

	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		<ul style="list-style-type: none"> <li>• Summary pending</li> </ul>	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	

	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
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	ChloroPrep 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 <math>\geq 5\%</math> 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	

	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
380.	5/26/2000	Differin Cream	adapalene	Acne vulgaris	<u>Labeling</u>	• Approved down to 12 years of age	R	Galderma	NA	
381.	5/22/2000	Optivar	azelastine	Itching associated with Allergic Conjunctivitis	<u>Labeling</u>	• Safety and effectiveness established down to 3 years	B	Muro Pharma/Asta Medica	8/11/1999	
382.	4/26/2000	Relenza Rotadisk	zanamivir	Treatment of Influenza A and B	<u>Labeling</u>	• Approved down to 7 years of age	R	GlaxoSmithKline	NA	
383.	4/20/2000	Lantus	insulin glargine	Type 1 Diabetes	<u>Labeling</u>	• Safety and effectiveness established down to 6 years	B	Aventis	7/12/1999	
384.	4/12/2000	Trivagizole 3 Vaginal Cream	clotrimazole	Vaginal yeast infection	<u>Labeling</u>	• Approved for OTC use in patients 12 years of age and older	R	Taro	NA	
385.	4/4/2000	Humalog Injection	insulin lispro	Type 1 diabetes	<u>Labeling</u>	• Approved for use in the pediatric population; instructions on use of the diluted product in the pediatric population	R	Lilly	NA	
386.	3/17/2000	Lamisil AT Spray Pump	terbinafine	Jock itch, athletes foot, ringworm	<u>Labeling</u>	• Approved for OTC use	R	Novartis	NA	
387.	2/4/2000	Tri-Nasal Spray	triamcinolone	Allergic rhinitis	<u>Labeling</u>	• Approved down to 12 years of age	R	Muro	NA	
388.	1/12/2000	Advil	ibuprofen	Fever, minor aches & pain, cold symptoms	<u>Labeling</u>	• Extended age range from 2 years to 6 months for the over-the-counter use based on a large safety database (14,291 patients)	B	Whitehall	7/1/1998	
389.	12/8/1999	Alocril	nedocromil	Allergic Conjunctivitis	<u>Labeling</u>	• Approved down to 3 years of age	R	Allergan	NA	
390.	11/8/1999	Omnicef	cefdinir	Bronchitis	<u>Labeling</u>	• Approved for use in adolescents	R	Abbott	NA	
391.	10/22/1999	Zantac	ranitidine	Gastroesophageal Reflux	<u>Labeling</u>	• Small studies in newborns 0 to 1 month receiving ECMO did not demonstrate efficacy but provided information on dose and PK	B	Glaxo	1/19/1999	

	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
392.	9/17/1999	Accolate Tablets	zafirlukast	Prophylaxis and chronic treatment of asthma		<ul style="list-style-type: none"> <li>Approved down to 7 years of age; efficacy extrapolated from demonstrated efficacy in patients 15 years and older</li> </ul>	R	AstraZeneca	NA	
393.	8/24/1999	Ceftin Oral Suspension	cefuroxime	Acute bacterial sinusitis		<ul style="list-style-type: none"> <li>Approved down to 3 years of age</li> </ul>	R	Lifecyle Ventures	NA	
394.	8/18/1999	Derma-Smoother/FS Topical Oil	fluocinolone	Atopic dermatitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 6 years of age; previously approved in adults only</li> </ul>	R	Hill	NA	
395.	7/26/1999	Relenza Rotadisk	zanamivir	Treatment of influenza A and B	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication approved down to 12 years of age</li> </ul>	R	GlaxoSmithKline	NA	
396.	7/23/1999	Topamax Tablets	topiramate	Adjunctive treatment of partial onset seizures and generalized tonic clonic seizures	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 2 years of age</li> </ul>	R	Ortho-McNeil	NA	
397.	7/14/1999	Omnicef	cefdinir	Otitis media	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved 5-day treatment regimen; previously labeled for a 5-10 day treatment regimen</li> </ul>	R	Abbott	NA	
398.	7/9/1999	Tagamet HB 200 Liquid OTC	cimetidine	Heartburn and indigestion	<u>Labeling</u>	<ul style="list-style-type: none"> <li>New indication approved down to 12 years of age; new OTC suspension</li> </ul>	R	GlaxoSmithKline	NA	
399.	7/2/1999	Zaditor Ophthalmic Soln.	ketotifen fumarate	Allergic conjunctivitis	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Approved down to 3 years of age; efficacy extrapolated from adult data</li> </ul>	R	Novartis	NA	
400.	6/17/1999	Cutivate Cream	fluticasone propionate	Treatment of corticosteroid responsive dermatoses	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended the age range from 5 years down to 3 months of age</li> </ul>	R	Elan	NA	
401.	4/15/1999	Motrin	ibuprofen	Fever, minor aches & pain, cold symptoms	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Extended age range from 2 years to 6 months for the over-the-counter use based on a large safety database (27,000 patients)</li> </ul>	B	McNeil	7/1/1998	
402.	12/17/1998	Ziagen	abacavir	HIV infection	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Labeling for 3 months - 12 years</li> <li>Information on dose, efficacy, PK</li> </ul>	B	GlaxoSmithKline	12/14/1998	

