>Macrocytosis was reported in the majority of pediatric patients receiving Retrovir 180 mg/m<sup>2</sup> every 6 hours in open-label studies</li> <li>New dosing regimen</li> </ul>	P	GlaxoSmithKline	NA	✓
97.	9/19/2008	Nasacort AQ	triamcinolone	Treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Expands pediatric use, or age range, to include patients 2 to 5 years of age</li> <li>Dosing and administration information provided</li> <li>Not recommended for children under 2 years of age</li> <li>An effect on adrenal function in children 2 to 5 years of age cannot be ruled out</li> <li>Pharmacokinetics were evaluated in children 2 to 5 years of age</li> <li>Safety and efficacy were evaluated in one clinical study involving pediatric patients 2 to 5 years old</li> <li>Studies in children &gt;6 months and less than 2 years of age were not performed due to safety concerns since controlled clinical studies have shown that intranasal corticosteroids may cause a reduction in growth velocity in pediatric patients.</li> </ul>	P	Sanofi-Aventis	NA	
98.	9/12/2008	GARDASIL	Human Papillomavirus Quadrivalent (Types 6, 11,	Prevention of vulvar and vaginal cancer caused by HPV	<u>Package Insert</u>	See Package Insert for new information on biologics	P	Merck	NA	

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			16, 18) Vaccine, Recombinant®	types 16 and 18						
99.	9/3/2008	Valtrex	valacyclovir	Chickenpox; active or at risk for herpes virus infection	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• New indication for treatment of chickenpox in pediatric patients 2 to &lt;18 years based on single-dose pharmacokinetic and multiple-dose safety data from an open-label trial with valacyclovir and supported by safety and extrapolated efficacy data from 3 randomized, double-blind, placebo-controlled trials evaluating oral acyclovir in pediatric patients with chickenpox</li> <li>• The efficacy and safety of valacyclovir have not been established in pediatric patients: <ul style="list-style-type: none"> <li>○ &lt;12 years of age with cold sores</li> <li>○ &lt;18 years of age with genital herpes</li> <li>○ &lt;18 years of age with herpes zoster</li> <li>○ &lt;2 years of age with chickenpox,</li> <li>○ for suppressive therapy following neonatal HSV infection</li> </ul> </li> <li>• Adverse events similar to that of adults</li> <li>• Information on PK parameters, AEs, clinical studies, and preparation of an extemporaneous formulation</li> </ul>	B, P	GlaxoSmithKline	2/26/2008	
100.	8/28/2008	Zemuron	rocuronium	Adjunct to general anesthesia	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Expanded pediatric indication to include 0-17 years. Previously approved in ages 3 months – 14 years</li> <li>• Not recommended for rapid sequence intubation in pediatric patients</li> <li>• In clinical studies of rocuronium, onset time and clinical duration varied with dose, the age of the patient, and anesthetic technique</li> <li>• The overall analysis of ECG data in pediatric patients indicates that the concomitant use of rocuronium with general anesthetic agents can prolong the QTc interval</li> <li>• The time to maximum block for an intubating dose was shortest in infants and</li> </ul>	B, P	Organon USA	4/3/2008	

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						<p>longest in neonates. The duration of clinical relaxation following an intubating dose is shortest in children &gt; 2 years to 11 years and longest in infants</p> <ul style="list-style-type: none"> <li>• Additional information on dose, clinical studies, and PK/PD parameters</li> </ul>				
101.	8/14/2008	Zyprexa	olanzapine	schizophrenia; bipolar disorder	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Safety and effectiveness have not been established for patients less than 18 years of age</li> <li>• In an analysis of placebo-controlled olanzapine monotherapy studies of adolescent patients, including those with schizophrenia or bipolar disorder, olanzapine was associated with: <ul style="list-style-type: none"> <li>○ Hyperglycemia - a statistically significantly greater mean change in fasting glucose levels compared to placebo</li> <li>○ Hyperlipidemia – statistically significant increases compared to placebo in fasting triglycerides, fasting total cholesterol and fasting LDL cholesterol</li> <li>○ Weight gain – olanzapine treated patients gained an average of 4.6 kg, compared to an average of 0.3 kg in placebo-treated patients with a median exposure of 3 weeks; Average weight gain during long-term therapy was 7.4 kg</li> </ul> </li> </ul>	B	Lilly	1/10/2007	
102.	7/29/2008	Cancidas	caspofungin	Empirical therapy for presumed fungal infections in febrile, neutropenic patients; Candidemia and certain <i>Candida</i> infections; Esophageal Candidiasis;	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Extended indication from adults to children 3 months and older based upon evidence from adequate and well-controlled studies in adults and PK data in pediatric patients and additional data from pediatric studies</li> <li>• The efficacy and safety have not been adequately studied in infants &lt; 3 months</li> <li>• The ability of caspofungin to penetrate the blood-brain barrier and to treat patients with meningitis and endocarditis is unknown</li> </ul>	B, P	Merck	4/15/2008	

