

Selected Biotechnology and Biotech-Related FDA Approvals, 2004*

New Products

Product	Company	Indication	Approval Date
Avastin™ (bevacizumab)	Genentech	First-line treatment of metastatic colorectal cancer, in combination with 5-fluorouracil-based chemotherapy	2/26/04
Captique™ Injectable Gel (non-animal stabilized hyaluronic acid)	Genzyme Corp. and Inamed Corp.	Facial wrinkle correction	11/12/04
CLOLAR™ (clofarabine)	Genzyme Corp.	Refractory or relapsed acute lymphoblastic leukemia in children	12/24/04
Codeprex™ Extended-Release Suspension CIII (codeine polistirex/ chlorpheniramine polistirex)	Celltech Group plc	Cough relief; 12-hour dosing	6/21/04
DepoDur™ (morphine sulfate extended- release liposome injection)	Endo Pharmaceuti- cals Inc. and SkyePharma plc	Pain following major surgery	5/18/04
ERBITUX™ (cetuximab)	ImClone Systems Inc. and Bristol- Myers Squibb	Combination treatment with irinotecan for metastatic colorectal cancer that is refractory to irinotecan alone and that expresses the epidermal growth factor receptor; for use as a single agent in patients intolerant of irinotecan and whose cancer expresses EGFR	2/12/04
Evoclin™ (clindamycin) Foam, 1%	Connetics Corp.	Acne vulgaris	10/22/04

(formerly
Actiza™)

FOSRENOL	AnorMED Inc. and Shire Pharmaceu- ticals Group	Reduction of blood phosphate levels in patients undergoing kidney dialysis	10/26/04
Hylaform® (Hylan-B gel)	Genzyme Corp. and Inamed Corp.	Correction of moderate to severe facial wrinkles and folds (such as nasolabial folds)	4/22/04
Hylaform® Plus (Hylan-B gel; large-particle size hyaluronic acid- based dermal filler)	Genzyme Corp. and Inamed Corp.	Correction of moderate to severe facial wrinkles and folds	10/13/04
ISTOLOL™ (timolol)	ISTA Pharmaceu- ticals and Senju Pharmaceutical Co.	Glaucoma	6/4/04
Kepivance™ (palifermin)	Amgen	Severe oral mucositis in cancer patients with hematologic blood cancers undergoing high-dose chemotherapy, with or without radiation, followed by a bone marrow transplant	12/15/04
LUNESTA™ (eszopiclone; formerly Estorra)	Sepracor Inc.	Insomnia	12/15/04
Luveris® (lutropin alfa for injection)	Serono	For concomitant use with Gonal-f® (foliotropin alfa for injection) for stimulation of follicular devel- opment in infertile hypogonadotropic hypogonadal women with profound luteinizing hormone deficiency	10/8/04
Macugen® (pegaptanib sodium injection)	Eyetech Pharmaceuticals Inc. and Pfizer***	Neovascular (wet) age-related macular degeneration	12/17/04
Metvixia (methyl	PhotoCure ASA and Galderma SA	Photodynamic treatment of actinic keratosis	7/27/04

aminoleyulinate;
developed under
the trade name
Metvix®)

NeuroSpec™ (Technetium [99m Tc] fanolesomab; formerly LeuTech®)	Palatin Technologies and Mallinckrodt Imaging (Tyco Healthcare)	Diagnosis of appendicitis in patients with equivocal signs	7/2/04
Nuflexxa™ (1% sodium hyaluronate)	Savient Pharmaceuticals Inc.	Pain associated with osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics	12/7/04**
ORTHOVISC® (high molecular weight hyaluronon)	Anika Therapeutics Inc. and Ortho Biotech Products LP	Pain in patients suffering from osteoarthritis of the knee who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics	2/4/04
PRIALT® (ziconotide intrathecal infusion)	Elan Corp. plc	Management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or IT morphine	12/28/04
SANCTURA™ (trospium chloride)	Indevus Pharmaceuticals Inc. and Odyssey Pharmaceuticals Inc. (subsidiary of PLIVA)	Overactive bladder with symptoms of urge urinary incontinence, urgency and urinary frequency	5/28/04
Sensipar® (cinacalcet HCl)	NPS Pharmaceuticals Inc. and Amgen	Secondary hyperparathyroidism in chronic kidney disease patients on dialysis and for the treatment of elevated calcium levels (hypercalcemia) in patients with parathyroid carcinoma	3/8/04
Tarceva™ (erlotinib)	OSI Pharmaceuticals Inc. and Genentech	Locally advanced or metastatic non-small-cell lung cancer after failure of at least one prior chemotherapy	11/18/04