	Pediatric Labeling Date	Trade Name	Generic or Proper (Biologics <sup>Ⓢ</sup> ) Name	Indications Studied	Product Labeling	Labeling Changes	BPCA (B)/ PREA (P)/ Rule (R)	Sponsor	Pediatric Exclusivity Granted Date	N P S
						parameters and AE profile				
403.	10/15/1998	Versed	midazolam	Sedation/anxiolysis/ amnesia	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Specified the effective dose, effective dose range, and time of onset</li> <li>Defined volume of distribution and similarity to adult protein binding and elimination</li> <li>Additional information on AE's and warnings about concomitant medications</li> <li>Identified a subpopulation (children with congenital heart disease and pulmonary hypertension) at higher risk for AE's and the need to start therapy at the lower end of the dosing range</li> </ul>	B	Roche	9/18/1998	
404.	2/10/1998	Amerge	naratriptan	Migraine	<u>Labeling</u>	<ul style="list-style-type: none"> <li>Summary pending</li> </ul>	R	Glaxo Wellcome	NA	

Products in this table fell within the scope of the Pediatric Rule, the Best Pharmaceuticals for Children Act (BPCA), and the Pediatric Research Equity Act (PREA), and contain new pediatric information. The products marked with a (#) are PREA labeling changes that were not based on information from clinical trials in pediatric patients. All other labeling changes are based on information from clinical trials in pediatric patients. This list only serves to highlight key information affecting the pediatric population at the time the particular application was approved resulting from the studies performed for the Pediatric Rule, BPCA and PREA. Biologics have a solid dot (●) by the proper name.

**Helpful Links:**

Drug and therapeutic biological labeling: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>

Biological labeling and reviews: <http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm122938.htm>.

BPCA 2002 Review Summaries: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm161894.htm>

FDAAA Full Reviews: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049872.htm>

**Legend:**

PK – Pharmacokinetics    PD – Pharmacodynamics

## 米国における治験推進法令に基づき 2011 年 2 月 25 日までに承認された小児適応

- 注： 1. 番号のあとに、担当領域と思われる領域を日本語で記載しています。
2. 内容の詳細については、別添の FDAPedLabelChange02252011.pdf をご覧ください。実際の適応については「Indication Studied」ではなく、「Labeling Changes」のコラムに記載されています。対象年齢についても留意ください。
3. 年齢・対象等が細かく分かれており、またマンパワーに限界があることから、治験実施中、開発準備中、承認済みかどうかの確認は、一部の薬以外は出来ていないことをご了承ください。必ず国内外の開発状況は各自でご確認ください
4. 専門領域以外に、関連分野（感染症やアレルギーなど）についてもご確認ください。
5. 厚生労働省へ要望を提出する際には、同種同効薬との位置づけや、承認状況なども勘案してください。また、同一疾患領域で、多品目の要望を一度に出すと、重要性を低く評価される傾向がありますので、プライオリティを考え要望品目数はある程度絞ってください。
6. 今回は、海外ガイドラインに記載されている薬についても要望提出の対象となります。例えば、片頭痛については以下のガイドライン等に記載されていれば、たとえ米・英・独・仏・豪・加での承認がなくても要望提出が可能です。Lewis D, Ashwal S, Hershey A, et al: Practice Parameter: pharmacological treatment of migraine headache in children and adolescents. Report of the American Academy of Neurology quality standards subcommittee and the practice committee of the child neurology society. Neurology 2004; 63(12):2215-2224.