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				Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies		<ul style="list-style-type: none"> <li>Dosing should be based on the patient's body surface area. Maximum loading dose and daily maintenance dose should not exceed 70 mg</li> <li>The safety profile in pediatrics is comparably to adults</li> <li>Information on dose, AEs, PK parameters, clinical studies and infusion preparation instructions</li> </ul>				
103.	7/24/2008	Navstel Intraocular Irrigating Solution Sterile#	balanced salt ophthalmic solution with hypromellose, dextrose and glutathione	Use as an intraocular irrigating solution during surgical procedures involving perfusion of the eye	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and efficacy have been demonstrated in pediatric patients</li> <li>New active ingredient</li> </ul>	P	Alcon	NA	✓
104.	7/1/2008	Flovent HFA	fluticasone propionate	Asthma in < 4 years	<u>Labeling</u>	<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	GlaxoSmithKline	NA	
105.	6/30/2008	Aciphex	rabeprazole	Gastroesophageal reflux in adolescent patients 12 years of age and above	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Use in adolescent patients 12 years of age and older is supported by extrapolation of results from studies in adults and safety and PK studies performed in adolescent patients</li> <li>Safety and effectiveness for GERD have not been established for pediatric patients &lt;12 years of age</li> <li>Safety and effectiveness for other uses have not been established in pediatric patients</li> <li>Adverse events (AEs) similar to those seen in adults</li> <li>Information on dose, AEs, clinical studies</li> </ul>	B, P	Eisai Medical Research	NA	
106.	6/24/2008	KINRIX	Diphtheria and	Active	<u>Package</u>	See Package Insert for new information on	P	GlaxoSmith	NA	

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			Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine®	<i>immunization against diphtheria, tetanus, pertussis, &amp; poliomyelitis as the fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series when previous DTaP vaccine doses have been with INFANRIX and/or PEDIARIX and for the first three doses and INFANRIX for the fourth dose</i>	<u>Insert</u>	biologics		hKline Biologicals		
107.	6/24/2008	Viramune Tablets 200 mg Viramune Oral Suspension 10 mg/mL	nevirapine	Use in combination with other antiretroviral agents for the treatment of HIV-1 infection	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Dosing information provided for children ages &gt;15 days to &lt;16 years old</li> <li>• Safety was evaluated in children 2 weeks and older in 5 clinical trials and important adverse events (all causality) include rash (21%), neutropenia (8.9%), anemia (7.3%) and hepatotoxicity (2.4%)</li> <li>• Safety, pharmacokinetics, and virologic and immunologic responses have been evaluated in HIV-infected pediatric patients age 3 months to 18 years</li> <li>• Safety and pharmacokinetics were evaluated in HIV-infected pediatric patients age 15 days to &lt; 3 months</li> <li>• Efficacy was evaluated in one clinical study with children 3 months to 16 years of age</li> </ul>	P	Boehringer Ingelheim	NA	

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						<ul style="list-style-type: none"> <li>• Post-marketing surveillance has shown anemia to be more commonly observed in children although development of anemia due to concomitant medication use cannot be ruled out</li> <li>• Potential drug interaction information is provided for children with respect to lopinavir/ritonavir</li> <li>• New dosing regimen</li> </ul>				
108.	6/23/2008	Aptivus	tipranavir	Co-administered with ritonavir for combination antiretroviral in patients who are treatment-experienced and infected with HIV-1 strains resistant to more than one protease inhibitor	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Extended indication from adults to children 2 years and older</li> <li>• The risk-benefit has not been established in patients &lt;2 years of age</li> <li>• Dosing is based on body weight or body surface area not to exceed adult dose</li> <li>• AEs are generally similar to those seen in adults however, rash was more frequent in pediatric patients than in adults; The frequency of rash through 48 weeks of treatment was 21%. Most rashes were mild and 5% were moderate. Overall 3% interrupted treatment due to rash</li> <li>• Information on dose, AEs, PK parameters, lab abnormalities, and clinical study</li> </ul>	B, P	Boehringer Ingelheim	3/7/2008	
109.	6/20/2008	Kaletra	lopinavir/ritonavir	Use in combination with other antiretroviral agents for HIV-1 infection	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Extended indication from 6 months - 12 years to 14 days - 18 years</li> <li>• The safety, efficacy, and pharmacokinetic profiles in pediatric patients &lt; 14 days have not been established</li> <li>• Dose should be calculated based on body weight or body surface area not to exceed adult dose</li> <li>• Because no data exists for dosage when administered with efavirenz, nevirapine, (fos)amprenavir, or nelfinavir, it is recommended that lopinavir/ ritonavir not be administered in combination with these drugs in patients &lt; 6 months of age</li> <li>• Infants &lt;6 months of age generally had</li> </ul>	B, P	Abbott	3/7/2008	

