

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
1,5-(Butylimino)-1,5 dideoxy,D-glucitol TN=	Treatment of Fabry's disease.	Oxford GlycoSciences 10, The Quadrant Abington Science Park, Abington Oxfordshire OX14 3YS UK, DD=05/12/1998 MA= / /
1,5-(Butylimino)-1,5 dideoxy,D-glucitol TN=	Treatment of Gaucher disease.	Oxford GlycoSciences 10, The Quadrant Abington Science Park, Abington Oxfordshire OX14 3YS UK, DD=05/29/1998 MA= / /
111Indium pentetreotide TN= SomatoTher	Treatment of somatostatin receptor positive neuroendocrine tumors.	Louisiana State University Medical Center Foundation 1600 Canal St. 10th Floor New Orleans, LA 70112 DD=06/10/1999 MA= / /
15AU81 TN=	Treatment of pulmonary arterial hypertension.	United Therapeutics Corp. 68 T.W. Alexander Dr. P.O. Box 14186 Research Triangle Park, NC 27709 DD=06/04/1997 MA= / /
166Ho-DOTMP TN=	Treatment of multiple myeloma.	NeoRx Corporation 410 W. Harrison Seattle, WA 98119 DD=02/10/1999 MA= / /
2'-deoxycytidine TN=	As a host-protective agent in the treatment of acute myelogenous leukemia.	Grant, Steven M.D. Massey Cancer Center, VCU P.O. Box 980230 Richmond, VA 23298 DD=09/09/1996 MA= / /
2-0-desulfated heparin TN= Aeropin	Treatment of cystic fibrosis.	Kennedy & Hoidal, M.D.'s University of Utah Health Sciences Center 50 North Medical Drive, Room 4R240 Salt Lake City, UT 84132 DD=09/17/1993 MA= / /
24,25 dihydroxycholecalciferol TN=	Treatment of uremic osteodystrophy.	Lemmon Company 1510 Delp Drive Kulpsville, PA 19443 DD=02/27/1987 MA= / /
3,4-diaminopyridine TN=	Treatment of Lambert-Eaton myasthenic syndrome.	Jacobus Pharmaceutical Company 37 Cleveland Avenue P.O. Box 5290 Princeton, NJ 08540 DD=12/18/1990 MA= / /

84N-0102

15T 94

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
3-(3,5-dimethyl-1H-2ylmethyle ne)-1,3-dihydro-indol-2-one TN=	Treatment of Kaposi's sarcoma.	Sugen, Inc. 230 East Grand Ave. South San Francisco, CA 94080 DD=09/11/1998 MA= / /
4-aminosalicylic acid TN= Pamisyl (P-D), Rezipas (Squibb)	Treatment of mild to moderate ulcerative colitis in patients intolerant to sulfasalazine.	Beeken, Warren M.D. University Of Vermont Given C-317 Burlington, VT 05405 DD=12/13/1989 MA= / /
40SD02 TN=	Treatment of chronic iron overload resulting from conventional transfusional treatment of beta-thalassemia major and sickle cell anemia.	Biomedical Frontiers, Inc. 1095 10th Ave., S.E. Minneapolis, MN 55414 DD=12/21/1998 MA= / /
5,6-dihydro-5-azacytidine TN=	Treatment of malignant mesothelioma.	ILEX Oncology, Inc. 11550 IH 10 West, Suite 300 San Antonio, TX 78230 DD=05/11/1992 MA= / /
5-aza-2'-deoxycytidine TN=	Treatment of acute leukemia.	Pharmachemie U.S.A., Inc. 1510 Delp Dr. Kulpsville, PA 19443 DD=08/03/1987 MA= / /
506U78 TN=	Treatment of chronic lymphocytic leukemia.	Glaxo Wellcome, Inc. Five Moore Dr. P.O. Box 13398 Durham, NC 27709 DD=09/02/1999 MA= / /
5a8, monoclonal antibody to CD4 TN=	For use in post-exposure prophylaxis for occupational exposure to human immunodeficiency virus.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=12/20/1993 MA= / /
6-hydroxymethylacylfulvene TN=	Treatment of histologically confirmed advanced or metastatic pancreatic cancer.	MGI Pharma, Inc. 6300 West Old Shakoppe Rd. Suite 110 Bloomington, MN 55438 DD=04/06/1999 MA= / /
6-hydroxymethylacylfulvene TN=	Treatment of ovarian cancer.	MGI Pharma, Inc. 6300 West Old Shakoppe Rd. Suite 110 Bloomington, MN 55438 DD=07/06/1999 MA= / /
6-hydroxymethylacylfulvene TN=	Treatment of renal cell carcinoma.	MGI Pharma, Inc. 6300 West Old Shakoppe Rd. Suite 110 Bloomington, MN 55438 DD=07/27/1999 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name		INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
8 Cyclopentyl 1,3-dipropylxanthine TN=		Treatment of cystic fibrosis.	SciClone Pharmaceuticals, Inc. 901 Mariner's Island Boulevard San Mateo, CA 94404 DD=03/24/1997 MA= / /
8-methoxsalen TN= Uvadex		For use in conjunction with the UVAR photopheresis to treat diffuse systemic sclerosis.	Therakos, Inc. Oaklands Corporate Center 437 Creamery Way Exton, PA 19341 DD=06/22/1993 MA= / /
8-methoxsalen TN= Uvadex		For the prevention of acute rejection of cardiac allografts.	Therakos, Inc. Oaklands Corporate Center 437 Creamery Way Exton, PA 19341 DD=05/12/1994 MA= / /
9-cis retinoic acid TN= Panretin		Treatment of acute promyelocytic leukemia.	Ligand Pharmaceuticals, Inc. 9393 Towne Centre Drive Suite 100 San Diego, CA 92121 DD=04/10/1992 MA= / /
9-nitro-20-(S)-camptothecin TN=		Treatment of pancreatic cancer.	Stehlin Foundation for Cancer Research 1315 St. Joseph Parkway, Suite 1818 Houston, TX 77002 DD=09/16/1996 MA= / /
AP1903 TN=		Treatment of acute graft-versus-host disease in patients undergoing bone marrow transplantation.	Ariad Gene Therapeutics, Inc. 26 Landsdowne St. Cambridge, MA 02139 DD=11/24/1999 MA= / /
APL 400-020 V-Beta DNA vaccine TN=		Treatment of cutaneous T cell lymphoma.	Wyeth-Lederle Vaccines and Pediatrics 211 Bailey Rd. West Henrietta, NY 14586 DD=03/08/1995 MA= / /
Acetylcysteine TN= Mucomyst/Mucomyst 10 IV		Intravenous treatment of patients presenting with moderate to severe acetaminophen overdose.	Apothecon P.O. Box 4500 Princeton, NJ 08543 DD=08/13/1987 MA= / /
Aconiazide TN=		Treatment of tuberculosis.	Lincoln Diagnostics P.O. Box 1128 Decatur, IL 62525 DD=06/20/1988 MA= / /
Adeno-associated viral-based vector cystic fibrosis gene therapy TN=		Treatment of cystic fibrosis.	Targeted Genetics Corporation 1100 Olive Way, Suite 100 Seattle, WA 98101 DD=02/15/1995 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Adenovirus-based vector Factor VIII complementary DNA to somatic cells TN= MiniAdFVIII	Treatment of hemophilia A.	GenStar Therapeutics Corporation 10835 Altman Row Suite 150 San Diego, CA 92121 DD=12/15/1999 MA= / /
Albendazole TN= Albenza	Treatment of hydatid disease (cystic echinococcosis due to E. granulosus larvae or alveolar echinococcosis due to E. multilocularis larvae).	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=01/17/1996 MA=06/11/1996
Albendazole TN= Albenza	Treatment of neurocysticercosis due to Taenia solium as: 1) chemotherapy of parenchymal, subarachnoidal and racemose (cysts in spinal fluid) neurocysticercosis in symptomatic cases and 2) prophylaxis of epilepsy and other sequelae in asymptomatic neurocysticercosis.	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=01/18/1996 MA=06/11/1996
Aldesleukin TN= Proleukin	Treatment of primary immunodeficiency disease associated with T-cell defects.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=03/22/1989 MA= / /
Aldesleukin TN= Proleukin	Treatment of metastatic renal cell carcinoma.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=09/14/1988 MA=05/05/1992
Aldesleukin TN= Proleukin	Treatment of metastatic melanoma.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=09/10/1996 MA=01/09/1998
Aldesleukin TN= Proleukin	Treatment of acute myelogenous leukemia.	Chiron Corporation 4560 Horton St. Emeryville, CA 94608 DD=07/31/1998 MA= / /
Aldesleukin TN= Proleukin	For the treatment non-Hodgkin's lymphoma.	Chiron Corporation 4560 Horton St. Emeryville, CA 94608 DD=11/24/1998 MA= / /
Alglucerase injection TN= Ceredase	For replacement therapy in patients with Gaucher's disease type I.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=03/11/1985 MA=04/05/1991
Alglucerase injection TN= Ceredase	Replacement therapy in patients with Type II and III Gaucher's disease.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=07/21/1995 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Alitretinoin TN= Panretin	Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.	Ligand Pharmaceuticals Inc. 10275 Science Center Drive San Diego, CA 92121 DD=03/24/1998 MA=02/02/1999
Allogeneic peripheral blood mononuclear cells sensitized against patient alloantigens by mixed lymphocyte culture TN= CYTOIMPLANT	Treatment of pancreatic cancer.	Applied Immunotherapeutics, LLC 14132 E. Firestone Boulevard Santa Fe Springs, CA 90670 DD=06/13/1997 MA= / /
Allopurinol sodium TN= Zyloprim for Injection	Management of patients with leukemia, lymphoma, and solid tumor malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels and who cannot tolerate oral therapy.	Catalytica Pharmaceuticals, Inc PO Box 1887 Greenville, NC 27835 DD=10/16/1992 MA=05/17/1996
Alpha-1-antitrypsin (recombinant DNA Origin) TN=	As supplementation therapy for alpha-1-antitrypsin deficiency in the ZZ phenotype population.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=01/01/1984 MA= / /
Alpha-galactosidase A TN= Fabrase	Treatment of Fabry's disease.	Desnick, Robert J. M.D. The Mount Sinai School Of Medicine Fifth Avenue at 100th Street, Box 1203 New York, NY 10029 DD=07/20/1990 MA= / /
Alpha-galactosidase A TN= CC-galactosidase	Treatment of alpha-galactosidase A deficiency (Fabry's disease).	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=06/17/1991 MA= / /
Alpha-galactosidase A TN=	Long-term enzyme replacement therapy for the treatment of Fabry disease.	Transkaryotic Therapies Inc. 195 Albany St. Cambridge, MA 02139 DD=06/22/1998 MA= / /
Alpha-melanocyte stimulating hormone TN=	Prevention and treatment of intrinsic acute renal failure due to ischemia.	Star, Robert A., M.D. UT-Southwestern Medical School 5323 Harry Hines Dallas, TX 75235 DD=08/19/1997 MA= / /
Alpha1-proteinase inhibitor (human) TN= Prolastin	For replacement therapy in the alpha-1-proteinase inhibitor congenital deficiency state.	Bayer Corporation Pharmaceutical Division, Biological Products 400 Morgan Lane New Haven, CT 06516 DD=12/07/1984 MA=12/02/1987

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Alpha1-proteinase inhibitor (human) TN=	For slowing the progression of emphysema in alpha1-antitrypsin deficient patients.	Centeon LLC 1020 First Ave. King of Prussia, PA 19406 DD=11/24/1999 MA= / /
Alprostadil TN=	Treatment of severe peripheral arterial occlusive disease (critical limb ischemia) in patients where other procedures, grafts or angioplasty, are not indicated.	Schwarz Pharma, Inc. P.O. Box 2038 Milwaukee, WI 53201 DD=10/20/1993 MA= / /
Alronidase TN= Aldurazyme	Treatment of patients with mucopolysaccharidosis-I.	BioMarin Pharmaceutical, Inc. 11 Pimental Court Novato, CA 94949 DD=09/24/1997 MA= / /
Altretamine TN= Hexalen	Treatment of advanced adenocarcinoma of the ovary.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street West Conshohocken, PA 19428 DD=02/09/1984 MA=12/26/1990
Amifostine TN= Ethyol	For use as a chemoprotective agent for cisplatin in the treatment of advanced ovarian carcinoma.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street West Conshohocken, PA 19428 DD=05/30/1990 MA=12/08/1995
Amifostine TN= Ethyol	For use as a chemoprotective agent for cyclophosphamide in the treatment of advanced ovarian carcinoma.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street West Conshohocken, PA 19428 DD=05/30/1990 MA= / /
Amifostine TN= Ethyol	For use as a chemoprotective agent for cisplatin in the treatment of metastatic melanoma.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street West Conshohocken, PA 19428 DD=05/30/1990 MA= / /
Amifostine TN= Ethyol	Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street, Suite 400 Conshohocken, PA 19428 DD=05/12/1998 MA=06/24/1999
Amifostine TN= Ethyol	For the reduction of the incidence and severity of toxicities associated with cisplatin administration.	U.S. Bioscience, Inc. One Tower Bridge 100 Front St., Suite #400 West Conshohocken, PA 19428 DD=11/24/1998 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Amifostine TN= Ethyol	Treatment of myelodysplastic syndromes.	US Bioscience, Inc. One Tower Bridge 100 Front St., Suite 400 West Conshohocken, PA 19428 DD=10/04/1999 MA= / /
Aminocaproic acid TN= Caprogel	For the topical treatment of traumatic hyphema of the eye.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=01/06/1995 MA= / /
Aminosalicylic acid TN= Paser Granules	Treatment of tuberculosis infections.	Jacobus Pharmaceutical Company 37 Cleveland Lane P.O. Box 5290 Princeton, NJ 08540 DD=02/19/1992 MA=06/30/1994
Aminosidine TN= Gabbromicina	Treatment of tuberculosis.	Kanyok, Thomas P. Pharm.D. University Of Illinois At Chicago College of Pharmacy 833 South Wood Street (m/c886) Rm. 176 Chicago, IL 60612 DD=05/14/1993 MA= / /
Aminosidine TN= Gabbromicina	Treatment of Mycobacterium avium complex.	Kanyok, Thomas P. Pharm.D. University of Illinois at Chicago College of Pharmacy 833 South Wood Street (m/c886) Rm. 176 Chicago, IL 60612 DD=11/15/1993 MA= / /
Aminosidine TN= Paromomycin	Treatment of visceral leishmaniasis (kala-azar).	Kanyok, Thomas P. Pharm.D. University of Illinois at Chicago College of Pharmacy 833 South Wood Street (m/c886) Rm. 176 Chicago, IL 60612 DD=09/09/1994 MA= / /
Amiodarone TN= Amio-Aqueous	Treatment of incessant ventricular tachycardia.	Wyeth-Ayerst Research PO Box 8299 Philadelphia, PA 19101 DD=08/17/1993 MA= / /
Amiodarone HCl TN= Cordarone	For the acute treatment and prophylaxis of life-threatening ventricular tachycardia or ventricular fibrillation.	Wyeth-Ayerst Laboratories P.O. Box 8299 Philadelphia, PA 19101 DD=03/16/1994 MA=08/03/1995
Ammonium tetrathiomolybdate TN=	Treatment of Wilson's disease.	Brewer, George J. M.D. University Of Michigan Medical School 4708 Medical Science Building II 0618 Ann Arbor, MI 48109 DD=01/31/1994 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Amphotericin B lipid complex TN= Abelcet	Treatment of invasive fungal infections.	Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=12/03/1996 MA=10/18/1996
Anagrelide TN= Agrylin	Treatment of polycythemia vera.	Roberts Pharmaceutical Corp. Meridian Center II 4 Industrial Way West Eatontown, NJ 07724 DD=06/11/1985 MA= / /
Anagrelide TN= Agrylin	Treatment of thrombocytosis in chronic myelogenous leukemia.	Roberts Pharmaceutical Corp. Meridian Center II 4 Industrial Way West Eatontown, NJ 07724 DD=07/14/1986 MA= / /
Anagrelide TN= Agrylin	Treatment of essential thrombocythemia.	Roberts Pharmaceutical Corp. Meridian Center III 6 Industrial Way West Eatontown, NJ 07724 DD=01/27/1988 MA=03/14/1997
Ananain, comosain TN= Vianain	For the enzymatic debridement of severe burns.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=01/21/1992 MA= / /
Ancestim TN= Stemgen	For use in combination with filgrastim to decrease the number of phereses required to collect peripheral blood progenitor cells capable of providing rapid multi-lineage hematopoietic reconstitution following myelosuppressive or myeloablative therapy.	Amgen, Inc. 1840 Dehavilland Drive Thousand Oaks, CA 91320 DD=07/05/1995 MA= / /
Ancrod TN=	To establish and maintain anticoagulation in heparin-intolerant patients undergoing cardiopulmonary bypass.	Knoll Pharmaceutical Company 3000 Continental Dr., North Mt. Olive, NJ 07828 DD=11/12/1997 MA= / /
Anti-thymocyte serum TN= Nashville Rabbit Anti-thymocyte Serum	Treatment of allograft rejection, including solid organ (kidney, liver, heart, lung, and pancreas) and bone marrow transplantation.	Applied Medical Research 1600 Hayes Street Nashville, TN 37203 DD=06/02/1993 MA= / /
Antiepilepsirine TN=	Treatment of drug resistant generalized tonic-clonic epilepsy in children and adults.	Children's Hospital 700 Children's Drive Columbus, OH 43205 DD=03/23/1989 MA= / /
Antihemophilic factor (human) TN= Alphanate	Treatment of von Willebrand's disease.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=01/05/1996 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Antihemophilic factor (recombinant) TN= Kogenate	Prophylaxis and treatment of bleeding in individuals with hemophilia A or for prophylaxis when surgery is required in individuals with hemophilia A.	Bayer Corporation 1884 Miles Avenue Elkhart, IN 46515 DD=09/25/1989 MA=02/25/1993
Antihemophilic factor/von Willebrand factor complex (human), dried, pasteurized TN= Humate-P	Treatment and prevention of bleeding in hemophilia A (classical hemophilia) in adult patients; and treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate in adult and pediatric patients.	Centeon Pharma GmbH Emil-von-Behring-Strasse 76 35041 Marburg Germany, DE DD=10/16/1992 MA=04/01/1999
Antithrombin III (human) TN= Thrombate III	For replacement therapy in congenital deficiency of AT-III for prevention and treatment of thrombosis and pulmonary emboli.	Bayer Corporation Pharmaceutical Division, Biological Products 400 Morgan Lane New Haven, CT 06516 DD=11/26/1984 MA=12/30/1991
Antithrombin III (human) concentrate IV TN= Kybernin P	For prophylaxis and treatment of thromboembolic episodes in patients with genetic AT-III deficiency.	Centeon Pharma GmbH Postfach 11 40 D-35001 Marburg Germany, DE DD=07/02/1985 MA= / /
Antithrombin III human TN= ATnativ	For the treatment of patients with hereditary antithrombin III deficiency in connection with surgical or obstetrical procedures or when they suffer from thromboembolism.	Kabivitrum, Inc. P.O. Box 430 Danville, CA 94526 DD=02/08/1985 MA=12/13/1989
Antithrombin III human TN= Antithrombin III human	Preventing or arresting episodes of thrombosis in patients with congenital AT-III deficiency and/or to prevent the occurrence of thrombosis in patients with AT-III deficiency who have undergone trauma or who are about to undergo surgery or parturition.	American National Red Cross 9312 Old Georgetown Road Bethesda, MD 20814 DD=01/02/1986 MA= / /
Antivenin, polyvalent crotalid (ovine) Fab TN= CroTAb	Treatment of envenomations inflicted by North American crotalid snakes.	Therapeutic Antibodies Inc. 1500 21st Avenue South, Suite 310 Nashville, TN 37212 DD=01/12/1994 MA= / /
Antivenom (crotalidae) purified (avian) TN=	Treatment of envenomation by poisonous snakes belonging to the Crotalidae family.	Ophidian Pharmaceuticals, Inc. 5445 East Cheryl Parkway Madison, WI 53711 DD=02/12/1991 MA= / /
Apomorphine TN=	Treatment of the on-off fluctuations associated with late-stage Parkinson's disease.	Pentech Pharmaceuticals, Inc. 1110 Lake Cook Rd. Suite 257 Buffalo Grove, IL 60089 DD=07/17/1995 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Apomorphine TN= Zydis	For use as rescue treatment for early morning motor dysfunction in late-stage Parkinson's disease.	Scherer DDS Frankland Road Swindon SN5 8RU Wiltshire UK, DD=10/20/1997 MA= / /
Apomorphine HCl TN=	Treatment of the on-off fluctuations associated with late-stage Parkinson's disease.	Mylan Pharmaceuticals, Inc. 781 Chestnut Ridge Rd. PO Box 4310 Morgantown, WV 26505 DD=04/22/1993 MA= / /
Aprotinin TN= Trasylol	For prophylactic use to reduce perioperative blood loss and the homologous blood transfusion requirement in patients undergoing cardiopulmonary bypass surgery in the course of repeat coronary artery bypass graft surgery, and in selected cases of primary coronary artery bypass graft surgery where the risk of bleeding is especially high (impaired hemostasis) or where transfusion is unavailable or unacceptable.	Bayer Corporation Pharmaceutical Division 400 Morgan Lane West Haven, CT 06516 DD=11/17/1993 MA=12/29/1993
Arcitumomab TN= 99m Tc-labeled CEA-Scan	Diagnosis and localization of primary, residual, recurrent and metastatic medullary thyroid carcinoma.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=05/10/1996 MA= / /
Arginine butyrate TN=	Treatment of beta-hemoglobinopathies and beta-thalassemia.	Perrine, Susan P., M.D. Boston University Cancer Research Center Boston, MA 02118 DD=04/07/1992 MA= / /
Arsenic trioxide TN=	Treatment of acute promyelocytic leukemia.	PolaRx, Inc. 787 7th Ave., 48th Floor New York, NY 10019 DD=03/03/1998 MA= / /
Artesunate TN=	Treatment of malaria.	World Health Organisation Special Programme for Research and Training in Tropical Diseases Via Appia , Geneva 27 Switzerland, CH DD=07/19/1999 MA= / /
Atovaquone TN= Mepron	Treatment of AIDS associated Pneumocystis Carinii Pneumonia.	Glaxo Wellcome Inc. 5 Moore Drive Research Triangle Park, NC 27709 DD=09/10/1990 MA=11/25/1992
Atovaquone TN= Mepron	Prevention of Pneumocystis carinii pneumonia (PCP) in high-risk, HIV-infected patients defined by a history of one or more episodes of PCP and/or a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to 200/mm3.	Glaxo Wellcome Research and Development 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709 DD=08/14/1991 MA=01/05/1999