### 1. 感染症

MENVEO : Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135

### 2. 感染症

Natroba Topical Suspension : spinosad  
Treatment of head lice infestation in patients 4 years of age and older.

### 3. ワクチン、腫瘍

GARDASIL : Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant  
Prevention of anal cancer and associated precancerous lesions caused by HPV types 16 and 18

### 4. 米国の小児適応取得なし

### 5. 米国の小児適応取得なし

### 6. 感染症、眼科

Moxeza ophthalmic solution : moxifloxacin hydrochloride  
Bacterial conjunctivitis

### 7. 精神、神経、心身症

Vyvanse : lisdexamfetamine  
ADHD

### 8. 外来小児科（治験準備中、検討会での検討済）

Ofimev Injection: acetaminophen

### 9. 外来小児科、産婦人科（避妊）

Lo Loestrin Fe : norethindrone acetate/ ethinyl estradiol  
Prevention of pregnancy

### 10. 呼吸器、アレルギー

Aridol Powder for Inhalation : mannitol

Assessment of bronchial hyperresponsiveness in patients without clinically apparent asthma

11. 精神、神経、心身症

Kapvay Extended Release Tablets : clonidine

Treatment of ADHD as monotherapy and as adjunctive therapy to stimulant medications

12. 外来小児科、産婦人科（避妊）/皮膚科（尋常性ざそう）

Beyaz : drospirenone/ ethinyl estradiol

Prevention of pregnancy; premenstrual dysphoric disorder; moderate acne vulgaris

13. 中毒、小児救急

Protopam : pralidoxime

Treatment of poisoning due to organophosphates (e.g., nerve agents)

14. 呼吸器、アレルギー

Zyrtec Allergy Orally Disintegrating Tablets : cetirizine

Temporary relief of symptoms due to hay fever or other upper respiratory allergies

15. 感染症

Augmentin XR : amoxicillin/clavulanate potassium

Community-acquired pneumonia or acute bacterial sinusitis

16. 外来小児科、産婦人科（性交後避妊）

ella : ulipristal acetate

Prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure

17. アレルギー、眼科

Lastacaft Ophthalmic Solution : alcaftadine

Prevention of itching associated with allergic conjunctivitis.

18. 精神、神経、心身症

Daytrana : methylphenidate

ADHD

19. 眼科（緑内障、眼圧上昇）

Isopto Carpine : pilocarpine hydrochloride

Reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension; management of acute angle closure glaucoma; prevention of postoperative elevated IOP associated with laser surgery and induction of miosis Labeling

20. 呼吸器、アレルギー

Dulera Inhalation Aerosol : mometasone furoate and formoterol fumarate

Asthma

21. 米国の小児適応なし

22. 外来小児科

Advil Congestion Relief : ibuprofen/phenylephrine HCl

Temporary relief of symptoms associated with cold and flu

23. アレルギー、耳鼻科

Nasonex : mometasone

Nasal congestion associated with seasonal allergic rhinitis

24. 眼科、感染症

Zymaxid : gatifloxacin



Bacterial conjunctivitis

25. 腫瘍、米国での有効性は確立していない

Taxotere : docetaxel

26. 耳鼻科、アレルギー、呼吸器（製造販売後試験結果、安全性情報の追加）

Omnaris : ciclesonide

Information on clinical study to assess effect of orally inhaled ciclesonide on growth