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						<p>lower lopinavir AUC<sub>12</sub> than children 6 months - 12 years of age</p> <ul style="list-style-type: none"> <li>Information on dose, PK parameters, clinical studies, and AEs</li> </ul>				
110.	6/20/2008	Pentacel	Diphtheria And Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus B Conjugate (Tetanus Toxoid Conjugate) Vaccine	Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to <i>Haemophilus influenzae</i> type b	<u>Package Insert</u>	See Package Insert for new information on biologics	P	Sanofi Pasteur	NA	
111.	6/5/2008	Zetia and Vytorin	ezetimibe and ezetimibe/simvastatin	Heterozygous familial hypercholesterol emia as an adjunct to diet	<u>Labeling</u>	<ul style="list-style-type: none"> <li>The effects of ezetimibe co-administered with simvastatin compared to simvastatin monotherapy have been evaluated in adolescent boys and girls with heterozygous familial hypercholesterolemia (HeFH)</li> </ul>	B, P	MSP Singapore	2/14/2008	
112.	5/9/2008	OraVerse Injection 0.4 mg (0.235 mg/mL)	phentolamine mesylate	Reversal of soft-tissue anesthesia, i.e., anesthesia of the lip and tongue, and the associated functional deficits resulting from an intraoral submucosal injection of a local anesthetic containing a vasoconstrictor		<ul style="list-style-type: none"> <li>Use in children less than 6 years of age or weighing less than 15 kg (33 lbs) is not recommended</li> <li>Dosing information provided for children weighing 15 to 30 kg (66 lbs)</li> <li>Safety and efficacy were established in 2 clinical trials in children 12 to 17 years old, one trial in children ages 6 to 11 years, as well as adult studies</li> <li>Safety has been evaluated in pediatric patients under the age of 6 years but not efficacy</li> <li>Pharmacokinetics have been evaluated in children weighing 15 kg or more</li> </ul>	P	Novalar Pharmaceuticals, Inc.	NA	

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						<ul style="list-style-type: none"> <li>• New indication</li> </ul>				
113.	5/8/2008	Desmopressin acetate Tablets, 0.1 mg and 0.2 mg	desmopressin acetate	Determine the capacity of the kidney to concentrate urine in pediatric patients (Renal Concentration Capacity Test or RCCT) and management of primary nocturnal enuresis (PNE)		<ul style="list-style-type: none"> <li>• Efficacy in RCCT was evaluated in a single trial with children 3 to 18 years old</li> <li>• Three studies evaluated efficacy in children 5 to 17 years old with PNE; an additional study evaluated efficacy in adolescents 12 to 17 years old</li> <li>• Fluid intake should be adjusted downward in children to decrease the potential occurrence of water intoxication and hyponatremia</li> <li>• Dosing information provided for children 3 to 18 years old for RCCT</li> <li>• Dosing information provided for pediatric patients 6 years of age and older with PNE</li> <li>• Tablet dosage and administration information provided for children with central diabetes insipidus</li> <li>• Pharmacokinetics and pharmacodynamics were evaluated in children</li> <li>• New indications and dosing regimen</li> </ul>	P	Ferring	NA	
114.	5/5/2008	Levaquin Tablets, 250 mg, 500 mg, and 750 mg#  Levaquin Oral Solution, 25 mg/mL#  Levaquin Injection and Levaquin Injection, 5 mg/mL#	levofloxacin  levofloxacin in 5% dextrose injection	Reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis (inhalational anthrax post-exposure)		<ul style="list-style-type: none"> <li>• New indication</li> <li>• Dosing information provided for children less than and greater than 50 kg</li> <li>• Efficacy is based on plasma concentrations achieved in humans, a surrogate endpoint reasonably likely to predict clinical benefit, and animal studies were used to evaluate survival; the product has not been tested in humans for the post-exposure prevention of inhalation anthrax</li> <li>• Safety in pediatric patients treated for more than 14 days has not been studied</li> <li>• Long-term safety data, including effects on cartilage, following administration in pediatric patients is limited</li> <li>• Due to possible side effects, use is not recommended for pediatric patients except in the prevention of anthrax after</li> </ul>	P	Ortho-McNeil-Janssen Pharmace uthical, Inc.	NA	✓



