

List of Orphan Designations and Approvals

This list contains products that are currently designated as orphans by the Office of Orphan Products Development. Those designated products that are also approved for marketing will have a status listing of "Designated/Approved" as well as a marketing approval date. **To search for a particular product, please use the Find option of your Web browser (generally this is found under the Edit menu)**

To open a copy of this list as an Excel Spreadsheet, click here [Orphan Designated Products Spreadsheet](#)

Generic Name: (R)-N-[2-(6-chloro-5-methoxy-1H-indol-3-yl)propyl]acetamide
Trade Name:

Orphan Indication: Treatment of circadian rhythm sleep disorders in blind people with no light perception

Sponsor: Phase 2 Discovery, Inc. **Contact:** Dr. Frank Zemlan

Address: Cincinnati, OH **Phone:** 5134756618 **Fax:**

Status: Designated **Designation Date:** 03-Oct-01 **Marketing Approval Date:**

Generic Name: 1,5-(Butylimino)-1,5 dideoxy,D-glucitol
Trade Name:

Orphan Indication: Treatment of Fabry's disease.

Sponsor: Oxford GlycoSciences **Contact:** Mr. Bruce Manning

Address: Oxfordshire OX14 3YS, UK **Phone:** (508) 393-3100 **Fax:** (508) 393-3780

Status: Designated **Designation Date:** 12-May-98 **Marketing Approval Date:**

Generic Name: 1,5-(Butylimino)-1,5 dideoxy,D-glucitol
Trade Name:

Orphan Indication: Treatment of Gaucher disease.

Sponsor: Oxford GlycoSciences **Contact:** Mr. Bruce Manning

Address: Oxfordshire OX14 3YS, UK **Phone:** (508) 393-3100 **Fax:** (508) 393-3780

Status: Designated **Designation Date:** 29-May-98 **Marketing Approval Date:**

Generic Name: 1-(11-dodecylamino-10-hydroxyundecyl)-3,7-dimethylxanthine hydrogen methanesulfonate
Trade Name:

Orphan Indication: Treatment of hormone refractory prostate carcinoma.

Sponsor: Cell Therapeutics, Inc. **Contact:** Ms. Jennie Allewell

Address: Seattle, WA **Phone:** (206) 282-7100 **Fax:**

Status: Designated **Designation Date:** 18-Jan-00 **Marketing Approval Date:**

Generic Name: 111Indium pentetreotide **Trade Name:** SomatoTher

Orphan Indication: Treatment of somatostatin receptor positive neuroendocrine tumors.

Sponsor: Louisiana State University Medical Center Foundation **Contact:** Mr. James Hardy

Address: New Orleans, LA **Phone:** (504) 568-3712 **Fax:** (504) 568-3460

Status: Designated **Designation Date:** 10-Jun-99 **Marketing Approval Date:**

Generic Name: 15AU81 **Trade Name:** Remodulin

Orphan Indication: Treatment of pulmonary arterial hypertension.

Sponsor: United Therapeutics Corp. **Contact:** Mr. Dean Bunce

Address: Research Triangle Park, NC **Phone:** (919) 485-8352 **Fax:** (919) 485-8352

Status: Designated **Designation Date:** 04-Jun-97 **Marketing Approval Date:**

Generic Name: 166Ho-DOTMP
Trade Name:

Orphan Indication: Treatment of multiple myeloma.

Sponsor: NeoRx Corporation **Contact:** Dr. Robert Caspari

Address: Seattle, WA **Phone:** (206) 281-7001 **Fax:**

Status: Designated **Designation Date:** 10-Feb-99 **Marketing Approval Date:**

Generic Name: 2'-3'-dideoxyadenosine

Trade Name:

Orphan Indication: Treatment of acquired immunodeficiency syndrome.**Sponsor:** National Cancer Institute, Dct **Contact:** Dr. Jay Greenblatt**Address:** Bethesda, MD **Phone:** (301) 496-7912 **Fax:****Status:** Designated/Withdrawn **Designation Date:** 21-Jul-87 **Marketing Approval Date:****Generic Name:** 2'-deoxycytidine

Trade Name:

Orphan Indication: As a host-protective agent in the treatment of acute myelogenous leukemia.**Sponsor:** Grant, Steven M.D. **Contact:** Dr. Steven Grant**Address:** Richmond, VA **Phone:** (804) 828-5122 **Fax:** (804) 828-8079**Status:** Designated **Designation Date:** 09-Sep-96 **Marketing Approval Date:****Generic Name:** 2-O-desulfated heparin **Trade Name:** Aeropin**Orphan Indication:** Treatment of cystic fibrosis.**Sponsor:** Kennedy & Hoidal, M.D.'s **Contact:** Dr. John Hoidal**Address:** Salt Lake City, UT **Phone:** (704) 355-2000 **Fax:****Status:** Designated **Designation Date:** 17-Sep-93 **Marketing Approval Date:****Generic Name:** 2-chloroethyl-3-sarcosinamide-1-nitrosourea