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Atovaquone TN= Mepron	Treatment and suppression of Toxoplasma gondii encephalitis.	Glaxo Wellcome Inc. 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709 DD=03/16/1993 MA= / /
Atovaquone TN= Mepron	Primary prophylaxis of HIV-infected persons at high risk for developing Toxoplasma gondii encephalitis.	Glaxo Wellcome Inc. 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709 DD=03/16/1993 MA= / /
Autologous DNP-conjugated tumor vaccine TN= M-Vax	For adjuvant therapy in melanoma patients with surgically resectable lymph node metastasis (Stage III and limited Stage IV disease).	Avax Technologies, Inc. 4520 Main St. Suite 930 Kansas City, MO 64111 DD=02/23/1999 MA= / /
Autolymphocyte therapy TN=	Treatment of renal cell carcinoma.	Cytogen Corporation 600 College Road East CN 5308 Princeton, NJ 08540 DD=07/12/1994 MA= / /
Azathioprine TN= Imuran	Treatment of oral manifestations of graft-versus-host disease.	Oral Solutions, Inc. 787 Seventh Ave., 48th Floor New York, NY 10019 DD=09/14/1999 MA= / /
B2036-PEG TN= Trovert	Treatment of acromegaly.	Sensus Corporation Suite 430, 98 San Jacinto Boulevard Austin, TX 78701 DD=06/24/1997 MA= / /
Bacitracin TN= Altracin	Treatment of antibiotic-associated pseudomembranous enterocolitis caused by toxins A and B elaborated by Clostridium difficile.	A. L. Laboratories, Inc. One Executive Drive P.O. Box 1399 Fort Lee, NJ 07024 DD=03/13/1984 MA= / /
Baclofen TN= Lioresal Intrathecal	Treatment of intractable spasticity caused by spinal cord injury, multiple sclerosis, and other spinal diseases (including spinal ischemia, spinal tumor, transverse myelitis, cervical spondylosis, and degenerative myelopathy).	Medtronic, Inc. 800 53rd Avenue N.E. Minneapolis, MN 55432 DD=11/10/1987 MA=06/25/1992
Baclofen TN=	Treatment of intractable spasticity due to multiple sclerosis or spinal cord injury.	Infusaid, Inc. 1400 Providence Highway Norwood, MA 02062 DD=12/16/1991 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Baclofen TN= Lioresal Intrathecal	Treatment of spasticity associated with cerebral palsy.	Medtronic, Inc. 800 53rd Avenue N.E. P.O. 1250 Minneapolis, MN 55440 DD=09/26/1994 MA= / /
Basiliximab TN= Simulect	Prophylaxis of solid organ rejection.	Novartis Pharmaceuticals Corporation 59 Route 10 East Hanover, NJ 07936 DD=12/12/1997 MA=05/12/1998
Beclomethasone dipropionate TN=	For oral administration in the treatment of intestinal graft-versus-host disease.	George B. McDonald, M.D. Fred Hutchinson Cancer Research Center 1100 Fairview Avenue North (SC-113); PO Box 19024 Seattle, WA 98109 DD=03/27/1998 MA= / /
Benzoate and phenylacetate TN= Ucephan	For adjunctive therapy in the prevention and treatment of hyperammonemia in patients with urea cycle enzymopathy due to carbamylphosphate synthetase, ornithine, transcarbamylase, or argininosuccinate synthetase deficiency.	B. Braun Medical Inc. 2525 McGaw Avenue P.O. Box 19791 Irvine, CA 92623 DD=01/21/1986 MA=12/23/1987
Benzydamine hydrochloride TN= Tantum	Prophylactic treatment of oral mucositis resulting from radiation therapy for head and neck cancer.	Angelini Pharmaceuticals, Inc. 70 Grand Avenue River Edge, NJ 07661 DD=05/18/1998 MA= / /
Benzylpenicillin, benzylpenicilloic, benzylpenilloic acid TN= Pre-Pen/MDM	Assessing the risk of administering penicillin when it is the preferred drug of choice in adult patients who have previously received penicillin and have a history of clinical sensitivity.	Hollister-Stier Laboratories LLC PO Box 3145 Spokane, WA 99220 DD=09/29/1987 MA= / /
Beractant TN= Survanta intratracheal suspension	Treatment of neonatal respiratory distress syndrome.	Ross Laboratories 625 Cleveland Avenue Columbus, OH 43215 DD=02/05/1986 MA=07/01/1991
Beractant TN= Survanta intratracheal suspension	Prevention of neonatal respiratory distress syndrome.	Ross Laboratories 625 Cleveland Avenue Columbus, OH 43215 DD=02/05/1986 MA=07/01/1991
Beractant TN= Survanta Intratracheal Suspension	Treatment of full-term newborn infants with respiratory failure caused by meconium aspiration syndrome, persistent pulmonary hypertension of the newborn, or pneumonia and sepsis.	Ross Laboratories 625 Cleveland Avenue Columbus, OH 43215 DD=12/20/1993 MA= / /
Beraprost TN=	Treatment of pulmonary arterial hypertension associated with any New York Heart Association classification (Class I, II, III, or IV).	United Therapeutics Corporation 68 T.W. Alexander Drive, PO Box 14186 Research Triangle Park, NC 27709 DD=04/29/1999 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name		INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Beta alethine TN= Betathine		Treatment of multiple myeloma.	Dovetail Technologies, Inc. Bldg. 337, Paint Branch Drive College Park, MD 20742 DD=03/24/1997 MA= / /
Beta alethine TN= Betathine		Treatment of metastatic melanoma.	Dovetail Technologies, Inc. Bldg. 337, Paint Branch Drive College Park, MD 20742 DD=03/24/1997 MA= / /
Betaine TN= Cystadane		Treatment of homocystinuria.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=05/16/1994 MA=10/25/1996
Bexarotene TN= Targretin		Treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.	Ligand Pharmaceuticals, Inc. 10275 Science Center Dr. San Diego, CA 92121 DD=06/18/1999 MA=12/29/1999
Bindarit TN=		Treatment of lupus nephritis.	Angelini Pharmaceuticals, Inc. 70 Grand Avenue River Edge, NJ 07661 DD=02/03/1998 MA= / /
Bispecific antibody 520c9x22 TN=		For in vivo serotherapy of patients with ovarian cancer.	Medarex, Inc. 1545 Route 22 East PO Box 953 Annandale, NJ 08801 DD=10/05/1993 MA= / /
Bleomycin TN= Blenoxane		Treatment of pancreatic cancer.	Genetronics, Inc. 11199 Sorrento Valley Rd. San Diego, CA 92121 DD=02/09/1999 MA= / /
Bleomycin sulfate TN= Blenoxane		Treatment of malignant pleural effusion.	Bristol-Myers Squibb Pharmaceutical Research Institute P.O. Box 4000 Princeton, NJ 08543 DD=09/17/1993 MA=02/20/1996
Botulinum toxin type A TN= Botox		Treatment of blepharospasm associated with dystonia in adults (patients 12 years of age and above).	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92713 DD=03/22/1984 MA=12/29/1989
Botulinum toxin type A TN= Botox		Treatment of strabismus associated with dystonia in adults (patients 12 years of age and above).	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92713 DD=03/22/1984 MA=12/29/1989

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Botulinum toxin type A TN= Botox	Treatment of cervical dystonia.	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 , 92623 DD=08/20/1986 MA= / /
Botulinum toxin type A TN= Dysport	Treatment of essential blepharospasm.	Porton International, Inc. 1155 15th Street, N.W., #315 Washington, DC 20005 DD=03/23/1989 MA= / /
Botulinum toxin type A TN= Botox	Treatment of dynamic muscle contracture in pediatric cerebral palsy patients.	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92713 DD=12/06/1991 MA= / /
Botulinum toxin type A TN=	Treatment of synkinetic closure of the eyelid associated with VII cranial nerve aberrant regeneration.	Associated Synapse Biologics 68 Harrison Avenue Boston, MA 02111 DD=09/15/1992 MA= / /
Botulinum toxin type A TN= Dysport	Treatment of spasmodic torticollis (cervical dystonia).	Ipsen Limited 1 Bath Road Maidenhead, Berkshire U.K. SL6 4UH, GB DD=08/12/1998 MA= / /
Botulinum toxin type A TN= Dysport	Treatment of dynamic muscle contractures in pediatric cerebral palsy patients.	Ipsen Limited 1 Bath Rd., Maidenhead Berkshire SL6 4UH England, GB DD=10/20/1999 MA= / /
Botulinum toxin type B TN= NeuroBloc	Treatment of cervical dystonia.	Elan Pharmaceuticals, Inc. 800 Gateway Blvd. South San Francisco, CA 94080 DD=01/16/1992 MA= / /
Botulinum toxin type F TN= Dysport	Treatment of essential blepharospasm.	Porton International, Inc. 1155 15th Street, N.W., #315 Washington, DC 20005 DD=12/05/1991 MA= / /
Botulinum toxin type F TN=	Treatment of spasmodic torticollis (cervical dystonia).	Porton International, Inc. 1155 15th Street, N.W., #315 Washington, DC 20005 DD=10/24/1991 MA= / /
Botulism immune globulin TN=	Treatment of infant botulism.	California Department of Health Services 2151 Berkeley Way Berkeley, CA 94704 DD=01/31/1989 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Bovine colostrum TN=	Treatment of AIDS-related diarrhea.	Hastings, Donald DVM 1030 North Parkview Drive Bismarck, ND 58501 DD=11/19/1990 MA= / /
Bovine immunoglobulin concentrate, Cryptosporidium parvum TN= Sporidin-G	Treatment and symptomatic relief of Cryptosporidium parvum infection of the gastrointestinal tract in immunocompromised patients.	GalaGen, Inc. 4001 Lexington Avenue North Arden Hills, MN 55126 DD=03/01/1994 MA= / /
Bovine whey protein concentrate TN= Immuno-C	Treatment of cryptosporidiosis caused by the presence of Cryptosporidium parvum in the gastrointestinal tract of patients who are immunodeficient/immunocompromised or immunocompetent.	Biomune Systems, Inc. 540 Arapeen Drive, Suite 202 Salt Lake City, UT 84108 DD=09/30/1993 MA= / /
Branched chain amino acids TN=	Treatment of amyotrophic lateral sclerosis.	Mount Sinai Medical Center One Gustave L. Levy Place New York, NY 10029 DD=12/23/1988 MA= / /
Bromhexine TN= Bisolvon	Treatment of mild to moderate keratoconjunctivitis sicca in patients with Sjogren's syndrome.	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road, Box 368 Ridgefield, CT 06877 DD=05/15/1989 MA= / /
Broxuridine TN= Broxine/Neomark	Radiation sensitizer in the treatment of primary brain tumors.	NeoPharm, Inc. 225 East Deerpath, Suite 250 Lake Forest, IL 60045 DD=09/18/1995 MA= / /
Buffered intrathecal electrolyte/dextrose injection TN= Elliotts B Solution	For use as a diluent in the intrathecal administration of methotrexate and cytarabine for the prevention or treatment meningeal leukemia and lymphocytic lymphoma.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=08/24/1994 MA=09/27/1996
Buprenorphine hydrochloride TN= Subutex	Treatment of opiate addiction in opiate users.	Reckitt & Colman Pharmaceuticals, Inc. 1901 Huguenot Road Richmond, VA 23235 DD=06/15/1994 MA= / /
Buprenorphine in combination with naloxone TN= Suboxone	Treatment of opiate addiction in opiate users.	Reckitt & Colman Pharmaceuticals, Inc. 1901 Huguenot Road Richmond, VA 23235 DD=10/27/1994 MA= / /
Busulfan TN= Spartaject	For use as preparative therapy for malignancies treated with bone marrow transplantation.	Sparta Pharmaceuticals, Inc. 111 Rock Road Horsham, PA 19044 DD=04/21/1994 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Busulfan TN= Busulfex	As preparative therapy in the treatment of malignancies with bone marrow transplantation.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 250 Minnetonka, MN 55305 DD=07/28/1994 MA=02/04/1999
Busulfan TN= Spartaject	Treatment of primary brain malignancies.	Sparta Pharmaceuticals, Inc. 111 Rock Road Horsham, PA 19044 DD=07/07/1997 MA= / /
Butyrylcholinesterase TN=	For the reduction and clearance of toxic blood levels of cocaine encountered during a drug overdose.	Shire Laboratories Inc. 1550 East Gude Drive Rockville, MD 20850 DD=03/25/1992 MA= / /
Butyrylcholinesterase TN=	Treatment of post-surgical apnea.	Shire Laboratories Inc. 1550 East Gude Drive Rockville, MD 20850 DD=09/30/1992 MA= / /
C1 esterase inhibitor (human) TN=	Treatment and prevention of angioedema caused by C1-esterase inhibitor deficiency.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=08/21/1996 MA= / /
C1-esterase-inhibitor, human, pasteurized TN= Berinert P	Prevention and/or treatment of acute attacks of hereditary angioedema.	Behringwerke Aktiengesellschaft (AG) Postfach 11 40 D-35001 Marburg Germany, DD=10/16/1992 MA= / /
C1-inhibitor TN= C1-inhibitor (human) vapor heated, Immuno	Treatment of acute attacks of angioedema.	Baxter Healthcare Corp. Hyland Division (Baxter Hyland) 550 North Brand Blvd. Glendale, CA 91203 DD=08/30/1990 MA= / /
C1-inhibitor TN= C1-inhibitor (human) vapor heated, Immuno	Prevention of acute attacks of angioedema, including short-term prophylaxis for patients requiring dental or other surgical procedures.	Baxter Healthcare Corp. Hyland Division (Baxter Hyland) 550 North Brand Blvd. Glendale, CA 91203 DD=08/30/1990 MA= / /
CAMPATH-1H TN=	Treatment of chronic lymphocytic leukemia.	L&I Partners, LP 11550 IH 10 West, Suite 300 San Antonio, TX 78230 DD=10/20/1997 MA= / /
CDP571 TN=	Treatment of Crohn's disease.	Celltech Therapeutics, Ltd. 216 Bath Road Slough SL1 4EN Berkshire UK, DD=12/11/1997 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
CT-2584 mesylate TN=	Treatment of adult soft tissue sarcoma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Suite 400 Seattle, WA 98119 DD=04/16/1999 MA= / /
CT-2584 mesylate TN=	Treatment of malignant mesothelioma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Seattle, WA 98119 DD=04/16/1999 MA= / /
CY-1503 TN= Cylexin	Treatment of post-ischemic pulmonary reperfusion edema following surgical treatment for chronic thromboembolic pulmonary hypertension.	Cytel Corporation 3525 John Hopkins Court San Diego, CA 92121 DD=12/22/1993 MA= / /
CY-1503 TN= Cylexin	Treatment of neonates and infants undergoing cardiopulmonary bypass during surgical repair of congenital heart lesions.	Cytel Corporation 3525 John Hopkins Court San Diego, CA 92121 DD=07/18/1997 MA= / /
CY-1899 TN=	Treatment of chronic active hepatitis B infection in HLA-A2 positive patients.	Cytel Corporation 3525 John Hopkins Court San Diego, CA 92121 DD=03/16/1994 MA= / /
Caffeine TN= Cafcit	Treatment of apnea of prematurity.	O.P.R. Development, L.P. 1501 Wakarusa Drive Lawrence, KS 66047 DD=09/20/1988 MA=09/21/1999
Calcitonin-human for injection TN= Cibacalcin	Treatment of symptomatic Paget's disease (osteitis deformans).	Novartis Pharmaceutical Corporation 59 Route 10 East Hanover, NJ 07936 DD=01/20/1987 MA=10/31/1986
Calcium acetate TN= Phos-Lo	Treatment of hyperphosphatemia in end stage renal failure.	Braintree Laboratories 60 Columbian Street P.O. Box 361 Braintree, MA 02184 DD=12/22/1988 MA=12/10/1990
Calcium acetate TN=	Treatment of hyperphosphatemia in end stage renal disease.	Pharmedic Company 28101 Ballard Road, Suite F Lake Forest, IL 60045 DD=06/27/1989 MA= / /
Calcium carbonate TN= R & D calcium carbonate/600	Treatment of hyperphosphatemia in patients with end stage renal disease.	R & D Laboratories, Inc. 4204 Glencoe Avenue Marina Del Rey, CA 90292 DD=06/06/1990 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name		INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Calcium gluconate TN= Calgonate		For use as a wash for hydrofluoric acid spills on human skin.	Calgonate Corp. 190 Commerce Drive Warwick, RI 02886 DD=11/20/1997 MA= / /
Calcium gluconate gel TN= H-F Gel		For use in the emergency topical treatment of hydrogen fluoride (hydrofluoric acid) burns.	LTR Pharmaceuticals, Inc. 145 Sakonnet Blvd. Narragansett, RI 02882 DD=05/21/1991 MA= / /
Calcium gluconate gel 2.5% TN=		Emergency topical treatment of hydrogen fluoride (hydrofluoric acid) burns.	Paddock Laboratories, Inc. 3940 Quebec Avenue North Minneapolis, MN 55427 DD=09/10/1990 MA= / /
Carbamylglutamic acid TN=		Treatment of N-acetylglutamate synthetase deficiency.	Orphan Europe Immeuble "Le Guillaumet" 60, avenue du President Wilson 92046 Paris France, DD=01/20/1998 MA= / /
Cascara sagrada fluid extract TN=		Treatment of oral drug overdosage to speed lower bowel evacuation.	Intramed Corporation 102 Tremont Way Augusta, GA 30907 DD=03/21/1989 MA= / /
Ceramide trihexosidase/alpha-galactosidas e A TN=		Treatment of Fabry's disease.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=01/19/1988 MA= / /
Chenodiol TN= Chenix		For patients with radiolucent stones in well opacifying gallbladders, in whom elective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age.	Solvay 901 Sawyer Road Marietta, GA 30062 DD=09/21/1984 MA=07/28/1983
Chlorhexidine gluconate mouthrinse TN= Peridex		For use in the amelioration of oral mucositis associated with cytoreductive therapy used in conditioning patients for bone marrow transplantation therapy.	Procter & Gamble Company Sharon Wood Technical Center 11370 Reed Hartman Highway Cincinnati, OH 45241 DD=08/18/1986 MA= / /
Choline chloride TN= Intrachol		Treatment of choline deficiency, specifically the choline deficiency, hepatic steatosis, and cholestasis, associated with long-term parenteral nutrition.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=02/10/1994 MA= / /
Chondrocyte-alginate gel suspension TN=		For use in correcting vesicoureteral reflux in the pediatric population.	Reprogenesis, Inc. 800 Huntington Ave. Boston, MA 02115 DD=12/01/1997 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Ciliary neurotrophic factor TN=	Treatment of amyotrophic lateral sclerosis.	Regeneron Pharmaceuticals Inc 777 Old Saw Mill River Road Tarrytown, NY 10591 DD=01/30/1992 MA= / /
Citric acid, glucono-delta-lactone and magnesium carbonate TN= Renacidin Irrigation	Treatment of renal and bladder calculi of the apatite or struvite variety.	United-Guardian, Inc. P.O. Box 2500 Smithtown, NY 11787 DD=08/28/1989 MA=10/02/1990
Cladribine TN= Leustatin	Treatment of acute myeloid leukemia.	R. W. Johnson Pharmaceutical Research Institute Route 202 P.O. Box 300 Raritan, NJ 08869 DD=07/20/1990 MA= / /
Cladribine TN= Leustatin Injection	Treatment of hairy cell leukemia.	R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan, NJ 08869 DD=11/15/1990 MA=02/26/1993
Cladribine TN= Leustatin Injection	Treatment of chronic lymphocytic leukemia.	R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan, NJ 08869 DD=12/31/1990 MA= / /
Cladribine TN= Leustatin Injection	Treatment of non-Hodgkin's lymphoma.	R. W. Johnson Pharmaceutical Research Institute Route 202 South, P.O. Box 300 Raritan, NJ 08869 DD=04/19/1993 MA= / /
Cladribine TN= Mylinax	Treatment of the chronic progressive form of multiple sclerosis.	R. W. Johnson Pharmaceutical Research Institute Route 202 PO Box 300 Raritan, NJ 08869 DD=04/19/1994 MA= / /
Clindamycin TN= Cleocin	Treatment of Pneumocystis carinii pneumonia associated with AIDS patients.	Pharmacia & Upjohn 7000 Portage Road Unit 0633-298-113 Kalamazoo, MI 49001 DD=10/28/1988 MA= / /
Clindamycin TN= Cleocin	Prevention of Pneumocystis carinii pneumonia in AIDS patients.	Pharmacia & Upjohn 7000 Portage Road Unit 0633-298-113 Kalamazoo, MI 49001 DD=10/28/1988 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Clofazimine TN= Lamprene	Treatment of lepromatous leprosy, including dapsone-resistant lepromatous leprosy and lepromatous leprosy complicated by erythema nodosum leprosum.	Novartis Pharmaceutical Corporation 59 Route 10 East Hanover, NJ 07936 DD=06/11/1984 MA=12/15/1986
Clonazepam TN= Klonopin	Treatment of hyperekplexia (startle disease).	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=08/04/1994 MA= / /
Clonidine TN= Duraclon	For continuous epidural administration as adjunctive therapy with intraspinal opiates for the treatment of pain in cancer patients tolerant to, or unresponsive to, intraspinal opiates.	Roxane Laboratories, Inc. PO Box 16532 Columbus, OH 43216 DD=01/24/1989 MA=10/02/1996
Clostridial collagenase TN=	Treatment of advanced (involutional or residual stage) Dupuytren's disease.	Hurst, L. M.D. & Badalamente, M. Ph.D. State University of New York at Stony Brook School of Medicine, Health Sciences Center T18-020 Stony Brook, NY 11794 DD=05/23/1996 MA= / /
Clotrimazole TN=	Treatment of sickle cell disease.	Brugnara, Carlo M.D. The Children's Hospital 300 Longwood Avenue, Bader 760 Boston, MA 02115 DD=04/24/1995 MA= / /
Coagulation Factor IX (human) TN= AlphaNine	For use as replacement therapy in patients with hemophilia B for the prevention and control of bleeding episodes, and during surgery to correct defective hemostasis.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=07/05/1990 MA=12/31/1990
Coagulation Factor IX (recombinant) TN= BeneFix	Treatment of hemophilia B.	Genetics Institute, Inc. 87 Cambridge Park Drive Cambridge, MA 02140 DD=10/03/1994 MA=02/11/1997
Coagulation factor IX TN= Mononine	Replacement treatment and prophylaxis of the hemorrhagic complications of hemophilia B.	Armour Pharmaceutical Company 500 Arcola Road, P.O. Box 1200 Collegeville, PA 19426 DD=06/27/1989 MA=08/20/1992
Coagulation factor VIIa (recombinant) TN= NovoSeven	Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.	Novo Nordisk Pharmaceuticals, Inc. 100 Overlook Center Suite 200 Princeton, NJ 08540 DD=06/06/1988 MA=03/25/1999