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						inhalational exposure <ul style="list-style-type: none"> <li>Pharmacokinetics were investigated in pediatric patients 6 months to 16 years old</li> </ul>				
115.	5/5/2008	Argatroban	argatroban	Heparin-Induced Thrombocytopenia (HIT) or HIT with Thrombosis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness, including the appropriate anticoagulation goals and duration of therapy, have not been established in pediatric patients</li> <li>Population PK/PD analysis of sparse data in 15 seriously ill pediatric patients ages &lt;6 months – 16 years diagnosed with HIT or suspected HIT requiring an alternative to heparin anticoagulation showed clearance in pediatric patients was 50% lower compared to healthy adults and led to dose recommendations</li> <li>Information on dose, AEs and PK</li> </ul>	B, P	Encysive	NA	
116.	4/30/2008	Cardiolite	technetium tc99m sestamibi	Medical imaging in Kawasaki disease	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness have not been established in the pediatric population</li> <li>No evidence of diagnostic efficacy or clinical utility of scan was found in 3 clinical studies of children and adolescents with Kawasaki disease</li> <li>A study of 445 pediatric patients failed to demonstrate the predictive value of Cardiolite rest and stress myocardial perfusion imaging to define children with Kawasaki disease at risk of developing cardiac events 6 months after receiving Cardiolite; only 3 cardiac events were observed. In all 3 cases, the scan was negative</li> <li>Adverse events similar to that of adults</li> <li>Information on dose, PK, and clinical studies</li> </ul>	B, P	Lantheus Medical Imaging	1/11/2008	
117.	4/15/2008	Patanase Nasal Spray	olopatadine hydrochloride	Relief of symptoms of seasonal allergic rhinitis (SAR) in patients 12 years	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness in children below the age of 12 years have not been established</li> <li>Symptoms of antihistamine overdose in</li> </ul>	P	Alcon Research, Ltd.	NA	

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				of age and older		<p>children may initially include agitation and restlessness followed by drowsiness</p> <ul style="list-style-type: none"> <li>• Efficacy and safety were evaluated in 3 clinical trials of 2 weeks duration in adult and adolescent patients, 12 years of age and older, with symptoms of SAR</li> <li>• Dosage and administration information provided for children 12 years and older</li> <li>• New indication, dosage form, dosing regimen, and route of administration</li> </ul>				
118.	4/7/2008	Orencia	abatacept	Moderate to severe polyarticular juvenile idiopathic arthritis		<ul style="list-style-type: none"> <li>• Indicated for reducing signs and symptoms in pediatric patients with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) ages 6 years and older.</li> <li>• The safety and effectiveness in pediatric patients &lt; 6 years of age and in pediatric patients for uses other than JIA have not been established</li> <li>• Abatacept was studied in 190 patients 6 - 17 years with polyarticular JIA.</li> <li>• AEs were generally similar to those seen in adults. Overall frequency of adverse events in the 4-month, lead-in, open-label period of the study was 70%; infections occurred at a frequency of 36%. A total of 6 serious adverse events were reported during the initial 4 months of treatment with abatacept.</li> <li>• Information on dosing, PK, immunogenicity, immunization needs, AEs, and clinical study</li> <li>• New indication</li> </ul>	P	Bristol-Myers Squibb	NA	
119.	4/3/2008	ROTARIX	Rotavirus Vaccine, Live, Oral	Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9)	<u>Package Insert</u>	See Package Insert for new information on biologics	P	GlaxoSmithKline Biologicals	NA	
120.	3/31/2008	Lancôme UV	avobenzone,	Sunscreen		<ul style="list-style-type: none"> <li>• Effectiveness extrapolated from adult</li> </ul>	P	L'Oreal	NA	

