

Current FDA-Related Drug Information

New Drugs Approved by the FDA New Dosage Forms and Indications Agents Pending FDA Approval Labeling Changes Related to Safety

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This monthly feature will help readers keep current on new drugs, new indications and dosage forms, and safety-related changes in labeling or use. Each month, new information will be added to the table (shown in bold type) and older information will be removed. Efforts have been made to ensure the accuracy of the information; however, if there are any questions, let us know at hospitalpharmacy@drugfacts.com.

TABLE 1. NEW DRUGS APPROVED BY THE FDA: DECEMBER 1, 2001–MARCH 24, 2002

Generic Name	Brand Name (Company)	Indication	Dosage Form and Strength (Date of Approval)	Product Information Web Site
Newly Approved Agents				
Interferon-beta-1A	Rebif (Serono)	Treatment of patients with relapsing forms of multiple sclerosis to decrease the frequency of clinical exacerbations and delay the accumulation of physical disability	Injection (3/02)	http://www.rebif.com/
Levonorgestrel/ethinyl estradiol	Lessina (Barr Laboratories)	Oral contraceptive for the prevention of pregnancy; generic equivalent of Levlite	Tablet 0.1 mg/0.02 mg (3/02)	*
Morphine sulfate extended-release	Avinza (Elan Corporation)	Treatment of chronic, moderate-to-severe pain in patients who require continuous, around-the-clock therapy for an extended period of time	Capsule 30, 60, 90, and 120 mg (3/02)	*
Desloratadine	Clarinx (Schering-Plough)	Treatment of allergies in adults and children 12 years of age	Tablet 5 mg (12/01)	http://www.clarinex.com/
*URL not available at time of publication				(continued)

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Generic Name	Brand Name (Company)	Indication	Dosage Form and Strength (Date of Approval)	Product Information Web Site
Newly Approved Agents (continued)				
Dutasteride	Duagen (Glaxo-SmithKline)	Treatment of benign prostatic hyperplasia	Capsule 0.5 mg 12/01	http://www.fda.gov/cder/foi/nda/2001/21319_Duagen_prntlbl.pdf
Fondaparinux sodium	Arixtra (Organon/Sanofi-Synthelabo)	Prophylaxis of thrombosis, pulmonary emboli, and arterial thrombosis	Injection 2.5 mg (12/01)	http://www.fda.gov/cder/foi/nda/2001/21-345_arixtra_prntlbl.pdf
Hydroxy-amphetamine Hydrobromide/Tropicide	Paremyd (Akorn)	Pupil dilation in routine ophthalmic diagnostic procedures and eye exams	Ophthalmic Drops 1%/0.25% (1/02)	*
Ibritumomab tiuxetan	Zevalin (IDEC Pharmaceuticals)	Treatment of low grade, follicular, CD20-positive transformed, relapsed or refractory, B-cell non-Hodgkin's lymphoma (NHL) and rituximab-refractory follicular NHL	Injection 3.2 mg (2/02)	www.idecpharm.com/site/science/zevalin_pi.pdf
Niacin extended-release/lovastatin	Advicor (Kos Pharmaceuticals)	Treatment of hyperlipidemia	Tablet (Niacin extended-release/lovastatin): 500 mg/20 mg; 750 mg/20 mg; 1000 mg/20 mg (12/01)	http://www.advicor.com/extended release
Nitisinone	Orfadin (Swedish Orphan International/Rare Disease Therapeutics)	Treatment of hereditary tyrosinemia type I (HT-1), a rare pediatric disease causing progressive liver failure and liver cancer	† (1/02)	*
Pegfilgrastim	Neulasta (Amgen)	Decrease the incidence of infection in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with clinically significant incidence of febrile neutropenia	Injection 6 mg (1/02)	www.neulasta.com
Pimecrolimus	Elidel (Novartis)	Treatment of mild to moderate atopic dermatitis (eczema) in patients 2 years of age	Cream 1% (12/01)	http://www.elidel.com/
*URL not available at time of publication				
†Dosage form and strength not available at time of publication				

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**TABLE 2. NEW DOSAGE FORMS AND INDICATIONS APPROVED BY THE FDA:
JANUARY 1–MARCH 24, 2002**