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Colfosceril palmitate, cetyl alcohol, tyloxapol TN= Exosurf Neonatal for Intratracheal Suspension	Prevention of hyaline membrane disease, also known as respiratory distress syndrome, in infants born at 32 weeks gestation or less.	Glaxo Wellcome Inc. 5 Moore Drive Research Triangle Park, NC 27709 DD=10/20/1989 MA=08/02/1990
Colfosceril palmitate, cetyl alcohol, tyloxapol TN= Exosurf Neonatal for Intratracheal Suspension	Treatment of established hyaline membrane disease at all gestational ages.	Glaxo Wellcome Inc. 5 Moore Drive Research Triangle Park, NC 27709 DD=10/20/1989 MA=08/02/1990
Colfosceril palmitate, cetyl alcohol, tyloxapol TN= Exosurf	Treatment of adult respiratory distress syndrome.	Glaxo Wellcome Research and Development 5 Moore Drive P.O. Box 13398 Research Triangle Park, NC 27709 DD=01/11/1993 MA= / /
Collagenase (lyophilized) for injection TN= Plaquase	Treatment of Peyronie's disease.	Advance Biofactures Corporation 35 Wilbur Street Lynbrook, NY 11563 DD=03/12/1996 MA= / /
Corticotropin-releasing factor, human TN= Acthrel	For use in differentiating pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushings syndrome.	Ferring Laboratories, Inc. 400 Rella Boulevard, Suite 201 Suffern, NY 10901 DD=11/24/1989 MA=05/23/1996
Corticotropin-releasing factor, human TN= Xercept	Treatment of peritumoral brain edema.	Neurobiological Technologies, Inc. 1387 Marina Way South Richmond, CA 94804 DD=04/06/1998 MA= / /
Coumarin TN= Onkolox	Treatment of renal cell carcinoma.	Drossapharm LTD 4002 Basel Switzerland, DD=12/22/1994 MA= / /
Cromolyn sodium TN= Gastrocrom	Treatment of mastocytosis.	Fisons Corporation 755 Jefferson Rd P.O. Box 1710 Rochester, NY 14603 DD=03/08/1984 MA=12/22/1989
Cromolyn sodium 4% ophthalmic solution TN= Opticrom 4% ophthalmic solution	Treatment of vernal keratoconjunctivitis.	Fisons Corporation 755 Jefferson Rd. P.O. Box 1710 Rochester, NY 14603 DD=07/24/1985 MA=10/03/1984
Cryptosporidium hyperimmune bovine colostrum IgG concentrate TN=	Treatment of diarrhea in AIDS patients caused by infection with Cryptosporidium parvum.	ImmuCell Corporation 56 Evergreen Drive Portland, ME 04103 DD=12/30/1991 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Cyclosporine 2% ophthalmic ointment TN=	Treatment of patients at high risk of graft rejection following penetrating keratoplasty.	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92623 DD=08/01/1991 MA= / /
Cyclosporine 2% ophthalmic ointment TN=	For use in corneal melting syndromes of known or presumed immunologic etiopathogenesis, including Mooren's ulcer.	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92623 DD=08/01/1991 MA= / /
Cyclosporine ophthalmic TN= Optimune	Treatment of severe keratoconjunctivitis sicca associated with Sjogren's syndrome.	University Of Georgia College Of Veterinary Medicine Department of Small Animal Medicine Athens, GA 30602 DD=11/09/1988 MA= / /
Cysteamine TN=	Treatment of nephropathic cystinosis.	Thoene, Jess G., M.D. University of Michigan Medical School 300 NIB, 1192 SE Ann Arbor, MI 48109 DD=05/01/1986 MA= / /
Cysteamine TN= Cystagon	Treatment of nephropathic cystinosis.	Mylan Laboratories, Inc. 781 Chestnut Ridge Road P.O. Box 4310 Morgantown, WV 26504 DD=01/25/1991 MA=08/15/1994
Cysteamine hydrochloride TN=	Treatment of corneal cystine crystal accumulation in cystinosis patients.	Sigma-Tau Pharmaceuticals, Inc. 800 South Frederick Avenue Gaithersburg, MD 20877 DD=08/19/1997 MA= / /
Cystic fibrosis Tr gene therapy (recombinant adenovirus) TN= AdGVCFTR.10	Treatment of cystic fibrosis.	GenVec, Inc. 12111 Parklawn Drive Rockville, MD 20852 DD=03/09/1995 MA= / /
Cystic fibrosis gene therapy TN=	Treatment of cystic fibrosis.	Genzyme Corporation One Mountain Rd. P.O. Box 9322 Framingham, MA 01701 DD=06/30/1992 MA= / /
Cystic fibrosis transmembrane conductance regulator TN=	For cystic fibrosis transmembrane conductance regulator protein replacement therapy in cystic fibrosis patients.	Genzyme Corporation P.O. Box 9322 Framingham, MA 01701 DD=01/14/1992 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Cystic fibrosis transmembrane conductance regulator gene TN=	Treatment of cystic fibrosis.	Genetic Therapy, Inc. 938 Clopper Road Gaithersburg, MD 20878 DD=01/08/1993 MA= / /
Cytarabine liposomal TN= DepoCyt	Treatment of neoplastic meningitis.	DepoTech Corporation 10450 Science Center Drive San Diego, CA 92121 DD=06/02/1993 MA=04/01/1999
Cytomegalovirus immune globulin (human) TN= CytoGam	Prevention or attenuation of primary cytomegalovirus disease in immunosuppressed recipients of organ transplants.	Massachusetts Public Health Biologic Laboratories 305 South Street Boston, MA 02130 DD=08/03/1987 MA=12/04/1998
Cytomegalovirus immune globulin intravenous (human) TN=	For use in conjunction with ganciclovir sodium for the treatment of cytomegalovirus pneumonia in bone marrow transplant patients.	Bayer Corporation Pharmaceutical Division, Biological Products 400 Morgan Lane New Haven, CT 06516 DD=01/28/1991 MA= / /
DMP 777 TN=	Therapeutic management of patients with lung disease attributable to cystic fibrosis.	DuPont Pharmaceuticals Company Chestnut Run, Maple Run Centre Rd. Wilmington, DE 19805 DD=06/04/1996 MA= / /
Daclizumab TN= Zenapax	Prevention of acute renal allograft rejection.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=03/05/1993 MA=12/10/1997
Dapsone TN=	Prophylaxis of toxoplasmosis in severely immunocompromised patients with CD4 counts below 100.	Jacobus Pharmaceutical Company, Inc. 37 Cleveland Lane P.O. Box 5290 Princeton, NJ 08540 DD=11/07/1994 MA= / /
Dapsone USP TN= Dapsone	Prophylaxis for Pneumocystis carinii pneumonia.	Jacobus Pharmaceutical Company 37 Cleveland Lane P.O. Box 5290 Princeton, NJ 08540 DD=12/24/1991 MA= / /
Dapsone USP TN= Dapsone	For the combination treatment of Pneumocystis carinii pneumonia in conjunction with trimethoprim.	Jacobus Pharmaceutical Company 37 Cleveland Lane P.O. Box 5290 Princeton, NJ 08540 DD=01/08/1992 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name		INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Daunorubicin citrate liposome injection TN= DaunoXome		Treatment of patients with advanced HIV-associated Kaposi's sarcoma.	NeXstar Pharmaceuticals, Inc. 650 Cliffside Drive San Dimas, CA 91773 DD=05/14/1993 MA=04/08/1996
Decitabine TN=		Treatment of myelodysplastic syndromes.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands, NL DD=03/08/1999 MA= / /
Decitabine TN=		Treatment of chronic myelogenous leukemia.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands, NL DD=03/08/1999 MA= / /
Defibrotide TN=		Treatment of thrombotic thrombocytopenic purpura.	Crinos International Via Belvedere 1 Villa Guardia, Italy, 22079 DD=07/05/1985 MA= / /
Dehydroepiandrosterone TN=		Treatment of systemic lupus erythematosus (SLE) and the reduction in the use of steroids in steroid-dependent SLE patients.	Genelabs Technologies, Inc. 505 Penobscot Drive Redwood City, CA 94063 DD=07/13/1994 MA= / /
Dehydroepiandrosterone sulfate sodium TN=		To accelerate the re-epithelialization of donor sites in those hospitalized burn patients who must undergo autologous skin grafting.	Pharmadigm, Inc. 2401 Foothill Drive Salt Lake City, UT 84109 DD=01/28/1997 MA= / /
Dehydroepiandrosterone sulfate sodium TN=		Treatment of serious burns requiring hospitalization.	Pharmadigm, Inc. 2401 Foothill Drive Salt Lake City, UT 84109 DD=01/29/1997 MA= / /
Denileukin diftitox TN= Ontak		Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.	Seragen, Inc. 97 South Street Hopkinton, MA 01748 DD=08/21/1996 MA=02/05/1999
Deslorelin TN= Somagard		Treatment of central precocious puberty.	Roberts Pharmaceutical Corp. Meridian Center II Four Industrial Way West Eatontown, NJ 07724 DD=11/05/1987 MA= / /
Desmopressin acetate TN=		Treatment of mild hemophilia A and von Willebrand's disease.	Rhone-Poulenc Rorer Pharmaceuticals, Inc. 500 Arcola Road Collegeville, PA 19426 DD=01/22/1991 MA=03/07/1994

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Dexamethasone TN=	For use in posterior segment drug delivery system in the treatment of idiopathic intermediate uveitis.	Oculex Pharmaceuticals, Inc. 639 N. Pastoria Avenue Sunnyvale, CA 94086 DD=09/11/1998 MA= / /
Dexrazoxane TN= Zinecard	For the prevention of cardiomyopathy associated with doxorubicin administration.	Pharmacia & Upjohn 7000 Portage Road Kalamazoo, MI 49001 DD=12/17/1991 MA=05/26/1995
Dextran 70 TN= Dehydrex	Treatment of recurrent corneal erosion unresponsive to conventional therapy.	Holles Laboratories, Inc. 30 Forest Notch Cohasset, MA 02025 DD=03/05/1990 MA= / /
Dextran and deferoxamine TN= Bio-Rescue	Treatment of acute iron poisoning.	Biomedical Frontiers, Inc. 1095 10th Avenue S.E. Minneapolis, MN 55414 DD=03/08/1991 MA= / /
Dextran sulfate (inhaled, aerosolized) TN= Uendex	For use as an adjunct to the treatment of cystic fibrosis.	Kennedy & Hoidal, M.D.'s University Of Utah Medical Center 50 North Medical Drive, Room 4R240 Salt Lake City, UT 84132 DD=10/05/1990 MA= / /
Dextran sulfate sodium TN=	Treatment of aquired immunodeficiency syndrome.	Ueno Fine Chemicals Industry, Ltd. 2-31 Koraibashi, Higashi-ku Osaka 541, Japan, DD=11/19/1987 MA= / /
Dianeal peritoneal dialysis solution with 1.1% amino acids TN= Nutrineal (Peritoneal Dialysis Solution with 1.1% Amino Acid	For use as a nutritional supplement for the treatment of malnourishment in patients undergoing continuous ambulatory peritoneal dialysis.	Baxter Healthcare Corporation 1620 Waukegan Road McGaw Park, IL 60085 DD=06/11/1992 MA= / /
Diazepam viscous solution for rectal administration TN=	For the management of selected, refractory, patients with epilepsy, on stable regimens of antiepileptic drugs (AEDs), who require intermittent use of diazepam to control bouts of increased seizure activity.	Athena Neurosciences, Inc. 800f Gateway Boulevard South San Francisco, CA 94080 DD=02/25/1992 MA=07/29/1997
Diethyldithiocarbamate TN= Imuthiol	Treatment of AIDS.	Connaught Laboratories Route 611, P.O. Box 187 Swiftwater, PA 18370 DD=04/03/1986 MA= / /
Digoxin immune FAB (Ovine) TN= Digibind	Treatment of potentially life threatening digitalis intoxication in patients who are refractory to management by conventional therapy.	Glaxo Wellcome Inc. 5 Moore Drive Research Triangle Park, NC 27709 DD=11/01/1984 MA=04/22/1986

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Digoxin immune fab(ovine) TN= Digidote	Treatment of life-threatening acute cardiac glycoside intoxication manifested by conduction disorders, ectopic ventricular activity and (in some cases) hyperkalemia.	Boehringer Mannheim Corp. 1301 Piccard Drive Rockville, MD 20850 DD=03/11/1985 MA= / /
Dihydrotestosterone TN= Androgel -DHT	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=02/05/1996 MA= / /
Dimethyl sulfoxide TN=	Treatment of increased intracranial pressure in patients with severe, closed-head injury, also known as traumatic brain coma, for whom no other effective treatment is available.	Pharma 21 c/o Univ. of Calif., San Diego 9500 Gilman Dr. La Jolla, CA 92093 DD=11/22/1994 MA= / /
Dimethylsulfoxide TN=	Topical treatment for the prevention of soft tissue injury following extravasation of cytotoxic drugs.	Cancer Technologies, Inc. 7301 East 22nd Street Suite 10E Tucson, AZ 85710 DD=04/15/1997 MA= / /
Dimethylsulfoxide TN=	Treatment of palmar-plantar erythrodysesthesia syndrome.	Cancer Technologies, Inc. 7301 East 22nd Street Suite 10E Tucson, AZ 85710 DD=04/06/1998 MA= / /
Dipalmitoylphosphatidylcholine /phosphatidylglycerol TN= ALEC	Prevention and treatment of neonatal respiratory distress syndrome.	Forum Products, Inc. 33 Flying Point Road Southampton, NY 11968 DD=07/28/1988 MA= / /
Disaccharide tripeptide glycerol dipalmitoyl TN= Immther	Treatment of pulmonary and hepatic metastases in patients with colorectal adenocarcinoma.	ImmunoTherapeutics, Inc. 3505 Riverview Circle Moorhead, MN 56560 DD=03/01/1990 MA= / /
Disodium clodronate TN=	Treatment of hypercalcemia of malignancy.	Discovery Experimental & Development, Inc. 29949 S.R. 54 West Wesley Chapel, FL 33543 DD=06/16/1993 MA= / /
Disodium clodronate tetrahydrate TN= Bonefos	Treatment of increased bone resorption due to malignancy.	Anthra Pharmaceuticals, Inc. 103 Carnegie Center, Suite 102 Princeton, NJ 08540 DD=03/05/1990 MA= / /
Dornase alfa TN= Pulmozyme	To reduce mucous viscosity and enable the clearance of airway secretions in patients with cystic fibrosis.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=01/16/1991 MA=12/30/1993

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Doxorubicin liposome TN= Doxil	Treatment of ovarian cancer.	Alza Corporation 1550 Plymouth St. PO Box 7210 Mountain View, CA 94039 DD=11/04/1998 MA=06/28/1999
Dronabinol TN= Marinol	For the stimulation of appetite and prevention of weight loss in patients with a confirmed diagnosis of AIDS.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road, Suite 210 Buffalo Grove, IL 60089 DD=01/15/1991 MA=12/22/1992
Duramycin TN=	Treatment of cystic fibrosis.	MoliChem Medicines Inc. 2135 North Lakeshore Drive Chapel Hill, NC 27514 DD=12/11/1997 MA= / /
Dynamine TN=	Treatment of Lambert Eaton myasthenic syndrome.	Mayo Foundation 200 First Street Southwest Rochester, MN 55905 DD=02/05/1990 MA= / /
Dynamine TN=	Treatment of hereditary motor and sensory neuropathy type I (Charcot-Marie-Tooth disease).	Mayo Foundation 200 First Street Southwest Rochester, MN 55905 DD=10/16/1991 MA= / /
Eflornithine HCl TN= Ornidyl	Treatment of Trypanosoma brucei gambiense infection (sleeping sickness).	Hoechst Marion Roussel P.O. Box 9627 Kansas City, MO 64134 DD=04/23/1986 MA=11/28/1990
Elcatonin TN=	Intrathecal treatment of intractable pain.	Innapharma, Inc. 10 Mountainview Road Upper Saddle River, NJ 07458 DD=09/25/1995 MA= / /
Enadoline hydrochloride TN=	Treatment of severe head injury.	Warner-Lambert Company Parke-Davis Pharmaceutical Research Division 2800 Plymouth Road Ann Arbor, MI 48105 DD=01/28/1997 MA= / /
Encapsulated porcine islet preparation TN= BetaRx	Treatment of type I diabetic patients who are already on immunosuppression.	VivoRx 2825 Santa Monica Blvd. 2nd Floor Santa Monica, CA 90404 DD=07/05/1995 MA= / /
Epidermal growth factor (human) TN=	For acceleration of corneal epithelial regeneration and the healing of stromal tissue in the condition of non-healing corneal defects.	Chiron Vision 500 Iolab Drive Claremont, CA 91711 DD=10/05/1987 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Epirubicin TN= Ellence	Treatment of breast cancer.	Pharmacia & Upjohn Company 0634-298-113 7000 Portage Rd. Kalamazoo, MI 49001 DD=09/14/1999 MA=09/15/1999
Epoetin alfa TN= Epogen	Treatment of anemia associated with end stage renal disease.	Amgen, Inc. 1840 Dehavilland Drive Thousand Oaks, CA 91320 DD=04/10/1986 MA=06/01/1989
Epoetin alfa TN= Epogen	Treatment of anemia associated with HIV infection or HIV treatment.	Amgen, Inc. 1840 Dehavilland Drive Thousand Oaks, CA 91320 DD=07/01/1991 MA=12/31/1990
Epoetin alfa TN=	Treatment of myelodysplastic syndrome.	R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan, NJ 08869 DD=12/20/1993 MA= / /
Epoetin alpha TN= Procrit	Treatment of anemia associated with end stage renal disease.	R. W. Johnson Pharmaceutical Research Institute Route 202 South P.O. Box 300 Raritan, NJ 08869 DD=08/27/1987 MA= / /
Epoetin alpha TN= Procrit	Treatment of anemia of prematurity in preterm infants.	R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan, NJ 08869 DD=07/21/1988 MA= / /
Epoetin alpha TN= Procrit	Treatment of HIV associated anemia related to HIV infection or HIV treatment.	R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan, NJ 08869 DD=03/07/1989 MA= / /
Epoetin beta TN= Marogen	Treatment of anemia associated with end stage renal disease.	Chugai-USA, Inc. 3780 Hawthorn Court Waukegan, IL 60087 DD=10/22/1987 MA= / /
Epoprostenol TN= Flolan	Treatment of primary pulmonary hypertension.	Glaxo Wellcome Inc. 5 Moore Drive Research Triangle Park, NC 27709 DD=09/25/1985 MA=09/20/1995

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Epoprostenol TN= Flolan	Treatment of secondary pulmonary hypertension due to intrinsic precapillary pulmonary vascular disease.	Glaxo Wellcome Inc. Five Moore Dr. PO Box 13398 Research Triangle Park, NC 27709 DD=03/22/1999 MA= / /
Erwinia L-asparaginase TN= Erwinase	Treatment of acute lymphocytic leukemia.	Porton International, Inc. 1155 15th Street, N.W., #315 Washington, DC 20005 DD=07/30/1986 MA= / /
Erythropoietin (recombinant human) TN=	Treatment of anemia associated with end stage renal disease.	McDonnell Douglas Corp P.O. Box 516, 107/2 MS10 St. Louis, MO 63166 DD=08/19/1987 MA= / /
Etanercept TN= Enbrel	Reduction in signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=10/27/1998 MA=05/27/1999
Etanercept TN= Enbrel	Treatment of Wegener's granulomatosis.	Immunex Corporation 51 University Street Seattle, WA 98101 DD=04/06/1999 MA= / /
Ethanolamine oleate TN= Ethamolin	Treatment of patients with esophageal varices that have recently bled, to prevent rebleeding.	Block Drug Company, Inc. 257 Cornelison Avenue Jersey City, NJ 07302 DD=03/22/1984 MA=12/22/1988
Etidronate disodium TN= Didronel	Treatment of hypercalcemia of malignancy inadequately managed by dietary modification and/or oral hydration.	MGI Pharma, Inc. 6300 West Old Shakoppe Rd. Suite 110 Bloomington, MN 55438 DD=03/21/1986 MA=04/21/1987
Etiololanedione TN=	Treatment of aplastic anemia.	SuperGen, Inc. Two Annabel Lane, Suite 220 Suite 10 San Ramon, CA 94583 DD=11/03/1995 MA= / /
Etiololanedione TN=	Treatment of Prader-Willi syndrome.	SuperGen, Inc. Two Annabel Lane, Suite 220 San Ramon, CA 94583 DD=05/07/1996 MA= / /
Exemestane TN= Aromasin	Treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.	Pharmacia & Upjohn 7000 Portage Road Mail Stop: 0636-298-113 Kalamazoo, MI 49001 DD=09/19/1991 MA=10/21/1999