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		Expert 40  La Roche-Posay Anthelios 40  Vichy Capital Soleil 40	ecamsule, octocrylene, titanium dioxide cream	OTC		<p>studies</p> <ul style="list-style-type: none"> <li>• Safety studies included pediatric patients 6 months of age and older</li> <li>• Age range based on standards established in over-the-counter monograph for sunscreens</li> <li>• New active ingredient</li> <li>•</li> </ul>		USA		
121.	3/26/2008	Ventolin HFA	albuterol	Treatment of symptoms of bronchospasm associated with obstructive airway disease	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Safety and effectiveness of albuterol administered with or without a spacer device in children &lt; 4 years of age has not been demonstrated</li> <li>• 3 randomized, double-blind, placebo-controlled studies in 250 children &lt; 4 years, in which efficacy was not demonstrated, suggest that either the optimal dose has not been defined in this age-group or the drug is not effective in this age-group</li> <li>• Information on clinical studies</li> </ul>	B	GlaxoSmit hKline	8/27/2008	
122.	3/25/2008	Reyataz	atazanavir	HIV in 6 years and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Extended indication from adults to children 6 years and older</li> <li>• The safety, activity, and pharmacokinetic profiles in pediatric patients ages 3 months to &lt; 6 years have not been established. Atazanavir should not be administered to pediatric patients below the age of 3 months due to the risk of kernicterus</li> <li>• Dosing is based on body weight or body surface area not to exceed adult dose</li> <li>• Adverse events (AEs) are generally similar to those seen in adults</li> <li>• Information on dose, AEs, PK parameters, lab abnormalities, and clinical study</li> </ul>	B, P	Bristol-Myers Squibb	NA	
123.	3/24/2008	Depakote ER Depakote Sprinkles	divalproex disodium	Pediatric Bipolar Disorder; Prophylaxis of Migraine	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Efficacy was not established in a double-blind, placebo controlled study of patients 10-17 years conducted to evaluate efficacy in the treatment of pediatric bipolar disorder</li> <li>• Efficacy was not established in a double-</li> </ul>	B, P	Abbott	12/14/2007	

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						<p>blind, placebo-controlled study of patients 12 – 17 years conducted to evaluate the efficacy in the prophylaxis of migraine</p> <ul style="list-style-type: none"> <li>• The safety and tolerability was similar to adults in 5 long-term safety studies</li> <li>• Additional information on clinical studies, AE profile in Depakote ER labeling</li> </ul>				
124.	3/20/2008	Prilosec	omeprazole	Maintenance healing of erosive esophagitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Efficacy was extrapolated from adults and older children to 1 to 2 year olds and supported with an open-label trial</li> <li>• Unique adverse reactions in pediatric patients included increased respiratory system adverse events and fever.</li> <li>• Safety and effectiveness in children less than 1 year of age have not been established</li> <li>• Dosing and administration information provided for patients 1 year and older weighing at least 5 kg.</li> <li>• New dosage form</li> </ul>	B, P	AstraZeneca	NA	
125.	3/20/2008	Zometa	zoledronic acid	Severe osteogenesis imperfecta	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Zoledronic acid is not indicated for use in children</li> <li>• Safety and effectiveness was studied in 152 pediatric patients with severe osteogenesis imperfecta aged 1 - 17 years. At one year, increases in BMD were observed in the zoledronic acid treatment group but the changes did not necessarily correlate with the risk for fracture or the incidence or severity of chronic bone pain</li> <li>• Information on PK, clinical study, and AE profile</li> </ul>	B	Novartis	12/21/2007	
126.	3/19/2008	ARTISS	Fibrin Sealant (Human)•	To adhere autologous skin grafts to surgically prepared wound beds resulting from burns	<u>Package Insert</u>	See Package Insert for new information on biologics	P	Baxter	NA	