27. 外来小児科、産婦人科（避妊）

Natazia : estradiol valerate and estradiol valerate/dienogest

Prevention of pregnancy

28. 嚢胞性線維症等による膵外分泌機能異常（栄養消化器肝臓？）

Pancreaze : pancrelipase

Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions

29. 感染症、H I V

Viread : tenofovir disoproxil fumarate

Treatment of HIV infection in combination with other antiretroviral agents

30. 皮膚科

Differin Lotion : adapalene

Acne

31. 放射線科

MultiHance Injection : gadobenate dimeglumine

Intravenous use in magnetic resonance imaging

32. 感染症、ワクチン（承認後の追加情報）

Pevnar 13 : Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

33. 感染症（追加情報、1-12歳の予防）

TamiFlu : oseltamivir

Prophylaxis of influenza

34. 感染症、ワクチン（追加情報）

MENVEO : Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine

Active immunization to prevent invasive

meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135

35. 循環器、腎臓

Benicar : olmesartan

Hypertension

36. 神経

Lamictal XR（徐崩製剤）: lamotrigine

Adjunctive therapy for Primary Generalized Tonic-Clonic seizures

37. 内分泌（追加情報）

Sandostatin and Sandostatin LAR : octreotide

Weight loss due to hypothalamic obesity from cranial insult

38. アレルギー、呼吸器（治験中か）

Xolair : omalizumab

Moderate to severe persistent asthma who have a positive skin test or in vitro reactivity

to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled

corticosteroids.

39. 感染症（有効性データ不十分）

Famvir : famciclovir

40. 神経（有効性は証明されなかった）

Flomax : tamsulosin

41. 神経（有効性は証明されなかった。安全性情報の追記）

Topamax : topiramate

42. 神経（安全性、有効性は証明されなかった）

Topamax : topiramate

43. 精神・神経・心身症（安全性情報の追記）

Daytrana : methylphenydate

44. 精神

Zyprexa : olanzapine

Treatment of manic or mixed episodes of bipolar I disorder and schizophrenia in adolescents ages 13-17

45. 精神

Seroquel : quetiapine

Treatment of schizophrenia in adolescents 13 to 17 years of age and the treatment of bipolar mania in children and adolescents 10 to 17 years of age

46. アレルギー、耳鼻科

Patanase : olopatadine

Seasonal allergic rhinitis

47. 精神、神経、心身症

Abilify : aripiprazole

Irritability associated with autistic disorder

48. 栄養消化器肝臓

Protonix : pantoprazole

GERD

49. 感染症、ワクチン

AFLURIA : Influenza Virus Vaccine

Active immunization for the prevention of influenza disease caused by virus types A and B contained in the vaccine

50. 感染症（新生児？）

Retrovir : zidovudine

Treatment of HIV-1 infection in combination with other antiretroviral agents

51. 精神、神経、心身症

Focalin XR : dexamethylphenidate

ADHD

52. 循環器、腎臓

Atacand : candesartan

Hypertension

53. ワクチン（添付文書追加情報）

54. ワクチン (添付文書追加情報)
55. ワクチン (添付文書追加情報)
56. 内分泌：家族性高コレステロール血症  
Crestor : rosuvastatin  
Heterozygous familial hypercholesterolemia
57. 内分泌：家族性高コレステロール血症  
Welchol : colesevelam  
Heterozygous familial hypercholesterolemia
58. 婦人科 (外来小児科?)  
Mirena : levonorgestrel-releasing intrauterine system  
Treatment of heavy menstrual bleeding for women using intrauterine contraception
59. 内分泌 (安全性情報追加)  
AndroGel : testosterone  
Use in adolescent boys with delayed puberty
60. 眼科、アレルギー  
Bepreve Ophthalmic Solution : bepotastine besilate  
Ocular itching associated with allergic conjunctivitis
61. 精神、神経、心身症  
Intuniv : guanfacine  
ADHD
62. 耳鼻科、アレルギー  
Astepro Nasal Spray : azelastine hydrochloride  
Seasonal and perennial allergic rhinitis
63. 感染症  
Valcyte : valganciclovir  
Prevention of cytomegalovirus Labeling  
Use in pediatric patients +4 months
64. 嚢胞性線維症等による膵外分泌機能異常 (栄養消化器肝臓?)  
Zenpep:pancrelipase  
Exocrine pancreatic insufficiency due to cystic fibrosis
65. 耳鼻科、アレルギー  
Xyzal : levocetirizine dihydrochloride  
Seasonal allergic rhinitis (SAR) in children 2 years of age and older  
; perennial allergic rhinitis (PAR) and chronic idiopathic urticaria (CIU) for  
children 6 months of age and older Labeling
66. ワクチン (追加情報)
67. 感染症  
Acyclovir/Hydrocortisone : acyclovir/hydrocortisone  
Recurrent herpes labialis (cold sores) in 12 years of age and older
68. 内分泌 (小児における有効性、安全性は確立していない)  
Actonel : risedronate  
Osteogenesis imperfecta
69. 婦人科、外来小児科 (避妊)