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Exisulind TN=	For the suppression and control of colonic adenomatous polyps in the inherited disease adenomatous polyposis coli.	Cell Pathways, Inc. 702 Electronic Drive Horsham, PA 19044 DD=02/14/1994 MA= / /
FIAU TN=	Adjunctive treatment of chronic active hepatitis B.	Oclassen Pharmaceuticals, Inc. 100 Pelican Way San Rafael, CA 94901 DD=07/24/1992 MA= / /
Factor XIII (human, 'pasteurized) TN= Fibrogammin P	Treatment of congenital factor XIII deficiency.	Centeon Pharma GmbH Postfach 1140 D-35001 Marburg Germany, DE DD=01/16/1985 MA= / /
Fampridine TN= Neurelan	Relief of symptoms of multiple sclerosis.	Acorda Therapeutics 15 Skyline Dr. Hawthorne, NY 10532 DD=06/02/1987 MA= / /
Fampridine TN= Neurelan	Treatment of chronic, incomplete spinal cord injury.	Acorda Therapeutics, Inc. 15 Skyline Dr. Hawthorne, NY 10532 DD=06/02/1997 MA= / /
Felbamate TN= Felbatol	Treatment of Lennox-Gastaut syndrome.	Wallace Laboratories 301B College Road East Princeton, NJ 08540 DD=01/24/1989 MA=07/29/1993
Fibrinogen (human) TN=	For the control of bleeding and prophylactic treatment of patients deficient in fibrinogen.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=08/23/1995 MA= / /
Fibronectin (human plasma derived) TN=	Treatment of non-healing corneal ulcers or epithelial defects which have been unresponsive to conventional therapy and the underlying cause has been eliminated.	Melville Biologics, Inc. 310 East 67th Street New York, NY 10021 DD=09/05/1988 MA= / /
Filgrastim TN= Neupogen	Treatment of patients with severe chronic neutropenia (absolute neutrophil count less than 500/mm3).	Amgen, Inc. 1840 Dehavilland Drive Thousand Oaks, CA 91320 DD=11/07/1990 MA=12/19/1994
Filgrastim TN= Neupogen	Treatment of patients with AIDS who, in addition, are afflicted with cytomegalovirus retinitis and are being treated with ganciclovir.	Amgen, Inc. One Amgen Center Dr. Thousand Oaks, CA 91320 DD=09/03/1991 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Filgrastim TN= Neupogen	Treatment of neutropenia associated with bone marrow transplants.	Amgen, Inc. 1840 Dehavilland Drive Thousand Oaks, CA 91320 DD=10/01/1990 MA=06/15/1994
Filgrastim TN= Neupogen	For use in the mobilization of peripheral blood progenitor cells for collection in patients who will receive myeloablative or myelosuppressive chemotherapy.	Amgen, Inc. 1840 Dehavilland Drive Thousand Oaks, CA 91320 DD=07/17/1995 MA=12/28/1995
Filgrastim TN= Neupogen	Reduction in the duration of neutropenia, fever, antibiotic use, and hospitalization, following induction and consolidation treatment for acute myeloid leukemia.	Amgen, Inc. One Amgen Center Dr. Thousand Oaks, CA 91320 DD=11/07/1996 MA=04/02/1998
Fludarabine phosphate TN= Fludara	Treatment of chronic lymphocytic leukemia (CLL), including refractory CLL.	Berlex Laboratories, Inc. 15049 San Pablo Avenue, P.O. Box 4099 Richmond, CA 94804 DD=04/18/1989 MA=04/18/1991
Fludarabine phosphate TN= Fludara	Treatment and management of patients with non-Hodgkins lymphoma.	Berlex Laboratories, Inc. 15049 San Pablo Avenue P.O. Box 4099 Richmond, CA 94804 DD=04/18/1989 MA= / /
Flumecinol TN= Zixoryn	Treatment of hyperbilirubinemia in newborn infants unresponsive to phototherapy.	Farmacon, Inc. 90 Grove Street, Suite 109 Ridgefield, CT 06877 DD=01/15/1985 MA= / /
Flunarizine TN= Sibelium	Treatment of alternating hemiplegia.	Janssen Research Foundation P.O. Box 200 Titusville, NJ 08560 DD=01/06/1986 MA= / /
Fluorouracil TN= Adrucil	For use in combination with leucovorin for therapy of metastatic adenocarcinoma of the colon and rectum.	Lederle Laboratories Division of American Cyanamid Company 401 N. Middletown Road Pearl River, NY 10965 DD=02/06/1989 MA= / /
Fluorouracil TN=	For use in combination with interferon alpha-2a, recombinant, for the treatment of esophageal carcinoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=10/27/1989 MA= / /
Fluorouracil TN=	For use in combination with interferon alpha-2a, recombinant, for the treatment of advanced colorectal carcinoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=04/18/1990 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Fluoxetine TN= Prozac	Treatment of autism.	Hollander, MD, Eric Mt. Sinai School of Medicine, Dept. of Psychiatry Box 1230, One Gustave L. Levy Place New York, NY 10029 DD=04/30/1999 MA= / /
Follitropin alfa, recombinant TN= Gonal-F	For the initiation and re-initiation of spermatogenesis in adult males with reproductive failure due to hypothalamic or pituitary dysfunction, hypogonadotropic hypogonadism.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=12/21/1998 MA= / /
Fomepizole TN= Antizole	Treatment of methanol or ethylene glycol poisoning.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=12/22/1988 MA=12/04/1997
Fosphenytoin TN= Cerebyx	For the acute treatment of patients with status epilepticus of the grand mal type.	Warner-Lambert Company 2800 Plymouth Road Ann Arbor, MI 48106 DD=06/04/1991 MA=08/05/1996
Fructose-1,6-diphosphate TN= Cordox	Treatment of painful vaso-occlusive episodes associated with sickle cell disease.	Cypros Pharmaceutical Corporation 2714 Loker Avenue West Carlsbad, CA 92008 DD=05/29/1998 MA= / /
Gabapentin TN= Neurontin	Treatment of amyotrophic lateral sclerosis.	Warner-Lambert Company Parke-Davis Pharmaceutical Research Division 2800 Plymouth Road Ann Arbor, MI 48105 DD=07/05/1995 MA= / /
Gamma hydroxybutyrate TN=	Treatment of narcolepsy and the auxiliary symptoms of cataplexy, sleep paralysis, hypnagogic hallucinations and automatic behavior.	Biocraft Laboratories, Inc. 18-01 River Road Fair Lawn, NJ 07410 DD=12/22/1987 MA= / /
Gammalinolenic acid TN=	Treatment of juvenile rheumatoid arthritis.	Zurier, Robert B. M.D. University of Massachusetts Medical Center 55 Lake Avenue Worcester, MA 01655 DD=07/27/1994 MA= / /
Ganaxolone TN=	Treatment of infantile spasms.	CoCensys, Inc. 201 Technology Drive , 92618 DD=05/25/1994 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Ganciclovir intravitreal implant TN= Vitrasert Implant	Treatment of cytomegalovirus retinitis.	Bausch & Lomb Surgical, Chiron Vision Products 9342 Jeronimo Road Irvine, CA 92718 DD=06/07/1995 MA=03/04/1996
Gemtuzumab zogamicin TN=	Treatment of CD33-positive acute myeloid leukemia.	Wyeth-Ayerst Laboratories PO Box 8299 Philadelphia, PA 19101 DD=11/24/1999 MA= / /
Gentamicin impregnated PMMA beads on surgical wire TN= Septopal	Treatment of chronic osteomyelitis of post-traumatic, postoperative, or hematogenous origin.	Lipha Pharmaceuticals, Inc. 9 West 57th Street Suite 3825 New York, NY 10019 DD=01/31/1991 MA= / /
Gentamicin liposome injection TN= Maitec	Treatment of disseminated Mycobacterium avium-intracellulare infection.	Liposome Company, Inc. One Research Way Princeton, NJ 08540 DD=07/10/1990 MA= / /
Glatiramer acetate TN= Copaxone	Treatment of multiple sclerosis.	Teva Pharmaceuticals USA 1510 Delp Drive Kulpsville, PA 19443 DD=11/09/1987 MA=12/20/1996
Glutamine TN=	For use with human growth hormone in the treatment of short bowel syndrome (nutrient malabsorption from the gastrointestinal tract resulting from an inadequate absorptive surface).	Nutritional Restart Pharmaceutical, L.P. 4364 South Alston Avenue Durham, NC 27713 DD=03/06/1995 MA= / /
Glyceryl trioleate and glyceryl trierucate TN=	Treatment of adrenoleukodystrophy.	Moser, Hugo W. M.D. Johns Hopkins University Kennedy Krieger Institute, 707 North Broadway Baltimore, MD 21205 DD=02/14/1995 MA= / /
Gonadorelin acetate TN= Lutrepulse	For induction of ovulation in women with hypothalamic amenorrhea due to a deficiency or absence in the quantity or pulse pattern of endogenous GnRH secretion.	Ferring Laboratories, Inc. 400 Rella Boulevard, Suite 201 Suffern, NY 10901 DD=04/22/1987 MA=10/10/1989
Gossypol TN=	Treatment of cancer of the adrenal cortex.	Reidenberg, Marcus M. M.D. The New York Hospital - Cornell Medical Center 525 East 68th Street, Box 70 New York, NY 10021 DD=10/22/1990 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Gp100 adenoviral gene therapy TN=	Treatment of metastatic melanoma.	Genzyme Corporation One Mountain Rd. P.O. Box 9322 Framingham, MA 01701 DD=03/25/1997 MA= / /
Growth hormone releasing factor TN=	For the long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.	ICN Pharmaceuticals, Inc. ICN Plaza 3300 Hyland Avenue Costa Mesa, CA 92626 DD=08/07/1989 MA= / /
Guanfacine TN= Tenex	Treatment of fragile X syndrome.	Watson Laboratories, Inc. 311 Bonnie Circle PO Box 1900 Corona, CA 91718 DD=08/05/1999 MA= / /
HLA-B7/Beta2M DNA Lipid (DMRIE/DOPE) Complex TN= Allovectin-7	Treatment of invasive and metastatic melanoma (Stages II, III, and IV).	Vical Incorporated 9373 Towne Centre Dr., Suite 100 San Diego, CA 92121 DD=09/30/1999 MA= / /
Halofantrine TN= Halfan	Treatment of mild to moderate acute malaria caused by susceptible strains of <i>P. falciparum</i> and <i>P. vivax</i> .	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=11/04/1991 MA=07/24/1992
Heme arginate TN= Normosang	Treatment of symptomatic stage of acute porphyria.	Leiras, Inc. 15049 San Pablo Avenue Richmond, CA 94804 DD=03/10/1988 MA= / /
Heme arginate TN= Normosang	Treatment of myelodysplastic syndromes.	Leiras, Inc. 15049 San Pablo Avenue Richmond, CA 94804 DD=03/01/1994 MA= / /
Hemin TN= Panhematin	Amelioration of recurrent attacks of acute intermittent porphyria (AIP) temporarily related to the menstrual cycle in susceptible women and similar symptoms which occur in other patients with AIP, porphyria variegata and hereditary coproporphyria.	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 DD=03/16/1984 MA=07/20/1983
Hemin and zinc mesoporphyrin TN= Hemex	Treatment of acute porphyric syndromes.	Bonkovsky, Herbert L. M.D. University Of Massachusetts Medical Center 55 Lake Avenue North Worcester, MA 01655 DD=12/20/1993 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Hepatitis B immune globulin intravenous (human) TN= Nabi-HB	Prophylaxis against hepatitis B virus reinfection in liver transplant patients.	NABI 12280 Wilkins Avenue Rockville, MD 20852 DD=03/08/1995 MA= / /
Herpes simplex virus gene TN=	Treatment of primary and metastatic brain tumors.	Genetic Therapy, Inc. 938 Clopper Road Gaithersburg, MD 20878 DD=10/16/1992 MA= / /
Histamine TN= Maxamine	Adjunct to cytokine therapy in the treatment of acute myeloid leukemia.	Maxim Pharmaceuticals, Inc. 8899 University Center Lane Suite 400 San Diego, CA 92122 DD=12/15/1999 MA= / /
Histrelin TN=	Treatment of acute intermittent porphyria, hereditary coproporphyrinuria, and variegate porphyria.	Anderson, Karl E., M.D. University of Texas Medical Branch at Galveston Route J-09, 700 The Strand Galveston, TX 77550 DD=05/03/1991 MA= / /
Histrelin acetate TN= Supprelin Injection	Treatment of central precocious puberty.	Roberts Pharmaceutical Corp. Meridian Center III 6 Industrial Way West Eatontown, NJ 07724 DD=08/10/1988 MA=12/24/1991
Human T-lymphotropic virus type III Gp160 antigens TN= Vaxsyn HIV-1	Treatment of AIDS.	MicroGeneSys, Inc. 1000 Research Parkway Meriden, CT 06450 DD=11/20/1989 MA= / /
Human acid precursor alpha-glucosidase, recombinant TN=	Treatment of glycogen storage disease type II.	Pharming/Genzyme LLC c/o Genzyme Corporation 5 Mountain Rd. Framingham, MA 01701 DD=09/10/1996 MA= / /
Human immunodeficiency virus immune globulin TN=	Treatment of AIDS.	NABI 5800 Park of Commerce Blvd., N.W. Boca Raton, FL 33487 DD=11/21/1989 MA= / /
Human immunodeficiency virus immune globulin TN=	Treatment of HIV-infected pregnant women and infants of HIV-infected mothers.	NABI 5800 Park of Commerce Blvd., N.W. Boca Raton, FL 33487 DD=03/25/1992 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Human immunodeficiency virus immune globulin TN= Hivig	Treatment of HIV-infected pediatric patients.	NABI 5800 Park of Commerce Blvd., N.W. Boca Raton, FL 33487 DD=01/04/1995 MA= / /
Human retinal pigmented epithelial cells on collagen microcarriers TN= Spheramine	Treatment of Hoehn and Yahr stage 3 and 4 Parkinson's disease.	Titan Pharmaceuticals, Inc. Post Office Plaza 50 Division Street, Suite 503 Somerville, NJ 08876 DD=07/18/1997 MA= / /
Humanized MAb (IDEC-131) to CD40L TN=	Treatment of systemic lupus erythematosus.	Idec Pharmaceuticals Corporation 3030 Callan Rd. San Diego, CA 92121 DD=02/09/1999 MA= / /
Humanized anti-CD2 monoclonal antibody TN=	Treatment of graft-versus-host disease.	MedImmune, Inc. 35 West Watkins Mill Rd. Gaithersburg, MD 20878 DD=11/13/1998 MA= / /
Humanized anti-human CD2 MAb TN= MEDI-507	For the induction of donor-specific immunologic unresponsiveness resulting in prophylaxis of organ rejection without the need for chronic immunosuppressive therapy, in patients receiving allogeneic renal transplants.	Biotransplant, Inc. Building 75, 3rd. Ave. Charlestown Navy Yard Charlestown, MA 02129 DD=09/17/1998 MA= / /
Humanized anti-tac TN= Zenapax	Prevention of acute graft-vs-host disease following bone marrow transplantation.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=03/05/1993 MA= / /
Hydroxycobalamin/sodium thiosulfate TN=	Treatment of severe acute cyanide poisoning.	Hall, Alan H. M.D. Medical Technology 6300 South Syracuse Way, Suite 300 Englewood, CO 80111 DD=10/04/1985 MA= / /
Hydroxyurea TN= Droxia	Treatment of patients with sickle cell anemia as shown by the presence of hemoglobin S.	Bristol-Myers Squibb Pharmaceutical Research Institute P.O. Box 4000 Princeton, NJ 08543 DD=10/01/1990 MA=02/25/1998
Ibuprofen i.v. solution TN= Salprofen	Prevention of patent ductus arteriosus.	Farmacon, Inc. 90 Grove Street, Suite 109 Ridgefield, CT 06877 DD=10/29/1996 MA= / /
Ibuprofen i.v. solution TN=	Treatment of patent ductus arteriosus.	Farmacon, Inc. Post House, Suite 213 1720 Post Road East Westport, CT 06880 DD=10/29/1996 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Icodextrin 7.5% with Electrolytes Peritoneal Dialysis Solution TN= Extraneal (with 7.5% Icodextrin) Peritoneal Dialysis Solutio	Treatment of those patients having end stage renal disease and requiring peritoneal dialysis treatment.	Baxter Healthcare Corporation Renal Division 1620 Waukegan Road McGaw Park, IL 60085 DD=07/18/1997 MA= / /
Idarubicin HCl for injection TN= Idamycin	Treatment of acute myelogenous leukemia, also referred to as acute nonlymphocytic leukemia.	Adria Laboratories, Inc. P.O. Box 16529 Columbus, OH 43216 DD=07/25/1988 MA=09/27/1990
Idarubicin HCl for injection TN= Idamycin	Treatment of acute lymphoblastic leukemia in pediatric patients.	Pharmacia & Upjohn 7000 Portage Road Unit 0633-298-113 Kalamazoo, MI 49001 DD=02/12/1991 MA= / /
Idoxuridine TN=	Treatment of nonparenchymatous sarcomas.	NeoPharm, Inc. 225 East Deerpath, Suite 250 Lake Forest, IL 60045 DD=04/08/1996 MA= / /
Ifosfamide TN= Ifex	Treatment of bone sarcomas.	Bristol-Myers Squibb Pharmaceutical Research Institute P.O. Box 4000 Princeton, NJ 08543 DD=08/07/1985 MA= / /
Ifosfamide TN= Ifex	Treatment of soft tissue sarcomas.	Bristol-Myers Squibb Pharmaceutical Research Institute P.O. Box 4000 Princeton, NJ 08543 DD=08/07/1985 MA= / /
Ifosfamide TN= Ifex	Treatment of testicular cancer.	Bristol-Myers Squibb Pharmaceutical Research Institute 5 Research Parkway, P.O. Box 5100 Wallingford, CT 06492 DD=01/20/1987 MA=12/30/1988
Imciromab pentetate TN= Myoscint	Detecting early necrosis as an indication of rejection of orthotopic cardiac transplants.	Centocor, Inc. 244 Great Valley Parkway Malvern, PA 19355 DD=01/25/1989 MA= / /
Imexon TN=	Treatment of multiple myeloma.	AmpliMed Corporation 2321 Camino La Zorrela Tucson, AZ 85718 DD=11/08/1996 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Imiglucerase TN= Cerezyme	Replacement therapy in patients with types I, II, and III Gaucher's disease.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=11/05/1991 MA=05/23/1994
Immune globulin intravenous, human TN= Gamimune N	Infection prophylaxis in pediatric patients affected with the human immunodeficiency virus.	Bayer Corporation Pharmaceutical Division, Biological Products 400 Morgan Lane New Haven, CT 06516 DD=02/18/1993 MA=12/27/1993
Imported fire ant venom, allergenic extract TN=	For skin testing of victims of fire ant stings to confirm fire ant sensitivity and if positive, for use as immunotherapy for the prevention of IgE-mediated anaphylactic reactions.	ALK Laboratories, Inc. Research Center 27 Village Lane Wallingford, CT 06492 DD=05/12/1992 MA= / /
Indium In 111 murine monoclonal antibody FAB to myosin TN= Myoscint	To aid in the diagnosis of myocarditis.	Centocor, Inc. 244 Great Valley Parkway Malvern, PA 19355 DD=08/07/1989 MA= / /
Indium-In-111 murine MAb(2B8-MX-DTPA) & Yttrium-Y90 murine MAb(2B8-MX-DTPA) TN= Melimmune	Treatment of B-cell non-Hodgkin's lymphoma.	IDEC Pharmaceuticals Corporation 3030 Callan Road San Diego, CA 92121 DD=09/06/1994 MA= / /
Infliximab TN= Remicade	Treatment of moderately to severely active Crohn's disease for the reduction of the signs and symptoms, in patients who have an inadequate response to conventional therapy; and treatment of patients with fistulizing Crohn's disease for the reduction in the number of draining enterocutaneous fistula(s).	Centocor, Inc. 200 Great Valley Parkway Malvern, PA 19355 DD=11/14/1995 MA=08/24/1998
Inosine pranobex TN= Isoprinosine	Treatment of subacute sclerosing panencephalitis.	Newport Pharmaceuticals 897 West Sixteenth Street Newport Beach, CA 92663 DD=09/20/1988 MA= / /
Interferon Beta-1a TN= Avonex	Treatment of juvenile rheumatoid arthritis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=10/14/1998 MA= / /
Interferon alfa-2a TN= Roferon A	Treatment of chronic myelogenous leukemia.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=06/06/1989 MA=10/19/1995

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Interferon alfa-2a (recombinant) TN= Roferon-A	Treatment of AIDS related Kaposi's sarcoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=12/14/1987 MA=11/21/1988
Interferon alfa-2a (recombinant) TN= Roferon-A	Treatment of renal cell carcinoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=04/18/1988 MA= / /
Interferon alfa-2a (recombinant) TN= Roferon-A	For use in combination with fluorouracil for the treatment of esophageal carcinoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=10/27/1989 MA= / /
Interferon alfa-2a (recombinant) TN= Roferon-A	For the concomitant administration with fluorouracil for the treatment of advanced colorectal cancer.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=05/14/1990 MA= / /
Interferon alfa-2a (recombinant) TN= Roferon-A	For the concomitant administration with Tecleukin for the treatment of metastatic renal cell carcinoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07119 DD=05/02/1990 MA= / /
Interferon alfa-2a (recombinant) TN= Roferon-A	For the treatment of metastatic malignant melanoma in combination with Tecleukin.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=05/11/1990 MA= / /
Interferon alfa-2b (recombinant) TN= Intron A	Treatment of AIDS-related Kaposi's sarcoma.	Schering Corporation 2000 Galloping Hill Road Kenilworth, NJ 07033 DD=06/24/1987 MA=11/21/1988
Interferon beta (recombinant human) TN= Avonex	Treatment of primary brain tumors.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=01/13/1993 MA= / /
Interferon beta-1a TN= Avonex	Treatment of multiple sclerosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=12/16/1991 MA=05/17/1996
Interferon beta-1a TN= Rebif	Treatment of patients with secondary progressive multiple sclerosis.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/11/1996 MA= / /
Interferon beta-1a (recombinant human) TN=	Treatment of acute non-A, non-B hepatitis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=07/24/1992 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name		INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Interferon beta-1a (recombinant human) TN= Avonex		Treatment of pulmonary fibrosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=01/07/1999 MA= / /
Interferon beta-1a (recombinant) TN= Rebif		Treatment of symptomatic patients with AIDS including all patients with CD4 T-cell counts less than 200 cells per mm ³ .	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=12/02/1992 MA= / /
Interferon beta-1b TN= Betaseron		Treatment of multiple sclerosis.	Chiron Corp. & Berlex Laboratories 4560 Horton Street Emeryville, CA 94608 DD=11/17/1988 MA=07/23/1993
Interferon gamma 1-b TN= Actimmune		Treatment of chronic granulomatous disease.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=09/30/1988 MA=12/20/1990
Interferon gamma-1b TN= Actimmune		Treatment of renal cell carcinoma.	Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 DD=12/04/1995 MA= / /
Interferon gamma-1b TN= Actimmune		Treatment of severe congenital osteopetrosis.	InterMune Pharmaceuticals, Inc. 2483 East Bayshore Rd., #103 Palo Alto, CA 94303 DD=09/30/1996 MA= / /
Interleukin-1 receptor antagonist, human recombinant TN= Antril		Treatment of juvenile rheumatoid arthritis.	Amgen, Inc. 1840 DeHavilland Drive Thousand Oaks, CA 91320 DD=09/23/1991 MA= / /
Interleukin-1 receptor antagonist, human recombinant TN= Antril		Prevention and treatment of graft versus host disease in transplant recipients.	Amgen, Inc. 1840 DeHavilland Dr. Thousand Oaks, CA 91320 DD=10/16/1992 MA= / /
Interleukin-2 TN= Teceleukin		Treatment of metastatic renal cell carcinoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=02/05/1990 MA= / /
Interleukin-2 TN= Teleleukin		Treatment of metastatic malignant melanoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=02/06/1990 MA= / /
Interleukin-2 TN= Teceleukin		In combination with interferon alfa-2a for the treatment of metastatic renal cell carcinoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=05/03/1990 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name		INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Interleukin-2 TN= Teceleukin		In combination with interferon alfa-2a for the treatment of metastatic malignant melanoma.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=05/11/1990 MA= / /
Iobenguane Sulfate I 131 TN=		For use as a diagnostic adjunct in patients with pheochromocytoma.	CIS-US, Inc. 10 De Angelo Drive Bedford, MA 01730 DD=11/14/1984 MA=03/25/1994
Iodine 131 6B-iodomethyl-19-norcholesterol TN=		For use in adrenal cortical imaging.	Beierwaltes, William M.D. University of Michigan Medical Center B1G412 /0028 University Hospital Ann Arbor, MI 48109 DD=08/01/1984 MA= / /
Iodine I 123 murine monoclonal antibody to alpha-fetoprotein TN=		Detection of hepatocellular carcinoma and hepatoblastoma.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=09/30/1988 MA= / /
Iodine I 123 murine monoclonal antibody to alpha-fetoprotein TN=		Detection of alpha-fetoprotein producing germ cell tumors.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=09/30/1988 MA= / /
Iodine I 123 murine monoclonal antibody to hCG TN=		Detection of hCG producing tumors such as germ cell and trophoblastic cell tumors.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=11/07/1988 MA= / /
Iodine I 131 murine monoclonal antibody IgG2a to B cell TN= Immurait, LI-2-I-131		Treatment of B-cell leukemia and B-cell lymphoma.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=09/18/1989 MA= / /
Iodine I 131 murine monoclonal antibody to alpha-fetoprotein TN=		Treatment of hepatocellular carcinoma and hepatoblastoma.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=09/30/1988 MA= / /
Iodine I 131 murine monoclonal antibody to alpha-fetoprotein TN=		Treatment of alpha-fetoprotein producing germ cell tumors.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=09/30/1988 MA= / /
Iodine I 131 murine monoclonal antibody to hCG TN=		Treatment of hCG producing tumors such as germ cell and trophoblastic cell tumors.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=11/07/1988 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name		INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Iodine I-131 radiolabeled chimeric MAb tumor necrosis treatment (TNT-1B) TN= 131IchTNT-1		Treatment of glioblastoma multiforme and anaplastic astrocytoma.	Techniclone Corporation 14282 Franklin Ave. Tustin, CA 92780 DD=02/12/1999 MA= / /
Isobutyramide TN= Isobutyramide oral solution		Treatment of beta-hemoglobinopathies and beta-thalassemia syndromes.	Perrine, Susan P., M.D. Boston University Cancer Research Center Boston, MA 02118 DD=12/18/1992 MA= / /
Isobutyramide TN=		Treatment of sickle cell disease and beta thalassemia.	Alpha Therapeutic Corporation 5555 Valley Boulevard Los Angeles, CA 90032 DD=05/25/1994 MA= / /
Japanese encephalitis vaccine (live, attenuated) TN=		Prevention of Japanese encephalitis.	Boran Pharmaceuticals 3F, Koryo Academytel, 437-3 Ahyun-Dong, Mapo-Gu, Seoul 121-010 South Korea, KR DD=05/19/1999 MA= / /
L-2-oxothiazolidine-4-carboxyli c acid TN= Procysteine		Treatment of adult respiratory distress syndrome.	Transcend Therapeutics, Inc. 640 Memorial Drive, 3rd Floor West Cambridge, MA 02139 DD=06/14/1994 MA= / /
L-2-oxothiazolidine-4-carboxyli c acid TN= Procysteine		Treatment of amyotrophic lateral sclerosis.	Transcend Therapeutics, Inc. 640 Memorial Drive, 3rd Floor West Cambridge, MA 02139 DD=07/30/1996 MA= / /
L-5 hydroxytryptophan TN=		Treatment of postanoxic intention myoclonus.	Circa Pharmaceuticals, Inc. 33 Ralph Avenue P.O. Box 30 Copiague, NY 11726 DD=11/01/1984 MA= / /
L-5-hydroxytryptophan TN=		Treatment of tetrahydrobiopterin deficiency.	Watson Laboratories, Inc. 311 Bonnie Circle P.O. Box 1900 Corona, CA 91718 DD=01/20/1999 MA= / /
L-baclofen TN=		Treatment of trigeminal neuralgia.	Fromm, Gerhard M.D. University Of Pittsburgh School of Medicine Pittsburgh, PA 15261 DD=07/13/1990 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
L-baclofen TN= Neuralgon	Treatment of intractable spasticity associated with spinal cord injury or multiple sclerosis.	Pharmascience Laboratories 8400 Darnley Road Montreal, Quebec H4T 1M4 Canada, DD=12/17/1991 MA= / /
L-baclofen TN= Neuralgon	Treatment of intractable spasticity in children with cerebral palsy.	Pharmascience Labs 8400 Darnley Road Montreal, Quebec H4T 1M4 Canada, DD=01/30/1992 MA= / /
L-baclofen TN=	Treatment of trigeminal neuralgia.	Pharmascience Inc. 6111 Royalmount, #100 Montreal, Quebec Canada H4P 2T4, DD=01/06/1998 MA= / /
L-cycloserine TN=	Treatment of Gaucher's disease.	Lev, Meir M.D. The City College, City University Of NY Medical School Convent Avenue at 138 Street New York, NY 10031 DD=08/01/1989 MA= / /
L-cysteine TN=	For the prevention and lessening of photosensitivity in erythropoietic protoporphyria.	Micheline M. Mathews-Roth, MD Channing Laboratory, Brigham and Women's Hospital 181 Longwood Avenue Boston, MA 02115 DD=05/16/1994 MA= / /
L-glutamyl-L-tryptophan TN=	Treatment of AIDS-related Kaposi's sarcoma.	Cytran Incorporated 10230 N.E. Points Dr. Suite 530 Kirkland, WA 98033 DD=10/20/1999 MA= / /
L-leucovorin TN= Isovorin	For use in conjunction with high-dose methotrexate in the treatment of osteosarcoma.	Lederle Laboratories Division of American Cyanamid Company 401 N. Middletown Road Pearl River, NY 10965 DD=08/01/1991 MA= / /
L-leucovorin TN= Isovorin	For use in combination chemotherapy with the approved agent 5-fluorouracil in the palliative treatment of metastatic adenocarcinoma of the colon and rectum.	Lederle Laboratories Division of American Cyanamid Company 401 N. Middletown Road Pearl River, NY 10965 DD=12/18/1990 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
L-threonine TN= Threostat	Treatment of amyotrophic lateral sclerosis.	Tyson And Associates 12832 Chadron Avenue Hawthorne, CA 90250 DD=02/06/1989 MA= / /
L-threonine TN=	Treatment of spasticity associated with familial spastic paraparesis.	Interneuron Pharmaceuticals, Inc. One Ledge Center 99 Hayden Avenue, Suite 200 Lexington, MA 02173 DD=07/24/1992 MA= / /
Lactic acid TN= Aphthaid	Treatment of severe aphthous stomatitis in severely, terminally immunocompromised patients.	Frontier Pharmaceutical, Inc. SUNY Farmingdale Conklin Hall Farmingdale, NY 11735 DD=06/29/1999 MA= / /
Lactobin TN= Lactobin	Treatment of AIDS-associated diarrhea unresponsive to initial antidiarrheal therapy.	Roxane Laboratories, Inc. 1809 Wilson Road P.O. Box 16532 Columbus, OH 43216 DD=09/12/1990 MA= / /
Lamotrigine TN= Lamictal	Treatment of Lennox-Gastaut syndrome.	Glaxo Wellcome Research and Development 5 Moore Drive P.O. Box 13398 Research Triangle Park, NC 27709 DD=08/23/1995 MA=08/24/1998
Leflunomide TN=	Prevention of acute and chronic rejection in patients who have received solid organ transplants.	Williams, MD, James W. Rush-Presbyterian-St. Luke's Medical Ctr., Dept. of General Surgery 1653 West Congress Parkway Oak Park, IL 60302 DD=10/18/1996 MA= / /
Lepirudin TN= Refluden	Treatment of heparin-associated thrombocytopenia type II.	Hoechst Marion Roussel Frankfurt am Main Germany DD=02/13/1997 MA=03/06/1998
Leucovorin TN= Leucovorin calcium	For use in combination with 5-fluorouracil for the treatment of metastatic colorectal cancer.	Immunex Corporation 51 University Street Seattle, WA 98101 DD=12/08/1986 MA=12/12/1991
Leucovorin TN= Leucovorin calcium	For rescue use after high dose methotrexate therapy in the treatment of osteosarcoma.	Immunex Corporation 51 University Street Seattle, WA 98101 DD=08/17/1988 MA=08/31/1988