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127.	3/14/2008	NovoLog	insulin aspart [rDNA origin] injection	Insulin analog indicated to improve glycemic control	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Efficacy was demonstrated in a clinical study with pediatric patients ages 4 to 18 years using an external insulin pump</li> <li>New dosing regimen</li> </ul>	P	Novo Nordisk	NA	
128.	3/12/2008	DAPTACEL	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed	<i>Active immunization as a booster dose against diphtheria, tetanus &amp; pertussis</i>	<u>Package Insert</u>	See Package Insert for new information on biologics	P	Sanofi Pasteur	NA	
129.	2/27/2008	Abilify	aripiprazole	Bipolar I Disorder	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended treatment of acute Bipolar Disorder indication from adults to pediatrics 10–17 years</li> <li>The efficacy for the maintenance treatment of Bipolar Disorder in the pediatric population has not been evaluated</li> <li>The recommended target dose in Bipolar Disorder is 10 mg/day.</li> <li>In the study of pediatric patients 10 – 17 years with Bipolar Mania, 4 common adverse reactions had a possible dose response relationship at 4 weeks; extrapyramidal disorder, somnolence, akathisia and salivary hypersecretion</li> <li>Information on dose, AEs, clinical studies</li> </ul>	B, P	Otsuka	11/14/2007	
130.	2/27/2008	Nexium	esomeprazole	Short-term treatment of GERD	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Expanded age range to include pediatric patients 1-11 years. Previously approved in 12-17 years</li> <li>Use in pediatric patients 1 to 17 years of age is supported by extrapolation from studies in adults, and safety and PK studies performed in pediatric and adolescent patients</li> <li>Safety and effectiveness in pediatric patients &lt;1 year of age have not been established</li> <li>Safety and effectiveness for other pediatric uses have not been established</li> <li>Information on dose, treatment related</li> </ul>	B	AstraZeneca	5/1/2009	

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						adverse events (AEs), clinical study <ul style="list-style-type: none"> <li>• New formulation</li> </ul>				
131.	2/21/2008	Humira	adalimumab	Treatment of juvenile idiopathic arthritis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 4 years of age and older</li> <li>• Has not been studied in children &lt;4 years of age; there are limited data on treatment in children with weight &lt;15 kg</li> <li>• Safety and efficacy in pediatric patients for uses other than JIA have not been established</li> <li>• Adalimumab was studied in 171 patients 4 - 17 years with polyarticular JIA.</li> <li>• AEs were generally similar to those seen in adults. 45% of children experienced an infection while receiving adalimumab with or without concomitant MTX in the first 16 weeks of treatment. Serious infections were observed in 4% of patients within approximately 2 years of initiation of treatment</li> <li>• Information on dose, AEs, lab abnormalities, PK parameters, immunogenicity, immunization needs and clinical study</li> <li>• New indication</li> </ul>	P	Abbott	NA	
132.	2/1/2008	Asmanex Twisterhaler 110mcg inhalation powder	mometasone furoate	Maintenance treatment of asthma as prophylactic therapy in children 4 years of age and older		<ul style="list-style-type: none"> <li>• Not indicated for relief of acute bronchospasm or in children less than 4 years of age</li> <li>• Clinical studies, including 52 week safety trial conducted in children 4 – 11 years of age</li> <li>• Pediatric dosing information provided</li> <li>• Child may not get the most benefit for 1 to 2 weeks or longer after starting treatment</li> <li>• New dosage form</li> </ul>	P	Schering Corporation	NA	

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133.	1/31/2008	Inspra	eplerenone	Hypertension	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Effectiveness was not established in a study of 304 hypertensive pediatric patients 4 - 17 years; eplerenone, at doses up to 100 mg/ day, did not lower blood pressure effectively</li> <li>Therefore, it has not been studied in hypertensive patients &lt;4 years old</li> <li>Eplerenone has not been studied in hypertensive patients &lt; 4 years or in pediatric patients with heart failure</li> <li>Adverse events similar to that of adults</li> </ul>	B, P	Pfizer	10/24/2007	
134.	1/28/2008	Xyzal 0.5 mg/mL Oral Solution#	levocetirizine dihydrochloride	Relief of symptoms associated with seasonal and perennial allergic rhinitis (SAR and PAR) and treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (CIU)	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Dosing information provided</li> <li>Studies waived in children less than 6 months of age with PAR and CIU</li> <li>Waived in children less than 2 years of age with SAR</li> <li>New dosage form pediatric</li> </ul>	P	UCB	NA	✓
135.	1/23/2008	Moxatag	amoxicillin	Use for tonsillitis and/or pharyngitis secondary to Streptococcus pyogenes patients 12 years of age and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness in pediatric patients younger than 12 years have not been established</li> <li>One clinical study evaluated safety and effectiveness in pediatric patients 12 years of age and older with no significant differences in treatment response or adverse reactions between adults and children</li> <li>A prospective study of 51 children suggested that overdoses of less than 250 mg/kg are not associated with significant clinical symptoms and do not require gastric emptying</li> <li>Waiver of studies in children ages 0 to less than two years because too few children have the disease</li> </ul>	P	Middlebrook Pharmaceuticals	NA	