Plan B One Step : levonorgestrel  
Emergency  
contraception - OTC in women 17 years and older;  
RX for women younger than age 17 years

70. 栄養消化器肝臓 (1歳以下での有効性、安全性は確立していない)  
Nexium : esomeprazole  
Short-term treatment of GERD

71. 神経  
Lamictal XR (徐放錠) : lamotrigine  
Adjunctive therapy for partial onset seizures with or  
without secondary generalization in patients +13 years of age

72. 眼科、感染症 (有効性、安全性は証明されなかった)  
Besivance: besifloxacin ophthalmic suspension

73. 神経 (有効性、安全性は証明されなかった)  
Lamictal: lamotrigine

74. 耳鼻科、感染症  
Cetraxal : ciprofloxacin otic solution  
Treatment of acute otitis externa due to susceptible isolates of  
Pseudomonas aeruginosa or Staphylococcus aureus

75. 片頭痛 (神経、外来小児科?)  
Axert : almotriptan  
Acute treatment of pediatric migraine in adolescent patients  
age 12-17 years

76. 嚢胞性線維症等による膵外分泌機能異常 (栄養消化器肝臓?)  
Creon : pancrelipase  
Exocrine pancreatic insufficiency due to cystic fibrosis or other conditions

77. 麻酔  
Suprane : desflurane  
Safety study of 2 agents used for maintenance of anesthesia in non-intubated patients

78. 皮膚科、感染症  
Ulesfia Lotion, 5% benzyl alcohol  
Treatment of head lice

79. 精神  
Lexapro Tablets 5 mg, 10 mg, and 20 mg and Oral solution 5 mg/mL : escitalopram oxalate  
Major depressive disorder in adolescents

80. 眼科  
TobraDex ST : tobramycin/dexamethasone  
Steroid-responsive inflammatory ocular conditions

81. 感染症  
Ziagen : abacavir  
HIV infection

82. 内分泌 (安全性と有効性は確立していない)  
Casodex : bicalutamide  
Gonadotropin-independent precocious puberty in boys with  
familial male-limited precocious puberty (testotoxicosis)

83. 感染症  
Prezista : darunavir  
Treatment of HIV infection in pediatric patients 6 years and older when co-administered with ritonavir (Prezista/rtv), and with other antiretroviral agents
84. 皮膚科、外来小児科  
Epiduo : adapalene and benzoyl peroxide  
Topical treatment of acne vulgaris in patients 12 years of age and older
85. 栄養消化器肝臓  
PegIntron : Peginterferon alfa-2b  
Co-administered with ritonavir to treat chronic hepatitis C in patients 3 years of age and older with compensated liver disease previously untreated with interferon alpha
86. 内分泌（安全性と有効性は確立していない）  
Arimidex : anastrozole  
Male pubertal patients with gynecomastia and female pediatric patients with McCune-Albright syndrome with progressive precocious
87. 腫瘍（安全性と有効性は確立していない）  
Neulasta : Pefilgrastim  
Sarcoma
88. 栄養消化器肝臓  
Prevacid : lansoprazole  
Symptomatic GERD in infants
89. 内分泌、糖尿病  
Apidra : insulin glulisine recombinant  
Diabetes Mellitus
90. 皮膚科  
Acanya Gel : clindamycin/benzoyl peroxide combination  
Acne vulgaris in patients 12 years of age and older
91. 神経、外来小児科（片頭痛：安全性と有効性は確立していない）  
Zomig Nasal Spray : zolmitriptan  
Migraine
92. 血液（血友病）添付文書追加情報
93. 感染症  
Zmax Oral Susp : azithromycin  
Community-Acquired Pneumonia
94. 眼科  
Akten Ophthalmic gel 3.5% : lidocaine hydrochloride  
Ocular surface anesthesia during ophthalmologic procedures
95. 感染症  
Videx EC : didanosine  
HIV infection in Labeling
96. 感染症  
Retrovir syrup, capsules and tablets : zidovudine
97. 耳鼻科、アレルギー