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Leupeptin TN=	For use as an adjunct to microsurgical peripheral nerve repair.	Neuromuscular Adjuncts, Inc. S.U.N.Y. at Stony Brook H.S.C. T18-020 Stony Brook, NY 11794 DD=09/18/1990 MA= / /
Leuprolide acetate TN= Lupron Injection	Treatment of central precocious puberty.	Tap Pharmaceuticals, Inc. 2355 Waukegan Road Deerfield, IL 60015 DD=07/25/1988 MA=04/16/1993
Levocarnitine TN= Carnitor	Treatment of genetic carnitine deficiency.	Sigma-Tau Pharmaceuticals, Inc. 800 South Frederick Avenue Gaithersburg, MD 20877 DD=02/28/1984 MA=04/10/1986
Levocarnitine TN= Carnitor	Treatment of primary and secondary carnitine deficiency of genetic origin.	Sigma-Tau Pharmaceuticals, Inc. 800 South Frederick Avenue Gaithersburg, MD 20877 DD=07/26/1984 MA=12/16/1992
Levocarnitine TN= Carnitor	Treatment of manifestations of carnitine deficiency in patients with end stage renal disease who require dialysis.	Sigma-Tau Pharmaceuticals, Inc. 800 South Frederick Avenue, Suite 300 Gaithersburg, MD 20877 DD=09/06/1988 MA=12/15/1999
Levocarnitine TN= Carnitor	For the prevention of secondary carnitine deficiency in valproic acid toxicity.	Sigma-Tau Pharmaceuticals, Inc. 800 South Frederick Avenue Gaithersburg, MD 20877 DD=11/15/1989 MA= / /
Levocarnitine TN= Carnitor	For the treatment of secondary carnitine deficiency in valproic acid toxicity.	Sigma-Tau Pharmaceuticals, Inc. 800 South Frederick Avenue Gaithersburg, MD 20877 DD=11/15/1989 MA= / /
Levocarnitine TN= Carnitor	Treatment of pediatric cardiomyopathy.	Sigma-Tau Pharmaceuticals, Inc. 800 South Frederick Avenue Gaithersburg, MD 20877 DD=11/22/1993 MA= / /
Levocarnitine TN= Carnitor	Treatment of zidovudine-induced mitochondrial myopathy.	Sigma-Tau Pharmaceuticals, Inc. 800 S. Frederick Avenue, Suite 300 Gaithersburg, MD 20877 DD=04/07/1997 MA= / /
Levomethadyl acetate hydrochloride TN= Orlaam	Treatment of heroin addicts suitable for maintenance on opiate agonists.	Biodevelopment Corporation 8180 Greensboro Drive, Suite 1000 McLean, VA 22102 DD=01/24/1984 MA=07/09/1993

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Lidocaine patch 5% TN= Lidoderm Patch	For relief of allodynia (painful hypersensitivity), and chronic pain in post-herpetic neuralgia.	Hind Health Care, Inc. 3707 Williams Rd., Suite 101 San Jose, CA 95117 DD=10/24/1995 MA=03/19/1999
Liothyronine sodium injection TN= Triostat	Treatment of myxedema coma/precoma.	SmithKline Beecham Pharmaceuticals One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101 DD=07/30/1990 MA=12/31/1991
Lipid/DNA human cystic fibrosis gene TN=	Treatment of cystic fibrosis.	Genzyme Corporation One Mountain Road P.O. Box 9322 Framingham, MA 01701 DD=04/08/1996 MA= / /
Liposomal N-Acetylglucosminyl-N-Acetylmuramyl-L-Ala-D-isoGln-L-Ala-glycerolipalmitoyl TN= ImmTher	Treatment of osteosarcoma.	Endorex Corp. 900 North Shore Drive Lake Bluff, IL 60044 DD=06/10/1998 MA= / /
Liposomal N-Acetylglucosminyl-N-Acetylmuramyl-L-Ala-D-isoGln-L-Ala-glycerolipalmitoyl TN= ImmTher	Treatment of Ewing's sarcoma.	Endorex Corp. 900 North Shore Drive Lake Bluff, IL 60044 DD=06/10/1998 MA= / /
Liposomal amphotericin B TN= AmBisome	Treatment of cryptococcal meningitis.	Fujisawa USA, Inc. 3 Parkway North Center Deerfield, IL 60015 DD=12/10/1996 MA=08/11/1997
Liposomal amphotericin B TN= AmBisome	Treatment of visceral leishmaniasis.	Fujisawa USA, Inc. 3 Parkway North Center Deerfield, IL 60015 DD=12/06/1996 MA=08/11/1997
Liposomal amphotericin B TN= AmBisome	Treatment of histoplasmosis.	Fujisawa USA, Inc. 3 Parkway North Center Deerfield, IL 60015 DD=12/10/1996 MA= / /
Liposomal cyclosporin A TN= Cyclospire	For aerosolized administration in the prevention and treatment of lung allograft rejection and pulmonary rejection events associated with bone marrow transplantation.	Vernon Knight, M.D. Baylor College of Medicine, Dept. of Molecular Physiology One Baylor Plaza Houston, TX 77030 DD=04/30/1998 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Liposomal-cis-bis-neodecanoat o-trans-R,R-1,2-diaminocyclohe xane-Pt (II) TN=	Treatment of malignant mesothelioma.	Aronex Pharmaceuticals, Inc. 8707 Technology Forest Place The Woodlands, TX 77381 DD=09/01/1999 MA= / /
Liposome encapsulated recombinant interleukin-2 TN=	Treatment of brain and CNS tumors.	Biomira USA, Inc. 1002 Eastpark Boulevard Cranbury, NJ 08512 DD=11/25/1991 MA= / /
Liposome encapsulated recombinant interleukin-2 TN=	Treatment of cancers of the kidney and renal pelvis.	Biomira USA, Inc. 1002 Eastpark Boulevard Cranbury, NJ 08512 DD=06/20/1994 MA= / /
Lisofylline TN=	Treatment of patients undergoing induction therapy for acute myeloid leukemia.	Cell Therapeutics, Inc. 201 Elliot Ave. W., Suite 400 Seattle, WA 98119 DD=06/10/1999 MA= / /
Lodoxamide tromethamine TN= Alomide Ophthalmic Solution	Treatment of vernal keratoconjunctivitis.	Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134 DD=10/16/1991 MA=09/23/1993
Lucinactant TN= Surfaxin	Treatment of acute respiratory distress syndrome in adults.	Discovery Laboratories, Inc. 350 South Main Street Suite 307 Doylestown, PA 18901 DD=07/17/1995 MA= / /
Lucinactant TN= Surfaxin	Treatment of respiratory distress syndrome in premature infants.	Discovery Laboratories, Inc. 350 South Main Street Suite 307 Doylestown, PA 18901 DD=10/18/1995 MA= / /
Lucinactant TN= Surfaxin	Treatment of meconium aspiration syndrome in newborn infants.	Discovery Laboratories, Inc. 350 South Main Street Suite 307 Doylestown, PA 18901 DD=07/30/1996 MA= / /
MART-1 adenoviral gene therapy for malignant melanoma TN=	Treatment of metastatic melanoma.	Genzyme Corporation One Mountain Road P.O. Box 9322 Framingham, MA 01701 DD=03/28/1997 MA= / /
MN14 monoclonal antibody to carcinoembryonic antigen TN= Cea-Cide	For the treatment of small cell lung cancer.	Immunomedics, Inc. 300 American Rd. Morris Plains, NJ 07950 DD=09/18/1998 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
MN14 monoclonal antibody to carcinoembryonic antigen TN= Cea-Cide	Treatment of pancreatic cancer.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=11/24/1998 MA= / /
Mafenide acetate solution TN= Sulfamylon solution	For use as an adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds.	Mylan Laboratories, Inc. 781 Chestnut Ridge Road P.O. Box 4310 Morgantown, WV 26504 DD=07/18/1990 MA=06/05/1998
Marijuana TN=	Treatment of HIV-associated wasting syndrome.	Multidisciplinary Association for Psychedelic Studies, Inc. 3 Francis St. Belmont, MA 02478 DD=05/25/1999 MA= / /
Matrix metalloproteinase inhibitor TN= Galardin	Treatment of corneal ulcers.	Glycomed, Inc 860 Atlantic Avenue Alameda, CA 94501 DD=12/05/1991 MA= / /
Mazindol TN= Sanorex	Treatment of Duchenne muscular dystrophy.	Collipp, Platon J. M.D. 176 Memorial Drive Jesup, GA 31545 DD=12/08/1986 MA= / /
Mecamylamine TN= Inversine	Treatment of Tourette's syndrome.	Layton Bioscience, Inc. 105 Reservoir Rd. Atherton, CA 94027 DD=10/14/1998 MA= / /
Mecasermin TN= Myotrophin	Treatment of amyotrophic lateral sclerosis.	Cephalon, Inc. 145 Brandywine Parkway West Chester, PA 19380 DD=08/05/1991 MA= / /
Mecasermin TN=	Treatment of growth hormone insufficiency syndrome.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=12/12/1995 MA= / /
Mefloquine HCl TN= Mephaquin	Treatment of chloroquine-resistant Falciparummalaria.	Mepha AG 4143 Dornach POSTFASH 137 Aesch Basel, Switzerland, DD=07/22/1987 MA= / /
Mefloquine HCl TN= Mephaquin	Prevention of chloroquine-resistant Falciparum malaria.	Mepha AG 4143 Dornach POSTFASH 137 Aesch Basel, Switzerland, DD=07/22/1987 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Mefloquine HCl TN= Lariam	Treatment of acute malaria due to Plasmodium falciparum and Plasmodium vivax.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=04/13/1988 MA=05/02/1989
Mefloquine HCl TN= Lariam	Prophylaxis of Plasmodium falciparum malaria which is resistant to other available drugs.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=04/13/1988 MA=05/02/1989
Megestrol acetate TN= Megace	Treatment of patients with anorexia, cachexia, or significant weight loss ($\geq 10\%$ of baseline body weight) and confirmed diagnosis of AIDS.	Bristol-Myers Squibb Pharmaceutical Research Institute 2400 West Lloyd Expressway Evansville, IN 47721 DD=04/13/1988 MA=09/10/1993
Melanoma cell vaccine TN=	Treatment of invasive melanoma.	Morton, Donald L. M.D. John Wayne Cancer Institute St. John's Hospital and Health Center, 1328 22nd Street Santa Monica, CA 90404 DD=10/13/1994 MA= / /
Melanoma vaccine TN= Melacine	Treatment of stage III - IV melanoma.	Ribi ImmunoChem Research, Inc. 533 Old Corvallis Road Hamilton, MT 59840 DD=12/20/1989 MA= / /
Melatonin TN=	Treatment of circadian rhythm sleep disorders in blind people with no light perception.	Sack, Robert, M.D. Oregon Health Sciences University 3181 S.W. Sam Jackson Park Road Portland, OR 97201 DD=11/15/1993 MA= / /
Melphalan TN= Alkeran For Injection	Treatment of patients with multiple myeloma for whom oral therapy is inappropriate.	Glaxo Wellcome Inc. 5 Moore Drive Research Triangle Park, NC 27709 DD=02/24/1992 MA=11/18/1992
Mesna TN= Mesnex	For use as a prophylactic agent in reducing the incidence of ifosfamide-induced hemorrhagic cystitis.	Degussa Corporation 65 Challenger Road Ridgefield Park, NJ 07660 DD=11/14/1985 MA=12/30/1988
Mesna TN=	Inhibition of the urotoxic effects induced by oxazaphosphorine compounds such as cyclophosphamide.	Asta Medica , Inc. 890 East St. Tewksbury, MA 01876 DD=12/16/1987 MA= / /
Methionine/L-methionine TN=	Treatment of AIDS myelopathy.	Di Rocco, Alessandro M.D. Beth Israel Medical Center, Phillips Ambulatory Care Ctr. Philips Building, Suite 2Q; 10 Union Square East New York, NY 10003