<i>Generic Name</i>	<i>Brand Name (Company)</i>	<i>Indication</i>	<i>Dosage Form (Date)</i>
New Dosage Forms			
Mometasone	Nasonex (Schering Laboratories)	Dosage counter nasal spray device	Nasal spray (2/02)
Efavirenz	Sustiva (Bristol-Myers Squibb)	600 mg tablet for once daily administration	Tablet (2/02)
Interferon-beta-1b	Betaseron (Berlex Laboratories)	Room-temperature formulation	Injection (1/02)
Lansoprazole	Prevacid (TAP Pharmaceuticals)	Delayed-release powder for oral suspension (15 and 30 mg)	Packet (1/02)
Leuprolide acetate	Eligard 7.5 mg (Atrix Laboratories)	SC injection for treatment of advanced prostate cancer (formerly known as Leuprogel One-Month Depot)	Injection (1/02)
Pravastatin sodium	Pravachol (Bristol-Myers Squibb)	80 mg dosage strength	Tablet (2/02)
New Indications			
Clopidogrel	Plavix (Sanofi-Synthelabo/ Bristol-Myers Squibb)	Treatment of acute coronary syndrome	Tablet (2/02)
Infliximab	Remicade (Centcor)	Improve physical function in people with rheumatoid arthritis in conjunction with methotrexate therapy.	Injection (2/02)
Risperidone	Risperdal (Johnson & Johnson)	Longer-term efficacy for risperidone in the treatment of schizophrenia	Tablet (3/02)
Desloratadine	Clarinx (Schering-Plough)	Treatment of chronic idiopathic urticaria	Tablet (2/02)
Etanercept	Enbrel (Immunex)	Treatment of psoriatic arthritis including use with or without methotrexate	Injection (1/02)
Imatinib mesylate	Gleevec (Novartis)	Treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumors	Capsule (2/02)
Rabeprazole	Aciphex (Janssen Pharmaceutica)	Treatment of daytime and nighttime heartburn and other symptoms associated with GERD	Tablet (2/02)
Zoledronic acid	Zometa (Novartis)	Treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors in conjunction with standard antineoplastic therapy	Injection (2/02)

TABLE 3. AGENTS PENDING FDA APPROVAL

<i>Generic Name</i>	<i>Brand Name (Company)</i>	<i>Indication/ Comment</i>	<i>Date</i>
Approvable Agents			
Paroxetine mesylate	Asimia (Synthon Pharmaceuticals)	Treatment of depression and obsessive–compulsive and panic disorders.	3/02
AF0150	Imavist (Alliance Pharmaceutical)	Ultrasound contrast agent	8/01
Alfuzosin	UroXatral (SkyePharma)	Symptomatic treatment of benign prostatic hyperplasia	10/01
Escitalopram	Lexapro (Forest Laboratories)	Treatment of major depressive disorder	1/02
Flunisolide	Aerospan (Forest Laboratories)	Hydrofluoroalkane-formulated inhaled corticosteroid utilizing a non-CFC propellant and built-in spacer for treatment of asthma	5/01
Latanoprost/timolol	Xalcom (Pharmacia)	Reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers, prostaglandins, or other IOP-lowering medications	6/00
Lovastatin	Altacor (Andrx Group)	Controlled-release lovastatin for the treatment of hyperlipidemia	1/02
Oxybate, sodium	Xyrem (Orphan Medical)	Treatment of cataplexy related to narcolepsy	7/01
Pramlintide acetate	Symlin (Amylin Pharmaceuticals)	Treatment of people with type I or type II diabetes mellitus who require insulin therapy	10/01
Tibolone	Xyvion (Akzo Nobel)	Treatment of osteoporosis	4/01
Treprostinol sodium	Remodulin (United Therapeutics Corp.)	Treatment of pulmonary hypertension	2/02
Valsartan	Diovan (Novartis)	Treatment of heart failure	10/01
Ziconotide	(Elan)	Treatment of chronic pain	6/00
Recommended for Approval by an FDA Advisory Panel or the FDA			
Icodextrin	Extraneal (Baxter)	Peritoneal dialysis solution	8/01
Olanzapine	Zyprexa (Eli Lilly)	Injectable for the treatment of patients with schizophrenia, bipolar disorder, and dementia	2/01
Telithromycin	Ketek (Aventis Pharmaceuticals)	Treatment of community-acquired pneumonia in patients 18 years of age	4/01
Teriparatide	Forteo (Eli Lilly & Co.)	Treatment of osteoporosis in postmenopausal women	7/01
			<i>(continued)</i>