Nasacort AQ : triamcinolone

Treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older

98. 添付文書追加情報

GARDASIL : Human Papillomavirus Quadrivalent (Types 6, 11,  
Prevention of vulvar and vaginal cancer caused by HPV

99. 感染症

Valtrex : valacyclovir

Chickenpox; active or at risk for herpes virus infection

100. 麻酔科

Zemuron : rocuronium

Adjunct to general anesthesia

101. 精神、安全性と有効性は確立していない

Zyprexa : olanzapine

schizophrenia; bipolar disorder

102. 感染症

Candidas : caspofungin

Empirical therapy for presumed fungal infections in febrile, neutropenic patients;

Candidemia and certain Candida infections; Esophageal Candidiasis;

103. 眼科

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

104. アレルギー、呼吸器

Flovent HFA:fluticasone propionate

Asthma in < 4 years

105. 栄養消化器肝臓

Aciphex : rabeprazole

Gastroesophageal reflux in adolescent patients 12 years of age and above

106. ワクチン、添付文書追加情報

KINRIX

Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine

107. 感染症

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

108. 感染症

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

109. 感染症

Kaletra : lopinavir/ ritonavir

Use in combination with other antiretroviral agents for HIV-1 infection

110. ワクチン、添付文書追加情報

Pentacel

Diphtheria And Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and

Haemophilus B  
Conjugate (Tetanus Toxoid Conjugate) Vaccine

111. 内分泌 (家族性高コレステロール血症)  
Zetia and Vytorin : ezetimibe and ezetimibe/ simvastatin  
Heterozygous familial hypercholesterolemia as an adjunct to diet

112. 麻酔、口腔外科  
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

113. 腎臓  
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)

114. 感染症  
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 : evofloxacin, levofloxacin in 5% dextrose injection  
Reduce the incidence or progression of disease following exposure to aerosolized Bacillus anthracis  
(inhalational anthrax post-exposure)

115. 血液、安全性、有効性は確立していない  
Argatroban : argatroban  
Heparin-Induced Thrombocytopenia (HIT) or HIT with Thrombosis

116. 循環器、放射線科 (安全性と有効性は確立していない)  
Cardiolite : technetium tc99m sestamibi  
Medical imaging in Kawasaki disease

117. 耳鼻科、アレルギー  
Patanase Nasal Spray : olopatadine hydrochloride  
Relief of  
symptoms of seasonal allergic rhinitis (SAR) in patients below 12 years not established

118. 小児リュウマチ  
Orencia : abatacept  
Moderate to severe polyarticular juvenile idiopathic arthritis

119. ワクチン、添付文書追加記載  
Rotavirus Vaccine, Live, Oral  
Prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9)

120. OTC皮膚科  
Lancome UV : avobenzone,  
Sunscreen

121. アレルギー、呼吸器  
Ventolin HFA : albuterol  
Treatment of symptoms of bronchospasm associated with obstructive airway disease