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Methotrexate sodium TN= Methotrexate	Treatment of osteogenic sarcoma.	DD=08/21/1996 MA= / / Lederle Laboratories Division of American Cyanamid Company 401 N. Middletown Road Pearl River, NY 10965 DD=10/21/1985 MA=04/07/1988
Methotrexate with laurocapram TN= Methotrexate/azone	Topical treatment of mycosis fungoides.	Durham Pharmaceuticals LLC 200 Westpark Corporate Center 4364 South Alston Avenue Durham, NC 27713 DD=10/15/1990 MA= / /
Methoxsalen TN= Uvadex	For use in conjunction with the UVAR photopheresis system to treat graft versus host disease.	Therakos, Inc. 437 Creamery Way Exton, PA 19431 DD=10/14/1998 MA= / /
Metronidazole TN= Metrogel	Treatment of perioral dermatitis.	Galderma Laboratories, Inc. P.O. Box 331329 Fort Worth, TX 76163 DD=10/24/1991 MA= / /
Metronidazole (topical) TN= Metrogel	Treatment of acne rosacea.	Galderma Laboratories, Inc. P.O. Box 331329 Fort Worth, TX 76163 DD=10/22/1987 MA=11/22/1988
Microbubble contrast agent TN= Filmix Neurosonographic Contrast Agent	Intraoperative aid in the identification and localization of intracranial tumors.	Cav-Con, Inc. 55 Knollwood Road Farmington, CT 06032 DD=11/16/1990 MA= / /
Midodrine HCl TN= Amatine	Treatment of patients with symptomatic orthostatic hypotension.	Roberts Pharmaceutical Corp. Meridian Center III 6 Industrial Way West Eatontown, NJ 07724 DD=12/05/1996 MA=09/06/1996
Mitoguazone TN= Zyrkamine	Treatment of diffuse non-Hodgkin's lymphoma, including AIDS-related diffuse non-Hodgkin's lymphoma.	ILEX Oncology, Inc. 11550 IH 10 West, Suite 300 San Antonio, TX 78230 DD=03/18/1994 MA= / /
Mitolactol TN=	Treatment of recurrent invasive or metastatic squamous carcinoma of the cervix.	Biopharmaceutics, Inc. 990 Station Road Bellport, NY 11713 DD=01/23/1989 MA= / /
Mitolactol TN=	As adjuvant therapy in the treatment of primary brain tumors.	Biopharmaceutics, Inc. 990 Station Road Bellport, NY 11713 DD=07/12/1995 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Mitomycin-C TN=	Treatment of refractory glaucoma as an adjunct to ab externo glaucoma surgery.	IOP Inc. 3100 Airway Avenue, Suite 106 Costa Mesa, CA 92626 DD=08/20/1993 MA= / /
Mitoxantrone TN= Novantrone	Treatment of hormone refractory prostate cancer.	Immunex Corporation 51 University Street Seattle, WA 98101 DD=08/21/1996 MA=11/13/1996
Mitoxantrone TN= Novantrone	Treatment of secondary-progressive multiple sclerosis.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=08/13/1999 MA= / /
Mitoxantrone TN= Novantrone	Treatment of progressive-relapsing multiple sclerosis.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=08/13/1999 MA= / /
Mitoxantrone HCl TN= Novantrone	Treatment of acute myelogenous leukemia, also referred to as acute nonlymphocytic leukemia.	Lederle Laboratories Division of American Cyanamid Company 401 N. Middletown Road Pearl River, NY 10965 DD=07/13/1987 MA=12/23/1987
Modafinil TN= Provigil	Treatment of excessive daytime sleepiness in narcolepsy.	Cephalon, Inc. 145 Brandywine Parkway West Chester, PA 19380 DD=03/15/1993 MA=12/24/1998
Monoclonal antibodies PM-81 and AML-2-23 TN=	For the exogenous depletion of CD14 and CD15 positive acute myeloid leukemic bone marrow cells from patients undergoing bone marrow transplantation.	Medarex, Inc. 1545 Route 22 East PO Box 953 Annandale, NJ 08801 DD=03/12/1990 MA= / /
Monoclonal antibody PM-81 TN=	Adjunctive treatment of acute myelogenous leukemia.	Medarex, Inc. 1545 Route 22 East PO Box 953 Annandale, NJ 08801 DD=06/27/1991 MA= / /
Monoclonal antibody for immunization against lupus nephritis TN=	Treatment of lupus nephritis.	VivoRx Autoimmune, Inc. 2825 Santa Monica Blvd., Suite 200 Santa Monica, CA 90404 DD=01/07/1993 MA= / /
Monoclonal antibody to hepatitis B virus (human) TN=	Prophylaxis of hepatitis B reinfection in patients undergoing liver transplantation secondary to end-stage chronic hepatitis B infection.	Protein Design Labs, Inc. 34801 Campus Dr. Fremont, CA 94555 DD=06/17/1991 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Monoclonal antibody-B43.13 TN= Ovarex MAb-B43.13	Treatment of epithelial ovarian cancer.	AltaRex US Corp. Suite 125, 303 Wyman Street Waltham, MA 02451 DD=11/25/1996 MA= / /
Monolaurin TN= Glylorin	Treatment of congenital primary ichthyosis.	Glaxo Wellcome Inc. 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709 DD=04/29/1993 MA= / /
Monooctanoin TN= Mactanin	For dissolution of cholesterol gallstones retained in the common bile duct.	Ethitek Pharmaceuticals, Inc. 7855 Gross Point Road, Unit L Skokie, IL 60077 DD=05/30/1984 MA=10/31/1985
Morphine sulfate concentrate (preservative free) TN= Infumorph	For use in microinfusion devices for intraspinal administration in the treatment of intractable chronic pain.	Elkins-Sinn, Inc. 2 Esterbrook Lane Cherry Hill, NJ 08003 DD=07/12/1990 MA=07/19/1991
Multi-vitamin infusion (neonatal formula) TN=	For establishment and maintenance of total parenteral nutrition in very low birth weight infants.	Astra Pharmaceuticals, L.P. 725 Chesterbrook Blvd. Wayne, PA 19087 DD=12/12/1989 MA= / /
Murine MAb (Lym-1) and Iodine 131-I radiolabeled murine MAb (Lym-1) to human B-cell lymphoma TN= Oncolym	Treatment of B-cell non-Hodgkin's lymphoma.	Berlex Laboratories 15049 San Pablo Ave. PO Box 4099 Richmond, CA 94804 DD=11/27/1998 MA= / /
Murine MAb to polymorphic epithelial mucin, human milk fat globule 1 TN= Theragyn	Adjuvant treatment of ovarian cancer.	Antisoma West Africa House Hanger Lane London W5 3QR, GB DD=03/22/1999 MA= / /
Mycobacterium avium sensitin RS-10 TN=	For use in the diagnosis of invasive Mycobacterium avium disease in immunocompetent individuals.	Statens Seruminstitut 5 Artillerivej DK-2300 Copenhagen S Denmark, DD=10/11/1995 MA= / /
N-acetyl-procainamide TN=	Prevention of life-threatening ventricular arrhythmias in patients with documented procainamide-induced lupus.	NAPA of the Bahamas 3560 Pennsylvania Avenue, Suite 7 Dubuque, IA 52002 DD=12/10/1996 MA= / /
N-acetylgalactosamine-4-sulfate, recombinant human TN=	Treatment of mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome).	BioMarin Pharmaceutical, Inc. 11 Pimental Court Novato, CA 94949 DD=02/17/1999 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
NG-29 TN= Somatrel	Diagnostic measure of the capacity of the pituitary gland to release growth hormone.	Ferring Laboratories, Inc. 400 Rella Boulevard, Suite 201 Suffern, NY 10901 DD=08/08/1989 MA= / /
Nafarelin acetate TN= Synarel Nasal Solution	Treatment of central precocious puberty.	Syntex (USA), Inc. 3401 Hillview Avenue Palo Alto, CA 94303 DD=07/20/1988 MA= / /
Naltrexone HCl TN= Trexan	For blockade of the pharmacological effects of exogenously administered opioids as an adjunct to the maintenance of the opioid-free state in detoxified formerly opioid-dependent individuals.	DuPont Pharmaceuticals E.I. Du Pont De Nemours & Co. Wilmington, DE 19880 DD=03/11/1985 MA=11/30/1984
Nebacumab TN= Centoxin	Treatment of patients with gram-negative bacteremia which has progressed to endotoxin shock.	Centocor, Inc. 200 Great Valley Parkway Malvern, PA 19355 DD=10/01/1986 MA= / /
Neurotrophin-1 TN=	Treatment of motor neuron disease/amyotrophic lateral sclerosis.	Ericsson, Arthur Dale, M.D. 6560 Fannin, Scurlock Tower, Suite 720 Houston, TX 77303 DD=09/13/1994 MA= / /
Nifedipine TN=	Treatment of interstitial cystitis.	Fleischmann, Jonathan M.D. MetroHealth Medical Center 3395 Scranton Road Cleveland, OH 44109 DD=06/13/1991 MA= / /
Nitazoxanide TN= Cryptaz	Treatment of immunocompromised patients with cryptosporidiosis.	Romark Laboratories, L.C. 6200 Courtney Campbell Causeway Suite 880 Tampa, FL 33607 DD=12/12/1996 MA= / /
Nitisinone TN= Orfandin	Treatment of tyrosinemia type 1.	Swedish Orphan AB Stureplan 15, IV S-111 45 Stockholm Sweden, DD=05/16/1995 MA= / /
Nitric oxide TN= INOmax	Treatment of persistent pulmonary hypertension in the newborn.	INO Therapeutics, Inc. 54 Old Highway 22 Clinton, NJ 08809 DD=06/22/1993 MA=12/23/1999
Nitric oxide TN=	Treatment of acute respiratory distress syndrome in adults.	INO Therapeutics, Inc. 54 Old Highway 22 Clinton, NJ 08809 DD=07/10/1995 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name		INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
OM 401 TN= Drepanol		Prophylactic treatment of sickle cell disease.	Omex International, Inc. 6001 Savoy, Suite 110 Houston, TX 77036 DD=10/24/1991 MA= / /
Octreotide TN= Sandostatin LAR		Treatment of acromegaly.	Novartis Pharmaceuticals Corporation 59 Route 10 East Hanover, NJ 07936 DD=08/24/1998 MA=11/25/1998
Octreotide TN= Sandostatin LAR		Treatment of severe diarrhea and flushing associated with malignant carcinoid tumors.	Novartis Pharmaceuticals Corporation 59 Route 10 East Hanover, NJ 07936 DD=08/24/1998 MA=11/25/1998
Octreotide TN= Sandostatin LAR		Treatment of diarrhea associated with vasoactive intestinal peptide tumors (VIPoma).	Novartis Pharmaceuticals Corporation 59 Route 10 East Hanover, NJ 07936 DD=08/24/1998 MA=11/25/1998
Ofloxacin TN= Ocuflax Ophthalmic Solution		Treatment of bacterial corneal ulcers.	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92713 DD=04/18/1991 MA=05/22/1996
Omega-3 (n-3) polyunsaturated fatty acid with all double bonds in the cis configuration TN=		Prevention of organ graft rejection.	Research Triangle Pharmaceuticals 4364 South Alston Avenue Durham, NC 27713 DD=11/22/1995 MA= / /
Oncorad Ov103 TN=		Treatment of ovarian cancer.	Cytogen Corporation 600 College Road East Princeton, NJ 08540 DD=04/24/1990 MA= / /
Oprelvekin TN= Neumega		Prevention of severe chemotherapy-induced thrombocytopenia.	Genetics Institute, Inc. 87 Cambridge Park Drive Cambridge, MA 02140 DD=12/17/1996 MA=11/25/1997
Oxaliplatin TN=		Treatment of ovarian cancer.	Debio Pharm S.A. Rue des Terreaux 17 CH-1000 Lausanne 9 Switzerland, DD=10/06/1992 MA= / /
Oxandrolone TN= Oxandrin		Adjunctive therapy for AIDS patients suffering from HIV-wasting syndrome.	Bio-Technology General Corp. 70 Wood Avenue, South Iselin, NJ 08830 DD=09/06/1991 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Oxandrolone TN= Hepandrin	Treatment of moderate/severe acute alcoholic hepatitis in the presence of moderate protein calorie malnutrition.	Bio-Technology General Corp. 70 Wood Avenue South Iselin, NJ 08830 DD=03/18/1994 MA= / /
Oxandrolone TN= Oxandrin	Treatment of patients with Duchenne's muscular dystrophy and Becker's muscular dystrophy.	Bio-Technology General Corp. 70 Wood Avenue South Iselin, NJ 08830 DD=04/22/1997 MA= / /
Oxymorphone TN= Numorphan H.P.	For relief of severe intractable pain in narcotic-tolerant patients.	DuPont Merck Pharmaceutical Company P.O. Box 80027 Wilmington, DE 19880 DD=03/19/1985 MA= / /
Oxypurinol TN=	Treatment of hyperuricemia in patients intolerant to allopurinol.	ILEX Oncology, Inc. 11550 IH-10 West, Suite 300 San Antonio, TX 78230 DD=11/09/1998 MA= / /
P1, P4-Di(uridine 5'-tetrphosphate), tetrasodium salt TN=	Treatment of cystic fibrosis.	Inspire Pharmaceuticals, Inc. 4222 Emperor Blvd., Suite 470 Durham, NC 27703 DD=10/27/1998 MA= / /
PEG-glucocerebrosidase TN= Lysodase	For use as chronic enzyme replacement therapy in patients with Gaucher's disease who are deficient in glucocerebrosidase.	National Institute of Mental Health, NIH 49 Convent Dr. MSC4405 Bldg. 49, Room B1EE16 Bethesda, MD 20892 DD=12/09/1992 MA= / /
PEG-interleukin-2 TN=	Treatment of primary immunodeficiencies associated with T-cell defects.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=02/01/1990 MA= / /
Paclitaxel TN= Taxol	Treatment of AIDS-related Kaposi's sarcoma.	Bristol-Myers Squibb Pharmaceutical Research Institute 5 Research Parkway P.O. Box 5100 Wallingford, CT 06492 DD=03/25/1997 MA=08/04/1997
Paclitaxel TN= Paxene	Treatment of AIDS-related Kaposi's sarcoma.	Baker Norton Pharmaceuticals, Inc. 4400 Biscayne Boulevard Miami, FL 33137 DD=04/15/1997 MA= / /
Papain, trypsin, and chymotrypsin TN= Wobe-Mugos	Treatment of multiple myeloma.	Marlyn Nutraceuticals, Inc. 14851 N. Scottsdale Rd. Scottsdale, AZ 85254 DD=12/21/1998 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Parovirus B19 (recombinant VP1 and VP2; S.frugiperda cells) vaccine TN= MEDI-491	Prevention of transient aplastic crisis in patients with sickle cell anemia.	MedImmune, Inc. 35 West Watkins Mill Rd. Gaithersburg, MD 20878 DD=05/07/1999 MA= / /
Patul-end TN=	Treatment of patulous eustachian tube.	Ear Foundation 24209 Castillo Street, Suite 100 Santa Barbara, CA 93105 DD=02/18/1997 MA= / /
Pegademase bovine TN= Adagen	For enzyme replacement therapy for ADA deficiency in patients with severe combined immunodeficiency.	Enzon, Inc. 20 Kingsbridge Road Piscataway, NJ 08854 DD=05/29/1984 MA=03/21/1990
Pegaspargase TN= Oncaspar	Treatment of acute lymphocytic leukemia.	Enzon, Inc. 20 Kingsbridge Road Piscataway, NJ 08854 DD=10/20/1989 MA=02/01/1994
Peginterferon alfa-2a TN= PEGASYS	Treatment of renal cell carcinoma.	Hoffman-La Roche Inc. 340 Kingsland St. Nutley, NJ 07110 DD=07/13/1998 MA= / /
Peginterferon alfa-2a TN= PEGASYS	Treatment of chronic myelogenous leukemia.	Hoffman-La Roche Inc. 340 Kingsland St. Nutley, NJ 07110 DD=09/30/1999 MA= / /
Pegylated arginine deiminase TN= Hepacid	Treatment of hepatocellular carcinoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=03/26/1999 MA= / /
Pegylated arginine deiminase TN= Melanocid	Treatment of invasive malignant melanoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=04/12/1999 MA= / /
Pegylated recombinant human megakaryocyte growth and development factor TN= MEGAGEN	For reducing the period of thrombocytopenia in patients undergoing hematopoietic stem cell transplantation.	Amgen, Inc. One Amgen Center Dr. Thousand Oaks, CA 91320 DD=10/20/1997 MA= / /
Peldesine TN=	Treatment of cutaneous T-cell lymphoma.	BioCryst Pharmaceuticals, Inc. 2190 Parkway Lake Drive Birmingham, AL 35244 DD=10/05/1993 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Pentamidine isethionate TN= Pentam 300	Treatment of Pneumocystis carinii pneumonia.	Fujisawa USA, Inc. 3 Parkway North Center Deerfield, IL 60015 DD=02/28/1984 MA=10/16/1984
Pentamidine isethionate TN=	Treatment of Pneumocystis carinii pneumonia.	Rhone-Poulenc Rorer Pharmaceuticals, Inc. 500 Arcola Road Collegeville, PA 19426 DD=10/29/1984 MA= / /
Pentamidine isethionate TN= Nebupent	Prevention of Pneumocystis carinii pneumonia in patients at high risk of developing this disease.	Fujisawa USA, Inc. 3 Parkway North Center Deerfield, IL 60015 DD=01/12/1988 MA=06/15/1989
Pentamidine isethionate (inhalation) TN= Pneumopent	Prevention of Pneumocystis carinii pneumonia in patients at high risk of developing this disease.	Fisons Corporation 755 Jefferson Rd., P.O. Box 1710 Rochester, NY 14603 DD=10/05/1987 MA= / /
Pentastarch TN= Pentaspan	As an adjunct in leukapheresis to improve the harvesting and increase the yield of leukocytes by centrifugal means.	Du Pont Pharmaceuticals E.I. Du Pont De Nemours & Co. Wilmington, DE 19898 DD=08/28/1985 MA=05/19/1987
Pentosan polysulfate sodium TN= Elmiron	Treatment of interstitial cystitis.	Alza Corporation 950 Page Mill Rd. PO Box 10950 Palo Alto, CA 94303 DD=08/07/1985 MA=09/26/1996
Pentostatin TN= Nipent	Treatment of patients with chronic lymphocytic leukemia.	SuperGen, Inc. Two Annabel Lane Suite 220 San Ramon, CA 94583 DD=01/29/1991 MA= / /
Pentostatin TN= Nipent	Treatment of cutaneous T-cell lymphoma.	SuperGen, Inc. Two Annabel Lane, Suite 220 San Ramon, CA 94583 DD=03/27/1998 MA= / /
Pentostatin TN= Nipent	Treatment of peripheral T-cell lymphomas.	SuperGen, Inc. Two Annabel Lane, Suite 220 San Ramon, CA 94583 DD=11/24/1999 MA= / /
Pentostatin for injection TN= Nipent	Treatment of hairy cell leukemia.	SuperGen, Inc. Two Annabel Lane Suite 220 San Ramon, CA 94583 DD=09/10/1987 MA=10/11/1991

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Pergolide TN= Permax	Treatment of Tourette's syndrome.	Sallee, Floyd R. M.D., Ph.D. Medical University of South Carolina 171 Ashley Avenue, Room PH246 Charleston, SC 29425 DD=11/20/1997 MA= / /
Phenylacetate TN=	For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma.	Elan Pharmaceutical Research Corp. 1300 Gould Dr. Gainesville, GA 30504 DD=03/06/1998 MA= / /
Phenylalanine ammonia-lyase TN= Phenylase	Treatment of hyperphenylalaninemia.	Ibex Technologies, Inc. 5485 Pare Montreal, Quebec Canada H4P 1P7, DD=03/08/1995 MA= / /
Phosphocysteamine TN=	Treatment of cystinosis.	Medea Research Laboratories Port Jefferson Business Center 200 Wilson Street, Building D-6 Port Jefferson, NY 11776 DD=09/12/1988 MA= / /
Physostigmine Salicylate TN= Antilirium	Treatment of Friedreich's and other inherited ataxias.	Forest Pharmaceuticals, Inc. 150 East 58th Street New York, NY 10155 DD=01/16/1985 MA= / /
Pilocarpine TN= Salagen	Treatment of xerostomia induced by radiation therapy for head and neck cancer.	MGI Pharma, Inc. 6300 West Old Shakopee Rd. Suite 110 Bloomington, MN 55438 DD=09/24/1990 MA=03/22/1994
Pilocarpine HCl TN= Salagen	Treatment of xerostomia and keratoconjunctivitis sicca in Sjogren's syndrome patients.	MGI Pharma, Inc. 6300 West Old Shakopee Rd. Suite 110 Bloomington, MN 55438 DD=02/28/1992 MA=02/11/1998
Piracetam TN= Nootropil	Treatment of myoclonus.	UCB Pharma, Inc. 1950 Lake Park Drive Smyrna, GA 30080 DD=10/02/1987 MA= / /
Polifeprosan 20 with carmustine TN= Gliadel	Treatment of malignant glioma.	Guilford Pharmaceuticals, Inc. 6611 Tributary Street Baltimore, MD 21224 DD=12/13/1989 MA=09/23/1996

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Poloxamer 188 TN= Florcor	Treatment of sickle cell crisis.	CytRx Corporation 154 Technology Parkway Norcross, GA 30092 DD=06/27/1989 MA= / /
Poloxamer 188 TN= Florcor	Treatment of severe burns requiring hospitalization.	CytRx Corporation 154 Technology Parkway Norcross, GA 30092 DD=02/22/1990 MA= / /
Poloxamer 188 TN=	Treatment of vasospasm in subarachnoid hemorrhage patients following surgical repair of a ruptured cerebral aneurysm.	CytRx Corporation 154 Technology Parkway Norcross, GA 30092 DD=08/05/1997 MA= / /
Poloxamer 331 TN= Protox	Initial therapy of toxoplasmosis in patients with AIDS.	CytRx Corporation 154 Technology Parkway Norcross, GA 30092 DD=03/21/1991 MA= / /
Poly I: poly C12U TN= Ampligen	Treatment of AIDS.	Hemispherx Biopharma, Inc. One Penn Center 1617 JFK Boulevard Philadelphia, PA 19103 DD=07/19/1988 MA= / /
Poly I: poly C12U TN= Ampligen	Treatment of renal cell carcinoma.	Hemispherx Biopharma, Inc. One Penn Center 1617 JFK Boulevard Philadelphia, PA 19103 DD=05/20/1991 MA= / /
Poly I: poly C12U TN= Ampligen	Treatment of chronic fatigue syndrome.	Hemispherx Biopharma, Inc. One Penn Center 1617 JFK Boulevard Philadelphia, PA 19103 DD=12/09/1993 MA= / /
Poly I: poly C12U TN= Ampligen	Treatment of invasive metastatic melanoma (stage IIb, III, IV).	Hemispherx Biopharma, Inc. One Penn Center 1617 JFK Boulevard Philadelphia, PA 19103 DD=12/09/1993 MA= / /
Poly-ICLC TN=	Treatment of primary brain tumors.	Salazar, Andres M. M.D. and Levy, Hilton B. Ph.D. 3202 Cleveland Avenue N.W. Washington, DC 20008 DD=03/17/1997 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Polyethylene glycol-modified uricase TN= Zurase	Treatment of tumor lysis syndrome in cancer patients undergoing chemotherapy.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=12/21/1998 MA= / /
Polyethylene glycol-modified uricase TN= Zurase	Prophylaxis of hyperuricemia in cancer patients prone to develop tumor lysis syndrome during chemotherapy.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=09/14/1999 MA= / /
Polymeric oxygen TN=	Treatment of sickle cell anemia.	Capmed USA P.O. Box 14 Bryn Mawr, PA 19010 DD=03/25/1992 MA= / /
Porcine Sertoli cells aseptically prepared for intracerebral co-implantation with fetal neural tissue TN= N-Graft	Treatment of Hoehn and Yahr stage four and five Parkinson's disease.	Titan Pharmaceuticals, Inc. Post Office Plaza 50 Division Street, Suite 503 Somerville, NJ 08876 DD=06/24/1997 MA= / /
Porcine fetal neural dopaminergic cells and/or precursors aseptically prepared and coated with anti-MHC-1 Ab for intracerebral implantation TN= NeuroCell-PD	Treatment of Hoehn and Yahr stage 4 and 5 Parkinson's disease.	Diacrin, Inc. One Kendall Square Cambridge, MA 02139 DD=12/17/1996 MA= / /
Porcine fetal neural dopaminergic cells and/or precursors aseptically prepared for intracerebral implantation. TN= NeuroCell-PD	Treatment of Hoehn and Yahr stage 4 and 5 Parkinson's disease.	Diacrin, Inc. One Kendall Square Cambridge, MA 02139 DD=12/17/1996 MA= / /
Porcine fetal neural gabaergic cells and/or precursors aseptically prepared and coated with anti-MHC-1 Ab for intracerebral implantation TN= NeuroCell-HD	Treatment of Huntington's disease.	Diacrin, Inc. One Kendall Square Cambridge, MA 02129 DD=12/10/1996 MA= / /
Porcine fetal neural gabaergic cells and/or precursors aseptically prepared for intracerebral implantation for Huntington's disease. TN= NeuroCell-HD	Treatment of Huntington's disease.	Diacrin, Inc. One Kendall Square Cambridge, MA 02139 DD=12/10/1996 MA= / /
Porfimer sodium TN= Photofrin	For the photodynamic therapy of patients with primary or recurrent obstructing (either partially or completely) esophageal carcinoma.	QLT Phototherapeutics, Inc. Lederle Laboratories 401 North Middletown Road Pearl River, NY 10965 DD=06/06/1989 MA=12/27/1995