regimen

Taxus™ Express2™ (paclitaxel- eluting coronary stent)	Angiotech Pharmaceuticals Inc. and Boston Scientific Corp.	Improving luminal diameter in native coronary arteries for treatment of de novo lesions	3/4/04
Truvada™ (emtricitabine and tenofovir disoproxil fumarate)	Gilead Sciences	HIV (as part of combination therapy)	8/2/04
TYSABRI® (natalizumab; formerly ANTEGREN®)	Biogen Idec and Elan Corp.	Reduction of clinical relapse frequency in relapsing forms of multiple sclerosis	11/23/04
Ventavis™ (iloprost) Inhalation Solution	CoTherix Inc. and Schering AG	Pulmonary arterial hypertension in patients with NYHA Class III or IV symptoms	12/29/04
Vidaza™ (azacitidine)	Pharmion Corp.	Myelodysplastic syndromes (all five subtypes)	5/19/04
Vitrase® (hyaluronidase for injection; lyo- philized, ovine)	ISTA Pharmaceuticals Inc.	Spreading agent to facilitate dispersion and absorption of other drugs	5/5/04
XIFAXAN™ (rifaximin)	Salix Pharmaceuticals Ltd.	Travelers' diarrhea caused by noninvasive strains of E. coli in patients 12 years of age and older	5/25/04
ZEGERID™ (omeprazole powder for oral suspension)	Santarus Inc.	20 mg dose approved for short-term treatment of active duodenal ulcer, for heartburn and other symptoms associated with gastro-esophageal reflux disease (GERD), for the short-term treatment of erosive esophagitis that has been diagnosed by endoscopy, and for the maintenance of healing of erosive esophagitis; 40 mg formulation subse- quently approved for reduction of risk of upper GI bleeding in critically ill	6/15/04; 12/22/04**

patients and the short-term treatment of benign gastric ulcers

Zylet™ (loteprednol etabonate and tobramycin ophthalmic suspension)	Pharmos Corp. and Bausch & Lomb	Steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of infection exists	12/14/04
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New Indications

BOTOX® (botulinum toxin type A)	Allergan	Primary axillary hyperhidrosis inadequately managed with topical agents	7/19/04
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Enbrel® (etanercept)	Amgen	New indication for the treatment of adults with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy; FDA approved new labeling allowing an indication of induction of major clinical response in patients with rheumatoid arthritis	4/30/04; 9/24/04
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Hectorol® (doxercaliferol) Capsules	Bone Care International Inc.	Additional indication of secondary hyperparathyroidism that develops in earlier stages of chronic kidney disease prior to dialysis	4/23/04
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HUMIRA® (adalimumab)	Cambridge Antibody Technology and Abbott Laboratories	Expanded indication to include improvement in physical function for adult patients with moderately to severely active RA	7/30/04
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INFUSE® Bone Graft (recombinant human bone morphogenetic protein-2/ absorbable collagen sponge)	Wyeth and Medtronic Sofamor Danek	Acute, open tibia shaft fractures in adults	4/30/04
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PROVIGIL® (modafinil) Tablets	Cephalon Inc.	Excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome and and shift-work sleep disorder	1/23/04
REMICADE® (infliximab)	Centocor (subsidiary of Johnson & Johnson)	FDA approved expanded label for Remicade in combination with methotrexate as first-line regimen in patients with moderate to severe rheumatoid arthritis	9/29/04
Saizen® (somatropin)	Serono	Replacement of endogenous growth hormone in adults with growth hormone deficiency	8/26/04

Other FDA Approvals of Interest

Campath® (alemtuzumab)	Genzyme Corp. and Belex Inc. (unit of Schering AG)	FDA approved single-use vial (drug is used for chronic B-cell lymphocytic leukemia in patients who have been treated with alkylating agents and who have failed fludarabine therapy)	10/18/04**
Eligard 45 mg (leuprolide)	QLT Inc. and Sanofi-Aventis Group	Six-month sustained release formulation (drug is used for palliative treatment of advanced prostate cancer)	12/14/04
Enbrel® (etanercept)	Amgen	Updated radiographic data demonstrating more than half of Enbrel patients in an open-label, long-term study experienced no progression of joint damage for up to five years; new 50 mg/ml prefilled syringe for use in all approved adult indications	9/24/04; 9/27/04
FUZEON® (enfuvirtide)	Trimeris Inc. and Roche	Product granted traditional approval (HIV drug previously granted accelerated approval in March 2003)	10/15/04
Gonal-f® RFF Pen (follitropin alfa injection)	Serono Inc.	FDA approved prefilled device (drug is used for infertility)	5/25/04

Norditropin Nordiflex® (somatropin [rDNA] injection)	Novo Nordisk A/S	Prefilled pen (treats adults with growth hormone deficiency)	10/1/04
Pegasys® (peginterferon alfa-2a)	Nektar Therapeutics Inc. and Roche	Prefilled syringes approved for treatment of chronic hepatitis C	1/8/04**
Rebif® Titration Pack (interferon beta-1a)	Serono Inc.	New-patient dosing of multiple sclerosis drug	12/22/04
Remodulin® (treprostinil sodium) Injection	United Therapeutics Corp.	FDA approved intravenous use of pulmonary arterial hypertension drug	11/24/04
Renagel® (sevelamer hydrochloride)	Genzyme Corp.	FDA approved new labeling showing the product's phosphorous and calcium-phosphorous control are consistent with the National Kidney Foundation's aggressive guidelines	3/9/04
Synagis® (palivizumab)	MedImmune Inc.	FDA approved liquid formulation (drug prevents serious lower respiratory tract disease caused by respiratory syncytial virus in patients at high risk of RSV disease)	7/26/04**
Vitrase® (hyaluronidase injection) Ovine	ISTA Pharmaceuticals Inc.	FDA approved single-use vial (product is used as a spreading agent for other drugs)	12/2/04

* Note: Recombinant products and monoclonal antibodies are in bold type. This list also includes small-molecule products developed by biotechnology companies, and other selected small-molecule, biologic and device products. This list covers new approvals, selected new indications and other selected approvals (e.g., new formulations or modes of administration). For a complete listing of FDA approvals from 1996 to the present, visit the agency's Web site at www.fda.gov.

** Date of company announcement.

*** Macugen also incorporates technology from Nektar Therapeutics.