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Recommended for Approval by an FDA Advisory Panel or the FDA (continued)			
Voriconazole	Vfend, Vfend IV (Pfizer)	Treatment of invasive aspergillosis, serious Candida infections, infections caused by <i>Scedosporium</i> spp. and <i>Fusarium</i> spp, rare and refractory infections, and empirical treatment of febrile neutropenia	10/01
Ziprasidone	Geodon (Pfizer)	Injectable for acute control and short-term management of agitated psychotic patients	2/01
Agents Not Recommended for Approval by an FDA Advisory Panel or the FDA			
Iodine I 131 tositumomab	Bexxar (Corixa)	Treatment of low-grade B-cell non-Hodgkin's lymphoma	3/02
Pleconaril	Picovir (ViroPharma)	Treatment of viral respiratory infection in adults	3/02
Tecastemizole	Soltara (Sepracor)	Treatment of allergic rhinitis	3/02
Cisplatin/ epinephrine	IntraDose Injectable Gel (Matrix Pharmaceutical)	Treatment of refractory or recurrent head and neck cancer	11/01
Irbesartan	Avapro (Bristol-Myers)	Prevention of the progression of kidney disease in patients with hypertension and type 2 diabetes	1/02
Oxybutynin	Oxytrol (Watson Pharmaceuticals)	Transdermal system for the treatment of overactive bladder	3/02
Agents Scheduled for Review by an FDA Advisory Panel			
Alosetron	Lotrenox (GlaxoSmithKline)	Treatment of irritable bowel syndrome	4/02
Losartan potassium	Cozaar (Merck)	Treatment of type II diabetic patients with nephropathy	4/02
New Drug or Supplemental Applications Filed by Manufacturer			
Anastrozole 3/02	Arimidex (AstraZeneca)	Treatment of early breast cancer in postmenopausal women	
Ciprofloxacin	Cipro (Bayer)	Once-daily modified release tablet formulation	3/02
Clobetasol propionate	Olux (Connetics Corporation)	Treatment of dermatoses of non-scalp areas	3/02
Etoricoxib	Arocoxia (Merck)	Treatment of arthritis and pain (application withdrawn 3/02 to allow for a resubmission with a broader list of indications)	10/01 (3/02)

(continued)

TABLE 3. AGENTS PENDING FDA APPROVAL CONTINUED

<i>Generic Name</i>	<i>Brand Name (Company)</i>	<i>Indication/ Comment</i>	<i>Date</i>
New Drug or Supplemental Applications Filed by Manufacturer (continued)			
Loratadine	Claritin (Schering-Plough)	All indications and formulations for conversion to otc status	3/02
Testosterone	Testim (Auxilium Pharmaceuticals)	Gel for the treatment of low testosterone levels in males	3/02
17-beta-estradiol	Estrasorb (Novavax)	Topical estrogen replacement therapy (lotion using micellar nanoparticle technology) for symptomatic menopausal women	6/01
Acamprosate	(Forest Laboratories)	Treatment of alcohol dependence	2/02
Aripiprazole	Abilitat (Bristol-Myers Squibb/Otsuka)	Treatment of schizophrenia and related disorders	10/01
Atomoxetine	(Lilly)	Treatment of ADHD	11/01
Bicalutamide	Casodex (AstraZeneca)	Treatment of early stage nonmetastatic prostate cancer	12/01
Duloxetine	(Lilly)	Treatment of depression	12/02
Eplerenone	(Pharmacia)	Treatment of hypertension	2/02
Eprosartan/ Hydrochlorothiazide	Teveten/HCTZ (Unimed Pharmaceuticals)	Treatment of hypertension	10/00
Estradiol	Estrace (Galen)	Intravaginal ring for estrogen replacement therapy	12/01
Ezetimibe	Zetia (Merck & Schering-Plough)	Treatment of lipid disorders	12/01
Fulvestrant	Faslodex (AstraZeneca)	Treatment of advanced breast cancer	3/01
Lansoprazole	Prevacid (TAP)	Pediatric use application for the treatment of GERD in children aged 1 to 11.	2/02
Lercanidipine	Zanidip (Forest Laboratories)	Treatment of hypertension	10/01
Levothyroxine sodium	Synthroid (Abbott)	Treatment of hypothyroidism	4/01
Meropenem	Merrem I.V. (AstraZeneca)	Treatment of hospital- and community-acquired pneumonia	6/01
Nitroglycerin	Anogesic (Cellegy Pharmaceuticals)	Ointment for the treatment of pain associated with chronic anal fissures	6/01
			<i>(continued)</i>