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Porfimer sodium TN= Photofrin	For the photodynamic therapy of patients with transitional cell carcinoma in situ of the urinary bladder.	QLT Phototherapeutics, Inc. Lederle Laboratories 401 North Middletown Road Pearl River, NY 10965 DD=11/15/1989 MA= / /
Porfiromycin TN= Promycin	Treatment of head and neck cancer.	Vion Pharmaceuticals, Inc. 4 Science Park New Haven, CT 06511 DD=09/19/1995 MA= / /
Porfiromycin TN= Promycin	Treatment of cervical cancer.	Vion Pharmaceuticals, Inc. Four Science Park New Haven, CT 06511 DD=03/13/1997 MA= / /
Potassium citrate TN= Urocit-K	Prevention of uric acid nephrolithiasis.	University of Texas Health Science Center at Dallas 5323 Harry Hines Boulevard Dallas, TX 75235 DD=11/01/1984 MA=08/30/1985
Potassium citrate TN= Urocit-K	Prevention of calcium renal stones in patients with hypocitraturia.	University of Texas Health Science Center at Dallas 5323 Harry Hines Blvd Dallas, TX 75235 DD=09/16/1985 MA=08/30/1985
Potassium citrate TN= Urocit-K	For avoidance of the complication of calcium stone formation in patients with uric lithiasis.	University of Texas Health Science Center at Dallas 5323 Harry Hines Blvd Dallas, TX 75235 DD=05/29/1984 MA=08/30/1985
Primaquine phosphate TN=	For use in combination with clindamycin hydrochloride in the treatment of Pneumocystis carinii pneumonia associated with AIDS.	Sanofi Winthrop, Inc. 90 Park Avenue New York, NY 10016 DD=07/23/1993 MA= / /
Progesterone TN=	Establishment and maintenance of pregnancy in women undergoing in vitro fertilization or embryo transfer procedures.	Watson Laboratories, Inc. 311 Bonnie Circle Corona, CA 91720 DD=12/22/1994 MA= / /
Prostaglandin E1 enol ester (AS-013) TN=	Treatment of Fontaine Stage IV chronic critical limb ischemia.	Alpha Therapeutic Corp. 5555 Valley Blvd. Los Angeles, CA 90032 DD=06/12/1998 MA= / /
Protein C concentrate TN= Protein C Concentrate (human) Vapor Heated, Immuno	For replacement therapy in patients with congenital or acquired protein C deficiency for the prevention and treatment of warfarin-induced skin necrosis during oral anticoagulation.	Immuno Clinical Research Corp. 750 Lexington Avenue, 19th Floor New York, NY 10022 DD=06/19/1992 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Protein C concentrate TN= Protein C Concentrate (human) Vapor Heated, Immuno	For replacement therapy in congenital protein C deficiency for the prevention and treatment of thrombosis, pulmonary emboli, and purpura fulminans.	Baxter Healthcare Corporation Hyland Division (Baxter Hyland) 550 North Brand Blvd. Glendale, CA 91203 DD=06/23/1992 MA= / /
Pulmonary surfactant replacement, porcine TN= Curosurf	For the treatment and prevention of respiratory distress syndrome in premature infants.	Dey Laboratories 2751 Napa Valley Corporate Drive Napa, CA 94550 DD=08/02/1993 MA= / /
Purified extract of Pseudomonas aeruginosa TN= ImmuDyn	Treatment of immune thrombocytopenia purpura where it is required to increase platelet counts.	DynaGen, Inc. 99 Erie Street Cambridge, MA 02139 DD=09/22/1997 MA= / /
Purified type II collagen TN= Colloral	Treatment of juvenile rheumatoid arthritis.	AutoImmune, Inc. 128 Spring Street Lexington, MA 02421 DD=02/09/1995 MA= / /
R-VIII SQ TN= ReFacto	For long-term and/or hospital treatment of hemophilia A or for treatment of patients with hemophilia A in connection with surgical procedures.	Genetics Institute, Inc. 87 CambridgePark Drive Cambridge, MA 02140 DD=02/08/1996 MA= / /
RGG0853, E1A lipid complex TN=	Treatment of ovarian cancer.	Targeted Genetics Corporation 1100 Olive Way, Suite 100 Seattle, WA 98101 DD=10/27/1997 MA= / /
R11 retinamide TN=	Treatment of myelodysplastic syndromes.	Sparta Pharmaceuticals, Inc. 111 Rock Road Horsham, PA 19044 DD=05/06/1993 MA= / /
Radiolabeled monoclonal antibody to CD22 antigen on B-cells TN= LymphoCIDE	Treatment of non-Hodgkin's lymphoma.	Immunomedics, Inc. 300 American Rd. Morris Plains, NJ 07950 DD=07/13/1998 MA= / /
Recombinant bactericidal/permeability-increa sing protein TN= Neuprex	Treatment of severe meningococcal disease.	Xoma Corporation 1545 17th St. Santa Monica, CA 90404 DD=06/22/1998 MA= / /
Recombinant human C1-esterase inhibitor TN=	Prophylactic treatment of angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel Belgium, BE DD=02/23/1999 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Recombinant human C1-esterase inhibitor TN=	Treatment of (acute attacks of) angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel Belgium, BE DD=02/23/1999 MA= / /
Recombinant human CD4 immunoglobulin G TN=	Treatment of AIDS resulting from infection with HIV-1.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=08/30/1990 MA= / /
Recombinant human Clara Cell 10kDa protein TN=	Prevention of neonatal bronchopulmonary dysplasia in premature neonates with respiratory distress syndrome.	Claragen, Inc. 335 Paint Branch Drive College Park, MD 20742 DD=07/13/1998 MA= / /
Recombinant human acid alpha-glucosidase TN=	Treatment of glycogen storage disease type II.	Chen, Y.-T., M.D., Ph.D. Department of Pediatrics Duke University Medical Center Durham, NC 27710 DD=08/19/1997 MA= / /
Recombinant human gelsolin TN=	Treatment of the respiratory symptoms of cystic fibrosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02124 DD=01/12/1994 MA= / /
Recombinant human gelsolin TN=	Treatment of acute and chronic respiratory symptoms of bronchiectasis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/06/1995 MA= / /
Recombinant human insulin-like growth factor-I TN=	Treatment of post-poliomyelitis syndrome.	Cephalon, Inc. 145 Brandywine Parkway West Chester, PA 19380 DD=10/13/1995 MA= / /
Recombinant human insulin-like growth factor-I/insulin-like growth factor binding protein-3 TN=	Treatment of major burns that require hospitalization.	Celtrix Pharmaceuticals, Inc. 3055 Patrick Henry Dr. Santa Clara, CA 95054 DD=06/15/1999 MA= / /
Recombinant human interleukin-12 TN=	Treatment of renal cell carcinoma.	Genetics Institute, Inc. 87 CambridgePark Drive Cambridge, MA 02140 DD=10/20/1997 MA= / /
Recombinant human keratinocyte growth factor TN=	Reducing the incidence and severity of radiation-induced xerostomia.	Amgen Inc. One Amgen Center Dr. Thousand Oaks, CA 91320 DD=12/20/1999 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Recombinant human luteinizing hormone TN= LHadi	For use in association with recombinant human follicle stimulating hormone for the treatment of women with chronic anovulation due to hypogonadotropic hypogonadism.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=10/07/1994 MA= / /
Recombinant human nerve growth factor TN=	Treatment of HIV-associated sensory neuropathy.	Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 DD=04/16/1999 MA= / /
Recombinant human relaxin TN=	Treatment of progressive systemic sclerosis.	Connetics Corporation 3400 West Bayshore Road Palo Alto, CA 94303 DD=11/03/1995 MA= / /
Recombinant human superoxide dismutase TN= Oxsodrol	Prevention of bronchopulmonary dysplasia in premature neonates weighing less than 1500 grams.	Bio-Technology General Corp. 70 Wood Avenue, South Iselin, NJ 08830 DD=04/18/1991 MA= / /
Recombinant human thrombopoietin TN=	For use in accelerating platelet recovery in patients undergoing hematopoietic stem cell transplantation.	Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 DD=09/29/1997 MA= / /
Recombinant humanized MAb 5c8 TN=	Prevention and treatment of Factor VIII/Factor IX inhibitors in patients with hemophilia A or B.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=10/14/1998 MA= / /
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of solid organ transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999 MA= / /
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of pancreatic islet cell transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999 MA= / /
Recombinant humanized monoclonal antibody 5c8 TN=	Treatment of immune thrombocytopenic purpura.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=02/03/1998 MA= / /
Recombinant humanized monoclonal antibody 5c8 TN=	Treatment of systemic lupus erythematosus.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=02/18/1998 MA= / /
Recombinant methionyl brain-derived neurotrophic factor TN=	Treatment of amyotrophic lateral sclerosis.	Amgen, Inc. One Amgen Center Dr. Thousand Oaks, CA 91320 DD=11/28/1994 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Recombinant methionyl human stem cell factor TN=	Treatment of primary bone marrow failure.	Amgen, Inc. 1840 Dehavilland Drive Thousand Oaks, CA 91320 DD=11/22/1995 MA= / /
Recombinant retroviral vector - glucocerebrosidase TN=	For use as enzyme replacement therapy for patients with types I, II, or III Gaucher disease.	Genetic Therapy, Inc. 938 Clopper Road Gaithersburg, MD 20878 DD=11/15/1993 MA= / /
Recombinant secretory leucocyte protease inhibitor TN=	Treatment of congenital alpha-1 antitrypsin deficiency.	Amgen Inc. 3200 Walnut Street Boulder, CO 80301 DD=03/29/1991 MA= / /
Recombinant secretory leucocyte protease inhibitor TN=	Treatment of cystic fibrosis.	Amgen, Inc. 3200 Walnut Street Boulder, CO 80301 DD=03/29/1991 MA= / /
Recombinant soluble human CD4 (rCD4) TN=	Treatment of AIDS in patients infected with HIV virus.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=03/23/1989 MA= / /
Recombinant vaccinia (human papillomavirus) TN= TA-HPV	Treatment of cervical cancer.	Cantab Pharmaceuticals Research Limited 310 Cambridge Science Park Cambridge CB4 0WG Great Britain, DD=08/24/1994 MA= / /
Reduced L-glutathione TN= Cachexon	Treatment of AIDS-associated cachexia.	Telluride Pharmaceutical Corporation 146 Flanders Drive Hillsborough, NJ 08876 DD=02/14/1994 MA= / /
Respiratory Syncytial Virus Immune Globulin (human) TN= Hyperimmune RSV	Treatment of respiratory syncytial virus lower respiratory tract infections in hospitalized infants and young children.	MedImmune, Inc. 35 West Watkins Mill Road Gaithersburg, MD 20878 DD=09/27/1990 MA= / /
Respiratory syncytial virus immune globulin (Human) TN= Respigam	Prophylaxis of respiratory syncytial virus lower respiratory tract infections in infants and young children at high risk of RSV disease.	MedImmune & Massachussetts Public Health Biologics Labs. 35 West Watkins Mill Road Gaithersburg, MD 20878 DD=09/27/1990 MA=01/18/1996
Retroviral vector, R-GC and GC gene 1750 TN=	Treatment of Gaucher disease.	Genzyme Corporation One Mountain Road P.O. Box 9322 Framingham, MA 01701 DD=05/06/1997 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Rho (D) immune globulin intravenous (human) TN= WinRho SD	Treatment of immune thrombocytopenic purpura.	Rh Pharmaceuticals, Inc. 104 Chancellor Matheson Road Winnipeg, Manitoba Canada R3T 2N2, DD=11/09/1993 MA=03/24/1995
Ribavirin TN= Virazole	Treatment of hemorrhagic fever with renal syndrome.	ICN Pharmaceuticals, Inc. ICN Plaza 3300 Hyland Avenue Costa Mesa, CA 92626 DD=04/12/1991 MA= / /
Ricin (blocked) conjugated murine MCA (anti-B4) TN=	Treatment of B-cell leukemia and B-cell lymphoma.	ImmunoGen, Inc. 148 Sidney Street Cambridge, MA 02139 DD=11/17/1988 MA= / /
Ricin (blocked) conjugated murine MCA (anti-my9) TN=	Treatment of myeloid leukemia, including AML, and blast crisis of CML.	ImmunoGen, Inc. 148 Sidney Street Cambridge, MA 02139 DD=08/03/1989 MA= / /
Ricin (blocked) conjugated murine MCA (anti-my9) TN=	For use in the ex-vivo treatment of autologous bone marrow and subsequent reinfusion in patients with acute myelogenous leukemia.	ImmunoGen, Inc. 148 Sidney Street Cambridge, MA 02139 DD=02/01/1990 MA= / /
Ricin (blocked) conjugated murine MCA (n901) TN=	Treatment of small cell lung cancer.	ImmunoGen, Inc. 148 Sidney Street Cambridge, MA 02139 DD=01/25/1991 MA= / /
Ricin (blocked) conjugated murine mca (anti-b4) TN=	For the ex-vivo purging of leukemic cells from the bone marrow of non-T cell acute lymphocytic leukemia patients who are in complete remission.	ImmunoGen, Inc. 148 Sidney Street Cambridge, MA 02139 DD=01/24/1991 MA= / /
Ricin (blocked) conjugated murine monoclonal antibody (CD6) TN=	Treatment of cutaneous T-cell lymphomas, acute T-cell leukemia-lymphoma, and related mature T-cell malignancies.	ImmunoGen, Inc. 148 Sidney Street Cambridge, MA 02139 DD=09/06/1994 MA= / /
Rifabutin TN=	Treatment of disseminated Mycobacterium avium complex disease.	Pharmacia & Upjohn 7000 Portage Road Unit 0633-298-113 Kalamazoo, MI 49001 DD=12/18/1989 MA= / /
Rifabutin TN= Mycobutin	Prevention of disseminated Mycobacterium avium complex disease in patients with advanced HIV infection.	Adria Laboratories, Inc. P.O. Box 16529 Columbus, OH 43216 DD=12/18/1989 MA=12/23/1992

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Rifalazil TN=	Treatment of pulmonary tuberculosis.	PathoGenesis Corporation 201 Elliott Avenue West Suite 150 Seattle, WA 98119 DD=04/13/1999 MA= / /
Rifampin TN= Rifadin I.V.	For antituberculosis treatment where use of the oral form of the drug is not feasible.	Hoechst Marion Roussel P.O. Box 9627 Kansas City, MO 64134 DD=12/09/1985 MA=05/25/1989
Rifampin, isoniazid, pyrazinamide TN= Rifater	For the short-course treatment of tuberculosis.	Hoechst Marion Roussel P.O. Box 9627 Kansas City, MO 64134 DD=09/12/1985 MA=05/31/1994
Rifapentine TN= Priftin	Treatment of pulmonary tuberculosis.	Hoechst Marion Roussel P.O. Box 9627 Mail Station: H3-M2516 Kansas City, MO 64134 DD=06/09/1995 MA=06/22/1998
Rifapentine TN= Priftin	Treatment of Mycobacterium avium complex in patients with AIDS.	Hoechst Marion Roussel, Inc. P.O. Box 9627 Mail Station: H3-M2516 Kansas City, MO 64134 DD=06/09/1995 MA= / /
Rifapentine TN= Priftin	Prophylactic treatment of Mycobacterium avium complex in patients with AIDS and a CD4+ count less than or equal to 75/mm3.	Hoechst Marion Roussel, Inc. P.O. Box 9627 Mail Station: H3-M2516 Kansas City, MO 64134 DD=03/12/1996 MA= / /
Rifaximin TN= Normix	Treatment of hepatic encephalopathy.	Salix Pharmaceuticals, Inc. 3600 W. Bayshore Road Palo Alto, CA 94303 DD=02/10/1998 MA= / /
Riluzole TN= Rilutek	Treatment of amyotrophic lateral sclerosis.	Rhone-Poulenc Rorer Pharmaceuticals, Inc. 500 Arcola Road, P.O. Box 1200 Collegeville, PA 19426 DD=03/16/1993 MA=12/12/1995
Riluzole TN= Rilutek	Treatment of Huntington's disease.	Rhone-Poulenc Rorer Pharmaceuticals, Inc. 500 Arcola Road PO Box 5096 Collegeville, PA 19426 DD=10/15/1996 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Rituximab TN= Rituxan	Treatment of non-Hodgkin's B-cell lymphoma.	IDEC Pharmaceuticals Corporation 3030 Callan Road San Diego, CA 92121 DD=06/13/1994 MA=11/26/1997
S-adenosylmethionine TN=	Treatment of AIDS-myelopathy.	Di Rocco, Alessandro M.D. Beth Israel Medical Center, Phillips Ambulatory Care Center Philips Building, Suite 2Q; 10 Union Square East New York, NY 10003 DD=04/30/1998 MA= / /
SCH 58500 TN=	Treatment of primary ovarian cancer.	Schering Corporation 2000 Galloping Hill Rd. Kenilworth, NJ 07033 DD=04/12/1999 MA= / /
SU101 TN=	Treatment of malignant glioma.	Sugen, Inc. 230 East Grand Ave. South San Francisco, CA 94080 DD=05/25/1995 MA= / /
SU101 TN=	Treatment of ovarian cancer.	Sugen, Inc. 230 East Grand Ave. South San Francisco, CA 94080 DD=03/12/1996 MA= / /
Sacrosidase TN= Sucraid	Treatment of congenital sucrase-isomaltase deficiency.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=12/10/1993 MA=04/09/1998
Sargramostim TN= Leukine	Treatment of neutropenia associated with bone marrow transplant, for the treatment of graft failure and delay of engraftment, and for the promotion of early engraftment.	Immunex Corporation 51 University Street Seattle, WA 98101 DD=05/03/1990 MA=03/05/1991
Sargramostim TN= Leukine	To reduce neutropenia and leukopenia and decrease the incidence of death due to infection in patients with acute myelogenous leukemia.	Immunex Corporation 51 University Street Seattle, WA 98101 DD=03/06/1995 MA=09/15/1995
Satumomab pendetide TN= Oncoscint CR/OV	Detection of ovarian carcinoma.	Cytogen Corporation 600 College Road East Princeton, NJ 08540 DD=09/25/1989 MA=12/29/1992
Secalciferol TN= Osteo-D	Treatment of familial hypophosphatemic rickets.	Teva Pharmaceuticals USA 650 Cathill Rd. Sellersville, PA 18960 DD=07/26/1993 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Secretory leukocyte protease inhibitor TN=	Treatment of bronchopulmonary dysplasia.	Synergen, Inc. 1885 33rd Street Boulder, CO 80301 DD=06/30/1992 MA= / /
Selegiline HCl TN= Eldepryl	As an adjuvant to levodopa and carbidopa treatment of idiopathic Parkinson's disease (paralysis agitans), postencephalitic Parkinsonism, and symptomatic Parkinsonism.	Somerset Pharmaceuticals, Inc. 777 South Harbor Island Boulevard Tampa, FL 33602 DD=11/07/1984 MA=06/05/1989
Sermorelin acetate TN= Geref	Treatment of idiopathic or organic growth hormone deficiency in children with growth failure.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=09/14/1988 MA=09/26/1997
Sermorelin acetate TN= Geref	Adjunct to gonadotropin therapy in the induction of ovulation in women with anovulatory or oligo-ovulatory infertility who fail to ovulate in response to adequate treatment with clomiphene citrate alone and gonadotropin therapy alone.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=02/13/1990 MA= / /
Sermorelin acetate TN= Geref	Treatment of AIDS-associated catabolism/weight loss.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=12/05/1991 MA= / /
Serratia marcescens extract (polyribosomes) TN= Imuvert	Treatment of primary brain malignancies.	Cell Technology, Inc. 1668 Valtec Lane Boulder, CO 80306 DD=09/07/1988 MA= / /
Short chain fatty acid enema TN= Colomed	Treatment of chronic radiation proctitis.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=08/19/1997 MA= / /
Short chain fatty acid solution TN= Colomed	Treatment of the active phase of ulcerative colitis with involvement restricted to the left side of the colon.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=05/29/1990 MA= / /
Silver sulfadiazine and cerium nitrate TN= Flammacerium	Prevention of mortality in severely burned patients.	Synthes (USA) 1690 Russell Road PO Box 1766 Paoli, PA 19301 DD=11/17/1999 MA= / /
Sodium 1,3-propanedisulfonate TN=	Treatment of secondary amyloidosis.	Neurochem, Inc. 7220 Frederick Banting, Suite 100 Saint-Laurent, Quebec Canada H4S 2A1, CA DD=04/06/1999 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Sodium Monomercaptoundecahydro-clo so-dodecaborate TN= Borocell	For use in boron neutron capture therapy (BNCT) in the treatment of glioblastoma multiforme.	Neutron Technology Corp.& Neutron R&D Partner 877 Main Street, Suite 402 Boise, ID 83702 DD=04/15/1992 MA= / /
Sodium benzoate/sodium phenylacetate TN= Ammonul	For intravenous use in episodic hyperammonemic encephalopathy.	Ucyclyd Pharma 500 McCormick Dr., Suite J Glen Burnie, MD 21061 DD=11/22/1993 MA= / /
Sodium dichloroacetate TN=	Treatment of congenital lactic acidosis.	Stacpoole, Peter W. M.D., Ph.D. University of Florida P.O. Box 100277 Gainesville, FL 32610 DD=06/11/1990 MA= / /
Sodium dichloroacetate TN=	Treatment of homozygous familial hypercholesterolemia.	Stacpoole, Peter W. M.D., Ph.D. University of Florida P.O. Box 100277 Gainesville, FL 32610 DD=06/11/1990 MA= / /
Sodium dichloroacetate TN=	Treatment of lactic acidosis in patients with severe malaria.	Stacpoole, Peter W. M.D., Ph.D. University Of Florida P.O. Box 100277 Gainesville, FL 32610 DD=11/10/1994 MA= / /
Sodium dichloroacetate TN=	Treatment of congenital lactic acidosis.	Cypros Pharmaceutical Corporation 2714 Loker Avenue West Carlsbad, CA 92008 DD=12/31/1997 MA= / /
Sodium dichloroacetate TN= Ceresine	Treatment of severe head injury.	Cypros Pharmaceutical Corporation 2714 Loker Avenue West Carlsbad, CA 92008 DD=06/14/1999 MA= / /
Sodium gamma hydroxybutyrate TN= Xyrem	Treatment of narcolepsy.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 250 Minnetonka, MN 55305 DD=11/07/1994 MA= / /
Sodium phenylbutyrate TN=	Treatment for sickling disorders, which include S-S hemoglobinopathy, S-C hemoglobinopathy, and S-thalassemia hemoglobinopathy.	Brusilow, Saul W. M.D. Johns Hopkins Medical Institutions 600 North Wolfe Street, Park 336 Baltimore, MD 21205 DD=07/02/1992 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Sodium phenylbutyrate TN= Buphenyl	Treatment of urea cycle disorders: carbamylphosphate synthetase deficiency, ornithine transcarbamylase deficiency, and argininosuccinic acid synthetase deficiency.	Ucyclyd Pharma 500 McCormick Dr., Suite J Glen Burnie, MD 21061 DD=11/22/1993 MA=04/30/1996
Sodium phenylbutyrate TN=	For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma.	Elan Pharmaceutical Research Corporation 1300 Gould Dr. Gainesville, GA 30504 DD=04/24/1998 MA= / /
Sodium tetradecyl sulfate TN= Sotradecol	Treatment of bleeding esophageal varices.	Elkins-Sinn, Inc. 2 Esterbrook Lane Cherry Hill, NJ 08003 DD=06/10/1986 MA= / /
Soluble recombinant human complement receptor type 1 TN=	Prevention or reduction of adult respiratory distress syndrome.	T Cell Sciences, Inc. 119 Fourth Avenue Needham Heights, MA 02194 DD=11/21/1994 MA= / /
Somatostatin TN= Zecnil	Adjunct to the non-operative management of secreting cutaneous fistulas of the stomach, duodenum, small intestine (jejunum and ileum), or pancreas.	Ferring Laboratories, Inc. 400 Rella Boulevard, Suite 201 Suffern, NY 10901 DD=06/20/1988 MA= / /
Somatostatin TN=	Treatment of bleeding esophageal varices.	UCB Pharmaceuticals, Inc. 1950 Lake Park Drive Smyrna, GA 30080 DD=12/22/1994 MA= / /
Somatrem for injection TN= Protropin	For long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=12/09/1985 MA=10/17/1985
Somatrem for injection TN= Protropin	Treatment of short stature associated with Turner's syndrome.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=12/09/1985 MA= / /
Somatropin TN= Nutropin	For use in the long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=03/06/1987 MA=10/17/1985
Somatropin TN= Norditropin	Treatment of growth failure in children due to inadequate growth hormone secretion.	Novo Nordisk Pharmaceuticals 100 Overlook Center Suite 200 Princeton, NJ 08540 DD=07/10/1987 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Somatropin TN= Saizen	Treatment of idiopathic or organic growth hormone deficiency in children with growth failure.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/06/1987 MA= / /
Somatropin TN= Humatrope	Treatment of short stature associated with Turner syndrome.	Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285 DD=05/08/1990 MA=12/30/1996
Somatropin TN= Genotropin	Treatment of adults with growth hormone deficiency.	Pharmacia & Upjohn 7000 Portage Road Kalamazoo, MI 49001 DD=09/06/1994 MA=10/31/1997
Somatropin (rDNA) TN= Saizen	For the enhancement of nitrogen retention in hospitalized patients suffering from severe burns.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=05/03/1989 MA= / /
Somatropin (r-DNA) TN= Serostim	For use with glutamine in the treatment of short bowel syndrome (nutrient malabsorption from the gastrointestinal tract resulting from an inadequate absorptive surface).	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/06/1995 MA= / /
Somatropin (r-DNA) for injection TN= Serostim	Treatment of children with AIDS-associated failure-to-thrive including AIDS-associated wasting.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=03/26/1996 MA= / /
Somatropin (rDNA origin) TN= Nutropin Depot	Long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.	Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 DD=10/28/1999 MA=12/22/1999
Somatropin [rDNA] TN= Genotropin	Treatment of short stature in patients with Prader-Willi syndrome.	Pharmacia & Upjohn 7000 Portage Rd. 0633-298-113 Kalamazoo, MI 49001 DD=07/06/1999 MA= / /
Somatropin for injection TN= Humatrope	For the long-term treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone.	Eli Lilly and Company Lilly Corporate Center Indianapolis, IN 46285 DD=06/12/1986 MA=03/08/1987
Somatropin for injection TN= Nutropin	Treatment of short stature associated with Turner's syndrome.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=03/23/1989 MA=12/30/1996