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						<ul style="list-style-type: none"> <li>• New dosage form</li> </ul>				
136.	1/17/2008	TamiFlu	oseltamivir	Safety information resulting from studies that established treatment of uncomplicated acute illness due to influenza infection in patients 1 year and older	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Influenza can be associated with a variety of neurologic and behavioral symptoms which can include events such as hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease.</li> <li>• These events have been reported in patients receiving oseltamivir, primarily among pediatric patients, appear to be uncommon, and often had an abrupt onset and rapid resolution</li> <li>• If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient</li> </ul>	B	Roche	3/22/2004	✓
137.	1/10/2008	Alvesco Inhalation Aerosol, 80 mcg & 160 mcg	ciclesonide	Treatment of asthma in patients 12 years of age and older.	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Not indicated for children under the age of 12 years</li> <li>• Five clinical studies evaluated safety in children 12 years of age and older</li> <li>• Safety and effectiveness have not been established in children under 12 years of age</li> <li>• Waiver of studies in children 0 to less than 6 months of age due to too few patients with the disease</li> <li>• New dosage form</li> </ul>	P	Nycomed US Inc.	NA	
138.	1/2/2008	EVICEL	Fibrin Sealant (Human)•	Adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques is ineffective or	<u>Package Insert</u>	See Package Insert for new information on biologics	P	Johnson/Johnson Wound Management	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
139.	12/27/2007	AndroGel	testosterone	impractical Use in adolescent boys with delayed puberty	Labeling	<ul style="list-style-type: none"> <li>• Safety and efficacy in males &lt; 18 years old have not been established</li> <li>• Improper use may result in acceleration of bone age and premature closure of epiphyses</li> </ul>	B	Unimed	8/22/2007	
140.	12/27/2007	Voluven	6% Hydroxyethyl Starch 130/0.4 In 0.9% Sodium Chloride Injection•	Plasma volume substitute for treatment and prophylaxis of hypovolemia	Package Insert	See Package Insert for new information on biologics	P	Fresenius Kabi Norge AS	NA	
141.	12/19/2007	Hepsera	adefovir dipivoxil	Chronic hepatitis B virus infection	Labeling	<ul style="list-style-type: none"> <li>• Extended indication from adults to pediatric patients 12 years and older</li> <li>• Not recommended for children &lt;12 years of age. Efficacy was not significantly different from placebo in a clinical study in children &lt;12 years</li> <li>• Safety ≥12 – &lt; 18 years was similar to that observed in adults</li> <li>• Information on PK, AEs, clinical study, clinical resistance</li> </ul>	B, P	Gilead	NA	
142.	12/12/2007	Derma-Smoothe/FS Topical Oil	fluocinolone	Treatment of atopic dermatitis in pediatric patients 3 months and older for up to 4 weeks.		<ul style="list-style-type: none"> <li>• Extended age range down to 3 months</li> <li>• Effectiveness and safety are not established in children less than 3 months old</li> <li>• Safety was evaluated in two pediatric clinical studies (including facial use)</li> <li>• Pediatric dosing and administration information provided</li> <li>• Studies waived in children under 3 months of age due to safety concerns of adrenal suppression</li> <li>• New indication</li> </ul>	P	Hill	NA	

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143.	11/29/2007	Triesence 40mg/mL	triamcinolone acetonide injectable suspension	Visualization during vitrectomy	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Efficacy and safety of corticosteroids in the pediatric population are based on the well-established course of effect of corticosteroids, which is similar in pediatric and adult populations</li> <li>• Adverse effects of corticosteroids in pediatric patients are similar to those in adults</li> <li>• New indication</li> </ul>	P	Alcon Research, Ltd.	NA	✓
144.	11/29/2007	Diovan	valsartan	Hypertension	<u>Labeling</u>	<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 due to safety findings possibly related to treatment or with glomerular filtration rate &lt; 30mL/min/1.73m<sup>2</sup></li> <li>• Information on dose, clinical studies in 1-16 years 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	Novartis	8/8/2007	
145.	11/21/2007	Omnaris Nasal Spray	ciclesonide	Treatment of seasonal allergic rhinitis (SAR) in patients 6 through less than 12 years of age	<u>Labeling</u>	<ul style="list-style-type: none"> <li>• Indication extended down to 6 years of age</li> <li>• Pediatric dosing information provided</li> <li>• Two clinical studies evaluated safety in children 6 to 11 years of age and the overall incidence of adverse events was comparable to those treated with placebo</li> <li>• Efficacy in children 2 to 5 years of age was not established in clinical trials conducted in this age group.</li> <li>• Waiver of studies in children ages 0 to less than 2 years of age for SAR because of local and systemic safety concerns as well as lack of disease and/or diagnosis difficulties in children</li> <li>• New indication</li> </ul>	P	Nycomed US Inc.	NA	