TABLE 3. AGENTS PENDING FDA APPROVAL CONTINUED

<i>Generic Name</i>	<i>Brand Name (Company)</i>	<i>Indication</i>	<i>Date</i>
New Drug or Supplemental Applications Filed by Manufacturer (continued)			
Olmesartan medoxomil	Benicar (Sankyo Pharmac/ Forest Laboratories)	Treatment of hypertension	12/01
Omapatrilat	Vanlev (Bristol-Myers Squibb)	Treatment of hypertension	12/01
OSI-774	Iressa (AstraZeneca)	Treatment of lung cancer	12/01
Rifaximin	Lumenax (Salix Pharmaceuticals)	Treatment of traveler's diarrhea	12/01
Risperidone	Risperdal Consta (Janssen Pharmaceuticals)	Long-acting injectable formulation	9/01
Ropivacaine	Naropin (AstraZeneca)	Regional anesthesia in pediatric patients	12/00
Rosuvastatin calcium	Crestor (AstraZeneca)	HMGCoA reductase inhibitor for the treatment of various lipid disorders	6/01
Selegiline	EMSAM (Somerset Pharmaceuticals)	Transdermal system for the treatment of depression	5/01
Tadalafil	Cialis (Lilly ICOS)	Treatment of erectile dysfunction	6/01
Tiotropium	Spiriva (Boehringer Ingelheim)	Treatment of patients with chronic obstructive pulmonary disease	12/01
Vardenafil	(Bayer)	Treatment of erectile dysfunction	9/01
Voriconazole	Vfend (Pfizer)	Treatment of serious fungal infections	12/00
Zolmitriptan	Zomig (AstraZeneca)	Nasal spray formulation for the treatment of migraine headaches	2/02
Zolpidem	(Biovail Corp.)	Treatment of insomnia using a melt-in-the-mouth formulation (FlashDose)	12/01

TABLE 4. LABELING CHANGES OR “DEAR HEALTH PROFESSIONAL LETTERS” RELATED TO SAFETY

<i>Generic Name Brand Name (Company)</i>	<i>Warning</i>	<i>Web Site</i>
Interferon alfa 2b, recombinant Intron A (Schering) Ribavirin, USP Capsules and Intron A Rebetron Combination Therapy (Schering) Interferon alfa-2a, recombinant Roferon-A (Roche)	A boxed warning has been added to all the alfa interferon products regarding the occurrence of neuropsychiatric, autoimmune, ischemic, and infectious disorders in patients taking alpha-interferons; additional safety information and direction for patient monitoring has also been added to the warnings section of the prescribing information.	http://www.fda.gov/medwatch/safety/2002/safety02.htm#intron
Kava	Potential risk of severe liver injury associated with the use of kava-containing dietary supplements	http://www.cfsan.fda.gov/%7Edms/ds-ltr29.html

TABLE 5. DEFINITIONS OF CLASSIFICATIONS

Approved agents	Agents that have been approved by the FDA for marketing in the United States.
New dosage form	Agents previously approved by the FDA for which a new dosage form or delivery system has been approved.
New indications	Agents previously approved by the FDA that have now received approval for a new indication.
Approvable agent	The FDA has granted these agents an approvable letter. Generally, an approvable letter is granted when the drug has met the requirements of the FDA for safety and effectiveness, but details need to be worked out regarding the product labeling, manufacturing, or postmarketing surveillance.
Recommended for approval	An FDA Advisory Panel has recommended this product for approval for marketing in the United States. However, this is not the final approval of the medicinal agent nor is the FDA obligated to follow the recommendations of the Advisory Panel.
Agents scheduled for review by an FDA Advisory Panel	A new drug application (NDA) has been filed for this agent. It is scheduled for review by an FDA Advisory Panel to make a recommendation on whether the product should be approved for marketing in the United States.
Agents withdrawn from the market	Agents that have been voluntarily or involuntarily withdrawn from the market by the manufacturer because of safety concerns or other reasons.