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Somatropin for injection TN= Nutropin	Treatment of growth retardation associated with chronic renal failure.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=08/04/1989 MA=11/17/1993
Somatropin for injection TN= Serostim	Treatment of AIDS-associated catabolism/weight loss.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=11/15/1991 MA=08/23/1996
Somatropin for injection TN= Nutropin	As replacement therapy for growth hormone deficiency in adults after epiphyseal closure.	Genentech, Inc. 460 Point San Bruno Boulevard South San Francisco, CA 94080 DD=11/18/1996 MA=12/15/1997
Sotalol HCl TN= Betapace	Treatment of life-threatening ventricular tachyarrhythmias.	Berlex Laboratories, Inc. 300 Fairfield Road Wayne, NJ 07470 DD=09/23/1988 MA=10/30/1992
Sotalol HCl TN= Betapace	Prevention of life threatening ventricular tachyarrhythmias.	Berlex Laboratories, Inc. 300 Fairfield Road Wayne, NJ 07470 DD=09/23/1988 MA= / /
Sterile talc TN= Steritalc	Treatment of malignant pleural effusion.	Novatech SA Avenue du Vent des Dames - Z.I. les Paluds 13685 Aubagne France, DD=12/08/1997 MA= / /
Sterile talc TN= Steritalc	Treatment of pneumothorax.	Novatech SA Avenue du Vent des Dames - Z.I. les Paluds 13685 Aubagne France, DD=12/08/1997 MA= / /
Sterile talc powder TN= Sclerosol Intrapleural Aerosol	Treatment of malignant pleural effusion.	Bryan Corporation 4 Plympton Street Woburn, MA 01801 DD=09/18/1995 MA=12/24/1997
Succimer TN= Chemet capsules	Treatment of lead poisoning in children.	Bock Pharmacal Company P.O. Box 419056 Saint Louis, MO 63141 DD=05/09/1984 MA=01/30/1991
Succimer TN= Chemet	Prevention of cystine kidney stone formation in patients with homozygous cystinuria who are prone to stone development.	Sanofi Winthrop, Inc. 90 Park Avenue New York, NY 10016 DD=11/05/1990 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Succimer TN= Chemet	Treatment of mercury intoxication.	Sanofi Winthrop, Inc. 90 Park Avenue New York, NY 10016 DD=03/22/1991 MA= / /
Sucralfate suspension TN=	Treatment of oral complications of chemotherapy in bone marrow transplant patients.	Darby Pharmaceuticals, Inc. 100 Banks Avenue Rockville Centre, NY 11570 DD=03/12/1990 MA= / /
Sucralfate suspension TN=	Treatment of oral ulcerations and dysphagia in patients with epidermolysis bullosa.	Darby Pharmaceuticals, Inc. 100 Banks Avenue Rockville Centre, NY 11570 DD=03/04/1991 MA= / /
Sulfadiazine TN=	For use in combination with pyrimethamine for the treatment of Toxoplasma gondii encephalitis in patients with and without AIDS.	Eon Labs Manufacturing, Inc. 227-15 North Conduit Avenue Laurelton, NY 11413 DD=03/14/1994 MA=07/29/1994
Sulfapyridine TN=	Treatment of dermatitis herpetiformis.	Jacobus Pharmaceutical Company 37 Cleveland Lane P.O. Box 5290 Princeton, NJ 08540 DD=09/10/1990 MA= / /
Superoxide dismutase (human) TN=	For protection of donor organ tissue from damage or injury mediated by oxygen-derived free radicals that are generated during the necessary periods of ischemia (hypoxia, anoxia), and especially reperfusion, associated with the operative procedure.	Pharmacia-Chiron Partnership 4560 Horton Street Emeryville, CA 94608 DD=03/06/1985 MA= / /
Superoxide dismutase (recombinant human) TN= Oxsodrol	Prevention of reperfusion injury to donor organ tissue.	Bio-Technology General Corp. 70 Wood Avenue, South Iselin, NJ 08830 DD=05/17/1988 MA= / /
Suramin TN= Metaret	Treatment of hormone-refractory prostate cancer.	Warner-Lambert Company Parke-Davis Pharmaceutical Research Division 2800 Plymouth Road Ann Arbor, MI 48105 DD=05/06/1997 MA= / /
Surface active extract of saline lavage of bovine lungs TN= Infasurf	Treatment and prevention of respiratory failure due to pulmonary surfactant deficiency in preterm infants.	ONY, Inc. 1576 Sweet Home Road Amherst, NY 14228 DD=06/07/1985 MA= / /
Synsorb Pk TN=	Treatment of verocytotoxogenic E. coli infections.	Synsorb Biotech Inc. 201, 1204 Kensington Road, N.W. Calgary, Alberta Canada T2N 3P5, DD=07/17/1995 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name		INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Synthetic human secretin TN=		For use in the evaluation of exocrine pancreas function.	ChiRhoClin, Inc. 1550 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999 MA= / /
Synthetic human secretin TN=		For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999 MA= / /
Synthetic human secretin TN=		For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999 MA= / /
Synthetic porcine secretin TN=		For use in the evaluation of exocrine pancreas function.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999 MA= / /
Synthetic porcine secretin TN=		For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999 MA= / /
Synthetic porcine secretin TN=		For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999 MA= / /
T4 endonuclease V, liposome encapsulated TN=		To prevent cutaneous neoplasms and other skin abnormalities in xeroderma pigmentosum.	AGI Dermatics 205 Buffalo Avenue Freeport, NY 11520 DD=06/27/1989 MA= / /
Tacrolimus TN= Prograf		Prophylaxis of graft-versus-host-disease.	Fujisawa USA, Inc. 3 Parkway North Center Deerfield, IL 60015 DD=04/06/1998 MA= / /
Technetium Tc99m murine monoclonal antibody (IgG2a) to B cell TN= LymphoScan		Diagnostic imaging in the evaluation of the extent of disease in patients with histologically confirmed diagnosis of non-Hodgkin's B-cell lymphoma, acute B-cell lymphoblastic leukemia (in children and adults), and chronic B-cell lymphocytic leukemia.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=04/07/1992 MA= / /
Technetium Tc99m murine monoclonal antibody to hCG TN= Immuraid, hCG-Tc-99m		Detection of hCG producing tumors such as germ cell and trophoblastic cell tumors.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=08/07/1989 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Technetium Tc99m murine monoclonal antibody to human AFP TN= AFP-Scan	Detection of alpha-fetoprotein producing germ cell tumors.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=08/01/1989 MA= / /
Technetium Tc99m murine monoclonal antibody to human alpha-fetoprotein TN= Immuraid, AFP-Scan	Detection of hepatocellular carcinoma and hepatoblastoma.	Immunomedics, Inc. 300 American Road Morris Plains, NJ 07950 DD=08/01/1989 MA= / /
Temoporfin TN= Foscan	Palliative treatment of recurrent, refractory or second primary squamous cell carcinomas of the head and neck in patients considered to be incurable with surgery or radiotherapy.	Scotia Pharmaceuticals Ltd. Scotia House, Castle Business Park Stirling Scotland FK9 4TZ, GB DD=10/28/1999 MA= / /
Temozolomide TN= Temodar	Treatment of recurrent malignant glioma.	Schering-Plough Research Institute 2000 Galloping Hill Rd. Kenilworth, NJ 07033 DD=10/05/1998 MA=08/11/1999
Temozolomide TN= Temodal	Treatment of advanced metastatic melanoma.	Schering-Plough Research Institute 2000 Galloping Hill Rd. Kenilworth, NJ 07033 DD=10/14/1998 MA= / /
Teniposide TN= Vumon for injection	Treatment of refractory childhood acute lymphocytic leukemia.	Bristol-Myers Squibb Pharmaceutical Research Institute 5 Research Parkway P.O. Box 5100 Wallingford, CT 06492 DD=11/01/1984 MA=07/14/1992
Teriparatide TN= Parathar	Diagnostic agent to assist in establishing the diagnosis in patients presenting with clinical and laboratory evidence of hypocalcemia due to either hypoparathyroidism or pseudohypoparathyroidism.	Rhone-Poulenc Rorer Pharmaceuticals, Inc. 500 Arcola Road Collegeville, PA 19426 DD=01/09/1987 MA=12/23/1987
Teriparatide TN= Parathar	Treatment of idiopathic osteoporosis.	Henri Beaufour Institute USA, Inc. 27 Maple St. Milford, MA 01757 DD=10/28/1999 MA= / /
Terlipressin TN= Glypressin	Treatment of bleeding esophageal varices.	Ferring Laboratories, Inc. 400 Rella Boulevard, Suite 201 Suffern, NY 10901 DD=03/06/1986 MA= / /
Testosterone TN= Androgel	Treatment of weight loss in AIDS patients with HIV-associated wasting.	Unimed Pharmaceuticals, Inc. 2150 East Lake Cook Road Buffalo Grove, IL 60089 DD=02/05/1996 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Testosterone TN= TheraDerm Testosterone Transdermal System	For use as physiologic testosterone replacement in androgen deficient HIV+ patients with an associated weight loss.	TheraTech, Inc. 417 Wakara Way Salt Lake City, UT 84108 DD=09/22/1997 MA= / /
Testosterone propionate ointment 2% TN=	Treatment of vulvar dystrophies.	Star Pharmaceuticals, Inc. 1990 N.W. 44th Street Pompano Beach, FL 33064 DD=07/31/1991 MA= / /
Testosterone sublingual TN=	Treatment of constitutional delay of growth and puberty in boys.	Bio-Technology General Corp. 70 Wood Avenue, South Iselin, NJ 08830 DD=01/16/1991 MA= / /
Tetrabenazine TN=	Treatment of Huntington's disease.	Lifehealth Limited Richmond House, Old Brewery Court, Sandyford Road Newcastle upon Tyne NE2 1XG England, UK, DD=12/11/1997 MA= / /
Tetrabenazine TN=	Treatment of moderate/severe tardive dyskinesia.	Lifehealth Limited Richmond House, Old Brewery Court, Sandyford Road Newcastle upon Tyne NE2 1XG England, DD=05/12/1998 MA= / /
Thalidomide TN=	Treatment of graft versus host disease in patients receiving bone marrow transplantation.	Pediatric Pharmaceuticals, Inc. 718 Bradford Avenue Westfield, NJ 07090 DD=09/19/1988 MA= / /
Thalidomide TN=	Prevention of graft versus host disease in patients receiving bone marrow transplantation.	Pediatric Pharmaceuticals, Inc. 718 Bradford Avenue Westfield, NJ 07090 DD=09/19/1988 MA= / /
Thalidomide TN=	Treatment and maintenance of reactional lepromatous leprosy.	Pediatric Pharmaceuticals, Inc. 718 Bradford Avenue Westfield, NJ 07090 DD=11/15/1988 MA= / /
Thalidomide TN=	Treatment of graft versus host disease.	Andrulis Research Corporation 11800 Baltimore Avenue, Suite 113 Beltsville, MD 20705 DD=03/05/1990 MA= / /
Thalidomide TN=	Prevention of graft versus host disease.	Andrulis Research Corporation 11800 Baltimore Avenue, Suite 113 Beltsville, MD 20705 DD=03/05/1990 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Thalidomide TN=	Treatment of the clinical manifestations of mycobacterial infection caused by Mycobacterium tuberculosis and non-tuberculous mycobacteria.	Celgene Corporation P.O. Box 4914 7 Powder Horn Drive Warren, NJ 07059 DD=01/12/1993 MA= / /
Thalidomide TN=	Treatment of severe recurrent aphthous stomatitis in severely, terminally immunocompromised patients.	Celgene Corporation P.O. Box 4914 7 Powder Horn Drive Warren, NJ 07059 DD=05/01/1995 MA= / /
Thalidomide TN=	Treatment and prevention of recurrent aphthous ulcers in severely, terminally immunocompromised patients.	Andrulis Research Corporation 11800 Baltimore Avenue, Suite 113 Beltsville, MD 20705 DD=05/15/1995 MA= / /
Thalidomide TN= Thalomid	Treatment of erythema nodosum leprosum.	Celgene Corporation P.O. Box 4914 7 Powder Horn Drive Warren, NJ 07059 DD=07/26/1995 MA=07/16/1998
Thalidomide TN= Synovir	Treatment of HIV-associated wasting syndrome.	Celgene Corporation P.O. Box 4914 7 Powder Horn Drive Warren, NJ 07059 DD=03/11/1996 MA= / /
Thalidomide TN=	Treatment of primary brain malignancies.	Celgene Corporation 7 Powder Horn Dr. Warren, NJ 07059 DD=02/27/1998 MA= / /
Thalidomide TN=	Treatment of Kaposi's sarcoma.	Celgene Corporation 7 Powder Horn Dr. Warren, NJ 07059 DD=07/29/1998 MA= / /
Thalidomide TN= Thalomid	Treatment of multiple myeloma.	Celgene Corporation 7 Powder Horn Dr. Warren, NJ 07059 DD=10/14/1998 MA= / /
Thalidomide TN= Thalomid	Treatment of Crohn's disease.	Celgene Corporation 7 Powder Horn Dr. Warren, NJ 07059 DD=04/06/1999 MA= / /
Thymalfasin TN= Zadaxin	Treatment of chronic active hepatitis B.	SciClone Pharmaceuticals, Inc. 901 Mariner's Island Blvd. San Mateo, CA 94404 DD=05/03/1991 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Thymalfasin TN= Zadaxin	Treatment of DiGeorge anomaly with immune defects.	SciClone Pharmaceuticals, Inc. 901 Mariner's Island Blvd. San Mateo, CA 94404 DD=01/08/1998 MA= / /
Thyrotropin alpha TN= Thyrogen	As an adjunct in the diagnosis of thyroid cancer.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=02/24/1992 MA=11/30/1998
Tiaprside TN=	Treatment of Tourette's syndrome.	Sanofi-Synthelabo, Inc. 9 Great Valley Parkway PO Box 3026 Malvern, PA 19355 DD=04/21/1998 MA= / /
Tiopronin TN= Thiola	Prevention of cystine nephrolithiasis in patients with homozygous cystinuria.	Pak, Charles Y.C. M.D. The University of Texas Health Science Center at Dallas 5323 Harry Hines Boulevard Dallas, TX 75235 DD=01/17/1986 MA=08/11/1988
Tiratricol TN= Triacana	For use in combination with levo-thyroxine to suppress thyroid stimulating hormone in patients with well-differentiated thyroid cancer who are intolerant to adequate doses of levo-thyroxine alone.	Laphal Laboratoires 48 Bis, Rue des Belles-Feuilles 75116 Paris France, FR DD=08/13/1991 MA= / /
Tizanidine HCl TN= Zanaflex	Treatment of spasticity associated with multiple sclerosis and spinal cord injury.	Athena Neurosciences, Inc. 800 Gateway Boulevard South San Francisco, CA 94080 DD=01/31/1994 MA= / /
Tobramycin TN= Tobl	Treatment of bronchiectasis patients infected with Pseudomonas aeruginosa.	PathoGenesis Corporation 201 Elliott Avenue West Suite 150 Seattle, WA 98119 DD=06/18/1999 MA= / /
Tobramycin for inhalation TN= TOBI	Treatment of bronchopulmonary infections of Pseudomonas aeruginosa in cystic fibrosis patients.	Pathogenesis Corporation 201 Elliott Avenue West, Suite 150 Seattle, WA 98119 DD=10/13/1994 MA=12/22/1997
Topiramate TN= Topamax	Treatment of Lennox-Gastaut syndrome.	R. W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan, NJ 08869 DD=11/25/1992 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Toremifene TN= Fareston	Hormonal therapy of metastatic carcinoma of the breast.	Orion Corporation P.O. Box 65 02101 ESPOO Finland, DD=09/19/1991 MA=05/29/1997
Toremifene TN=	Treatment of desmoid tumors.	Orion Corporation P.O. Box 65 02101 Espoo Finland, DD=08/17/1993 MA= / /
Tositumomab and iodine I 131 tositumomab TN= Bexxar	Treatment of non-Hodgkin's B-cell lymphoma.	Coulter Pharmaceutical, Inc. 550 California Avenue Suite 200 Palo Alto, CA 94306 DD=05/16/1994 MA= / /
Transforming growth factor-beta 2 TN=	Treatment of full thickness macular holes.	Celtrix Pharmaceuticals, Inc. 3055 Patrick Henry Drive Santa Clara, CA 95054 DD=12/18/1992 MA= / /
Transgenic human alpha 1 antitrypsin TN=	Treatment of cystic fibrosis.	PPL Therapeutics (Scotland) Limited Roslin, Edinburgh EH25 9PP Scotland, GB DD=03/06/1998 MA= / /
Transgenic human alpha 1 antitrypsin TN=	Treatment of emphysema secondary to alpha 1 antitrypsin deficiency.	PPL Therapeutics (Scotland) Limited Roslin, Edinburgh EH25 9PP Scotland, GB DD=05/19/1999 MA= / /
Trastuzumab TN= Herceptin	Treatment of patients with pancreatic cancer that overexpress p185HER2.	Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 DD=12/14/1999 MA= / /
Treosulfan TN= Ovastat	Treatment of ovarian cancer.	Medac GmbH Fehlandtstrasse 3 D-20354 Hamburg Germany, DD=05/16/1994 MA= / /
Tretinoin TN=	Treatment of squamous metaplasia of the ocular surface epithelia (conjunctiva and/or cornea) with mucous deficiency and keratinization.	Hannan Ophthalmic Marketing Services, Inc 34 Sherrill Rd. Marshfield, MA 02050 DD=04/15/1985 MA= / /
Tretinoin TN= Vesanoid	Treatment of acute promyelocytic leukemia.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=10/24/1990 MA=11/22/1995

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Tretinoin TN= Atragen	Treatment of acute and chronic leukemia.	Aronex Pharmaceuticals, Inc. 8707 Technology Forest Place The Woodlands, TX 77381 DD=01/14/1993 MA= / /
Trientine HCl TN= Syprine	Treatment of patients with Wilson's disease who are intolerant, or inadequately responsive to penicillamine.	Merck Sharp & Dohme Research Division Of Merck And Company West Point, PA 19486 DD=12/24/1984 MA=11/08/1985
Trimetrexate glucuronate TN=	Treatment of metastatic carcinoma of the head and neck (i.e. buccal cavity, pharynx, and larynx).	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street West Conshohocken, PA 19428 DD=07/25/1985 MA= / /
Trimetrexate glucuronate TN=	Treatment of metastatic colorectal adenocarcinoma.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street West Conshohocken, PA 19428 DD=07/25/1985 MA= / /
Trimetrexate glucuronate TN=	Treatment of pancreatic adenocarcinoma.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street West Conshohocken, PA 19428 DD=07/25/1985 MA= / /
Trimetrexate glucuronate TN= Neutrexin	Treatment of Pneumocystis carinii pneumonia in AIDS patients.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street West Conshohocken, PA 19428 DD=05/15/1986 MA=12/17/1993
Trimetrexate glucuronate TN=	Treatment of patients with advanced non-small cell carcinoma of the lung.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street West Conshohocken, PA 19428 DD=01/13/1988 MA= / /
Trisaccharides A and B TN= Biosynject	Treatment of moderate to severe clinical forms of hemolytic disease of the newborn arising from placental transfer of antibodies against blood group substances A and B.	Chembiomed, Ltd. P.O. Box 8050, Station F Edmonton, Alberta Canada T6H 4NP, DD=04/12/1987 MA= / /
Trisaccharides A and B TN= Biosynject	For use in ABO-incompatible solid organ transplantation, including kidney, heart, liver and pancreas.	Chembiomed, Ltd. P.O. Box 8050, Station F Edmonton, Alberta Canada T6H 4NP, DD=04/20/1987 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Trisaccharides A and B TN= Biosynject	Prevention of ABO medical hemolytic reactions arising from ABO-incompatible bone marrow transplantation.	Chembiomed, Ltd. P.O. Box 8050, Station F Edmonton, Alberta Canada T6H 4NP, DD=04/15/1988 MA= / /
Trisodium citrate concentration TN= Hemocitrate	For use in leukapheresis procedures.	Hemotec Medical Products, Inc. Box 19255 Johnston, RI 02919 DD=06/15/1995 MA= / /
Troleandomycin TN=	Treatment of severe steroid-requiring asthma.	Szeffler, Stanley M. M.D. National Jewish Center for Immunology and Respiratory Medicine 1400 Jackson Street Denver, CO 80206 DD=09/21/1989 MA= / /
Tumor necrosis factor-binding protein I TN=	Treatment of symptomatic patients with AIDS including all patients with CD4 counts less than 200 cells per mm ³ .	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=01/06/1993 MA= / /
Tumor necrosis factor-binding protein II TN=	Treatment of symptomatic patients with the AIDS including all patients with CD4 T-cell counts less than 200 cells per mm ³ .	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=01/06/1993 MA= / /
Tyloxapol TN=	Treatment of cystic fibrosis.	Kennedy & Hoidal, M.D.'s University of Utah Health Sciences Center 50 North Medical Drive, Room 4R240 Salt Lake City, UT 84132 DD=03/08/1995 MA= / /
Ubiquinone TN= Ubiqgel	Treatment of mitochondrial cytopathies.	Gel-Tec, Division of Tishcon Corp. 30 New York Ave. PO Box 331 Westbury, NY 11590 DD=12/14/1999 MA= / /
Uridine 5'-triphosphate TN=	Treatment of cystic fibrosis.	Inspire Pharmaceuticals, Inc. 4222 Emperor Boulevard, Suite 470 Durham, NC 27703 DD=12/04/1995 MA= / /
Uridine 5'-triphosphate TN=	To facilitate the removal of lung secretions in the treatment of patients with primary ciliary dyskinesia.	Inspire Pharmaceuticals, Inc. 4222 Emperor Boulevard, Suite 470 Durham, NC 27703 DD=06/26/1996 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Urofollitropin TN= Metrodin	For induction of ovulation in patients with polycystic ovarian disease who have an elevated LH/FSH ratio and who have failed to respond to adequate clomiphene citrate therapy.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=11/25/1987 MA=09/18/1986
Urofollitropin TN= Fertinex	For the initiation and re-initiation of spermatogenesis in adult males with reproductive failure due to hypothalamic or pituitary dysfunction, hypogonadotropic hypogonadism.	Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061 DD=12/05/1997 MA= / /
Urogastrone TN=	For acceleration of corneal epithelial regeneration and healing of stromal incisions from corneal transplant surgery.	Chiron Vision 500 Iolab Drive Claremont, CA 91711 DD=11/01/1984 MA= / /
Ursodiol TN= URSO	Treatment of patients with primary biliary cirrhosis.	Axcan Pharma Inc. 3881, Industriel boulevard Laval, Quebec H7L 4S3 Canada, DD=06/20/1991 MA=12/10/1997
Valine, isoleucine and leucine TN= VIL	Treatment of hyperphenylalaninemia.	Leas Research Products 78 Fallon Drive North Haven, CT 06473 DD=01/05/1996 MA= / /
Valrubicin TN= Valstar	Treatment of carcinoma in situ of the urinary bladder.	Anthra Pharmaceuticals, Inc. 103 Carnegie Center, Suite 102 Princeton, NJ 08540 DD=05/23/1994 MA=09/25/1998
Vasoactive intestinal polypeptide TN=	Treatment of acute esophageal food impaction.	Research Triangle Pharmaceuticals 4364 South Alston Avenue Durham, NC 27713 DD=06/23/1993 MA= / /
Xenogeneic hepatocytes TN= HepatAssist Liver Assist System	Treatment of severe liver failure.	Circe Biomedical, Inc. 99 Hayden Ave. Lexington, MA 02421 DD=11/27/1998 MA= / /
Yttrium-90 radiolabeled humanized monoclonal anti-carcinoembryonic antigen IgG antibody TN= Cea-Cide	Treatment of ovarian carcinoma.	Immunomedics, Inc. 300 American Rd. Morris Plains, NJ 07950 DD=08/03/1999 MA= / /
Zalcitabine TN=	Treatment of AIDS.	National Cancer Institute, DCT NIH, Executive Plaza North, Room 7-18 Bethesda, MD 20892 DD=12/09/1986 MA= / /

LIST OF ORPHAN PRODUCTS DESIGNATIONS AND APPROVALS

Through December 31, 1999

NAME Generic Name TN=Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
Zalcitabine TN= Hivid	Treatment of AIDS.	Hoffmann-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110 DD=06/28/1988 MA=06/19/1992
Zidovudine TN= Retrovir	Treatment of AIDS related complex.	Glaxo Wellcome Inc. 5 Moore Drive Research Triangle Park, NC 27709 DD=05/12/1987 MA=03/19/1987
Zidovudine TN= Retrovir	Treatment of AIDS.	Glaxo Wellcome Inc. 5 Moore Drive Research Triangle Park, NC 27709 DD=07/17/1985 MA=03/19/1987
Zinc acetate TN= Galzin	Treatment of Wilson's disease.	Lemmon Company 1510 Delp Drive Kulpsville, PA 19443 DD=11/06/1985 MA=01/28/1997
pVGL1(VEGF2) TN=	Treatment of thromboangiitis obliterans.	Vascular Genetics, Inc. 200 Westpark Corporate Center 4364 South Alston Ave. Durham, NC 27713 DD=11/09/1999 MA= / /