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146.	11/9/2007	Kaletra Oral Solution, 80 mg/20 mg & Kaletra (1opinavir/ritonavir) Tablets, 200 mg/50 mg	lopinavir/ritonavir	HIV -1 protease inhibitor indicated in combination with other antiretroviral agents for the treatment of HIV -1 infection.	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Dosing and administration information provided for children</li> <li>Use of a lower strength tablet in a twice daily dosing regimen for pediatric patients weighing greater than 15 kg</li> <li>New dosing regimen</li> </ul>	P	Abbott Laboratories	NA	✓
147.	10/30/2007	Combigan 0.2%/0.5% ophthalmic solution	brimonidine tartrate/timolol maleate	Reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness supported by evidence from clinical studies in adults with additional data from a study in children with glaucoma ages 2 – 7 years old</li> <li>Not recommended for use in children under the age of 2 years due to safety concerns based on reports of apnea, bradycardia, hypotension, hypothermia, hypotonia, and somnolence in infants</li> <li>Safety and effectiveness have not been studied in children below the age of two years</li> <li>New active ingredient</li> </ul>	P	Allergan	NA	✓
148.	10/29/2007	Abilify	aripiprazole	Schizophrenia	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended schizophrenia indication from adults to adolescents 13–17 years</li> <li>Safety and effectiveness in pediatric patients with bipolar mania or agitation associated with schizophrenia or bipolar mania have not been established</li> <li>Efficacy for the maintenance treatment of schizophrenia in the pediatric population has not been evaluated</li> <li>In 6-week placebo controlled efficacy trial in patients 13 – 17 years with Schizophrenia 30 mg/day was not shown to be more efficacious than 10 mg/day</li> <li>Common adverse events observed were extrapyramidal disorder, somnolence, and tremor; these 3 AEs appear to have a possible dose response relationship</li> <li>Information on dose, AEs, clinical studies</li> </ul>	B	Otsuka)	11/14/2007	
149.	9/28/2007	Lamisil	terbinafine	Tinea capitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication in 4 years and older</li> </ul>	B	Novartis	12/4/2006	

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		Oral Granules				<ul style="list-style-type: none"> <li>Two randomized safety and efficacy trials were conducted in patients 4 to 12 years old with tinea capitis. Terbinafine was dosed on a mg/kg basis and treated for 6 weeks</li> <li>Although no hepatotoxicity was seen during trials, pre-treatment serum transaminases tests are advised.</li> <li>The most common adverse events observed in the trials were nasopharyngitis, headache, pyrexia, cough, vomiting, and upper respiratory tract infection</li> <li>New 125 mg and 187.5 mg oral granule formulations developed; take with food</li> <li>Information on dose, PK parameters, AE profile, and instructions for use</li> </ul>				
150.	9/20/2007	Norditropin Cartridges	somatropin [rDNA origin]	Treatment of short stature in children with Turner syndrome	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Safety and effectiveness based on studies in pediatric patients</li> <li>New Warning: Patients with Turner syndrome should be evaluated carefully for otitis media and other ear disorders since these patients have an increased risk of ear and hearing disorders. Somatropin treatment may increase the occurrence of otitis media in patients with Turner syndrome. In addition, patients with Turner syndrome should be monitored closely for cardiovascular disorders (e.g., stroke, aortic aneurysm/dissection, hypertension) as these patients are also at risk for these conditions</li> <li>Information on recommended dosing, adverse events (AEs) and clinical studies</li> <li>New indication</li> </ul>	P	Novo Nordisk	NA	
151.	9/11/2007	Levaquin	levofloxacin	Community-acquired pneumonia	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Levofloxacin is not indicated for pediatric patients &lt; 18 years of age</li> <li>In a prospective, long-term, surveillance study, levofloxacin treated children had a significantly higher incidence of musculoskeletal (MS) disorders (arthralgia,</li> </ul>	B, P	Ortho-McNeil	3/14/2007	