122. 感染症  
Reyataz : atazanavir  
HIV in 6 years and older

123. 精神、有効性が確立していない  
Depakote ER、Depakote Sprinkles : divalproex disodium  
Pediatric Bipolar Disorder; Prophylaxis of Migraine
124. 栄養消化器肝臓  
Prilosec : omeprazole  
Maintenance healing of erosive esophagitis
125. 内分泌、小児適応なし  
Zometa : zoledronic acid  
Severe osteogenesis imperfecta
126. 皮膚科、添付文書追加情報  
ARTISS : Fibrin Sealant (Human)  
To adhere autologous skin grafts to surgically prepared wound beds resulting from burns
127. 内分泌 (糖尿病)  
NovoLog : insulin aspart [rDNA origin] injection : Insulin analog  
indicated to improve glycemic control
128. ワクチン、添付文書追加情報  
DAPTACEL  
Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed
129. 精神  
Abilify : aripiprazole  
Bipolar I Disorder  
Extended treatment of acute Bipolar  
Disorder indication from adults to pediatrics 10-17 years
130. 栄養消化器肝臓  
Nexium : esomeprazole  
Short-term treatment of GERD
131. リューマチ (承認済み?)  
Humira : adalimumab  
Treatment of juvenile idiopathic arthritis
132. アレルギー、呼吸器  
Asmanex Twisthaler 110mcg inhalation powder : mometasone furoate  
Maintenance treatment of asthma as prophylactic therapy in children 4 years of age and older
133. 循環器、腎臓 : 有効性は証明されていない  
Inspra : eplerenone  
Hypertension
134. アレルギー、耳鼻科、皮膚科  
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)
135. 感染症 : 有効性は証明されていない  
Moxatag : amoxicillin  
Use for tonsillitis and/or pharyngitis secondary to Streptococcus pyogenes patients 12 years of age and  
older
136. 感染症 : 安全性情報の追加



TamiFlu : oseltamivir

137. アレルギー、呼吸器

Alvesco Inhalation Aerosol, 80 mcg & 160 mcg : ciclesonide  
Treatment of asthma in patients 12 years of age and older.

138. 外科、添付文書追加情報

EVICEL : Fibrin Sealant (Human)

Adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques is ineffective or

139. 内分泌、安全性と有効性は確立していない

AndroGel : testosterone

Use in adolescent boys with delayed puberty

140. 添付文書追加情報（救急、集中治療）

Voluven : 6% Hydroxyethyl Starch 130/0.4 In 0.9% Sodium Chloride Injection

Plasma volume substitute for treatment and prophylaxis of hypovolemia

141. 栄養消化器肝臓

Hepsera : adefovir dipivoxil

Chronic hepatitis B virus infection

142. 皮膚科、アレルギー

Derma-Smoothe/FS Topical Oil : fluocinolone

Treatment of atopic dermatitis in pediatric patients 3 months and older for up to 4 weeks.

143. 眼科（硝子体切除）

Triesence 40mg/mL : triamcinolone acetonide injectable suspension

Visualization during vitrectomy

144. 腎臓、循環器（高血圧）

Diovan : valsartan

Hypertension

145. 耳鼻科、アレルギー

Omnaris Nasal Spray : ciclesonide

Treatment of seasonal allergic rhinitis (SAR) in patients 6 through less than 12 years of age

146. 感染症

Kaletra Oral Solution, 80 mg/20 mg & Kaletra (lopinavir/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.

147. 眼科（緑内障、眼圧上昇）

Combigan 0.2%/0.5% ophthalmic solution : brimonidine tartrate/timolol maleate

Reduction of elevated intraocular pressure in patients with glaucoma or ocular hypertension

148. 精神

Abilify : aripiprazole

Schizophrenia

149. 皮膚科、感染症

Lamisil : terbinafine

Tinea capitis

150. 内分泌

Norditropin Cartridges : somatropin [rDNA origin]  
Treatment of short stature in children with Turner syndrome

151. 感染症、小児適応なし  
Levaquin : levofloxacin  
Community-acquired pneumonia

153. 精神、神経、心身症：小児適応なし  
Provigil : modafinil  
Narcolepsy

152. 精神  
Risperdal : risperidone  
Schizophrenia; short-term treatment of acute manic or mixed Episodes associated with Bipolar I Disorder

154. 静脈穿刺前麻酔  
Zingo : lidocaine  
Topical local analgesia prior to venipuncture or peripheral intravenous cannulation in children 3-18 years of age

155. 腎臓、循環器  
Toprol XL : metoprolol  
Hypertension

156. 感染症  
Lexiva Oral Suspension : fosamprenavir  
Treatment of HIV infection in patients 2-18 years of age

157. 皮膚科  
Extina Foam, 2% : ketoconazole  
Topical treatment of seborrheic dermatitis in immunocompetent patients 12 years of age and older

158. 眼科（眼圧上昇、緑内障）  
Betoptic S : betaxolol  
Elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension

159. 眼科（眼圧上昇、緑内障）  
Timolol GFS : timolol  
Elevated intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension

160. アレルギー、呼吸器  
Zyflo CR Extended Release Tablets : zileuton  
Prevention and chronic treatment of asthma in children 12 years of age and older

161. 耳鼻科、皮膚科、アレルギー  
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 skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age or older

162. 皮膚科、アレルギー  
Locoid Lotion 0.1% : hydrocortisone butyrate  
Treatment of mild to moderate atopic dermatitis in children 3 months of age and older

163. 眼科、感染症  
Azasite Ophthalmic Solution 1% azithromycin

Treatment of bacterial conjunctivitis caused by certain microorganisms in patients down to 1 year of age

165. 皮膚科、感染症

Altanax Ointment 1% : retapamulin

Treatment of impetigo in patients 9 months of age and older

166. 精神、神経、心身症：安全性、有効性は確立していない

Ambien : zolpidem

Insomnia associated with ADHD

167. 皮膚科、外来小児科（伝染性軟属腫）

Aldara : imiquimod

Molluscum contagiosum

168. 神経（治験中？）

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

169. 循環器。有効性は確立していない

Coreg : carvedilol

Heart failure

170. 精神、神経、心身症

Vyvanse Capsules : lisdexamfetamine

Treatment of ADHD in children 6 to 12 years of age

171. 麻酔、安全性と有効性は確立していない

Actiq : fentanyl

Treatment of breakthrough pain in opioid tolerant children

172. 血液、腫瘍、有効性は確立していない

Eloxatin : oxaliplatin

Solid tumors

173. 感染症

Emtriva : emtricitabine

HIV-1 infection in combination with other antiretroviral agents

174. 栄養消化器肝臓

Colazal : balsalazide

Mildly to moderately active ulcerative colitis in patients 5 years of age and older

175. リューマチ

Celebrex : celecoxib

Relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA)

176. 麻酔（非挿管患者の麻酔維持の適応はない）

Suprane : desflurane

Safety study of 2 agents used for maintenance of anesthesia in non-intubated patients

177. 皮膚科

Ziana Gel : clindamycin tretinoin

Treatment of acne vulgaris in patients 12 years of age and older

178. 内分泌

Humatrope for injection : somatropin [rDNA origin]

Treatment of short stature or growth failure in children with short stature homeobox-containing gene

(SHOX) deficiency

179. 皮膚科、アレルギー

Desonate Gel : desonide

Treatment of mild to moderate atopic dermatitis in children 3 months of age and older

180. OTC, アレルギー、眼科

Zaditor ophthalmic solution : ketotifen

Temporary relief of itchy eyes in children 3 years of age and older

181. 眼科、皮膚科、アレルギー

Allegra : fexofenadine 新しいサスペンション

Seasonal allergic rhinitis (SAR) uncomplicated skin manifestations of chronic idiopathic urticaria (CIU)

182. 内分泌

Tirosint capsules : levothyroxine

Replacement or supplemental therapy in hypothyroidism; treatment or prevention of euthyroid goiters

183. 精神、神経、心身症

Risperdal Tablets Risperdal Oral Solution Risperdal M-Tabs : risperidone\*

Treatment of irritability associated with autistic disorder in children 5 years of age and older

184. OTC, 皮膚科

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

185. OTC, 外科

DuraPrep Surgical Solution#

iodine; isopropyl alcohol

Preoperative skin preparation for use in children 2 months of age and older

186. 感染症

Fuzeon : enfuvirtide

HIV-1 infection treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy

187. 眼科、有効性は証明されていない

Azopt ophthalmic suspension : brinzolamide

Elevated intraocular pressure

188. 眼科、眼圧上昇

Betaxon ophthalmic suspension : levobetaxolol

Elevated intraocular pressure

189. 血液、腫瘍

Gleevec : imatinib mesylate

Treatment of newly diagnosed pediatric patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase

190. 神経

Lamictal Tablets Lamictal Chewable Dispersible Tablets : lamotrigine\*

Adjunctive therapy for primary generalized tonic-clonic seizures in children 2 years of age and older

191. 皮膚科、アレルギー

Verdeso Foam : desonide

Treatment of mild to moderate atopic dermatitis in patients 3 months of age and older of age