Trade Name:

Orphan Indication: Treatment for malignant gliomas**Sponsor:** Lawrence Panasci, MD **Contact:** Dr. Lawrence Panasci**Address:** Montreal, Quebec H3T 1E2, **Phone:** 5143408248 **Fax:** 5143408302**Status:** Designated **Designation Date:** 03-Aug-01 **Marketing Approval Date:****Generic Name:** 2-methoxyestradiol **Trade Name:** Panzem**Orphan Indication:** Treatment of multiple myeloma**Sponsor:** EntreMed, Inc. **Contact:** Dr. Edward Gubish, Jr.,**Address:** Rockville, MD **Phone:** 3012179858 **Fax:** 3012179594**Status:** Designated **Designation Date:** 10-Jul-01 **Marketing Approval Date:****Generic Name:** 24,25 dihydroxycholecalciferol

Trade Name:

Orphan Indication: Treatment of uremic osteodystrophy.**Sponsor:** Lemmon Company **Contact:** Ms. Deborah Jaskot**Address:** Kulpsville, PA **Phone:** (215) 256-8400 **Fax:****Status:** Designated **Designation Date:** 27-Feb-87 **Marketing Approval Date:****Generic Name:** 3'-azido-2',3'-dideoxyuridine **Trade Name:** AZDU**Orphan Indication:** Treatment of acquired immunodeficiency syndrome.**Sponsor:** Berlex Laboratories, Inc. **Contact:** Donald Gay**Address:** Alameda, CA **Phone:** (510) 769-4985 **Fax:****Status:** Designated/Withdrawn **Designation Date:** 20-Nov-89 **Marketing Approval Date:****Generic Name:** 3,4-diaminopyridine

Trade Name:

Orphan Indication: Treatment of Lambert-Eaton myasthenic syndrome.**Sponsor:** Jacobus Pharmaceutical Company **Contact:** Dr. Neil Lewis**Address:** Princeton, NJ **Phone:** (609) 921-7447 **Fax:****Status:** Designated **Designation Date:** 18-Dec-90 **Marketing Approval Date:****Generic Name:** 3,5,3'-triiodothyroacetate

Trade Name:

Orphan Indication: Treatment of well-differentiated papillary, follicular or combined papillary/follicular carcinomas of the thyroid gland.**Sponsor:** Elliot Danforth, Jr., M.D. **Contact:** Dr. Elliot Danforth, Jr.**Address:** Underhill, VT **Phone:** 8028992349 **Fax:** 8028992349**Status:** Designated **Designation Date:** 20-Sep-00 **Marketing Approval Date:****Generic Name:** 3-(3,5-dimethyl-1H-2ylmethylene)-1,3-dihydro-indol-2-one

Trade Name:

Orphan Indication: Treatment of Kaposi's sarcoma.**Sponsor:** Sugen, Inc. **Contact:** Dr. Stephen Carter**Address:** South San Francisco, CA **Phone:** (650) 553-8300 **Fax:** (650) 553-8301**Status:** Designated **Designation Date:** 11-Sep-98 Marketing Approval Date:**Generic Name:** 3-(3,5-Dimethyl-1H-2ylmethylene)-1,3-dihydro-indol-2-one

Trade Name:

Orphan Indication: Treatment of von Hippel-Lindau disease.**Sponsor:** Sugen, Inc. **Contact:** Dr. Paul Scigalla**Address:** South San Francisco, CA **Phone:** (650) 553-8792 **Fax:** (650) 553-8314**Status:** Designated **Designation Date:** 23-Mar-00 Marketing Approval Date:**Generic Name:** 3-(4-aminoisoindoline-1'-one)-1-piperidine-2,6-dione **Trade Name:** Revimid (proposed)**Orphan Indication:** Treatment for multiple myeloma**Sponsor:** Celgene Corporation **Contact:** Dr. Steve Thomas**Address:** Warren, NJ **Phone:** 7328053914 **Fax:** 7322714184**Status:** Designated **Designation Date:** 20-Sep-01 Marketing Approval Date:**Generic Name:** 4-aminosalicylic acid **Trade Name:** Pamisyl (P-D), Rezipas (Squibb)**Orphan Indication:** Treatment of mild to moderate ulcerative colitis in patients intolerant to sulfasalazine.**Sponsor:** Beeken, Warren M.D. **Contact:** Dr. Warren Beeken**Address:** Burlington, VT **Phone:** (802) 656-2554 **Fax:****Status:** Designated **Designation Date:** 13-Dec-89 Marketing Approval Date:**Generic Name:** 40SD02

Trade Name:

Orphan Indication: Treatment of chronic iron overload resulting from conventional transfusional treatment of beta-thalassemia major and sickle cell anemia.**Sponsor:** Biomedical Frontiers, Inc. **Contact:** Dr. Paul Dragsten**Address:** Minneapolis, MN **Phone:** (612) 378-0228 **Fax:** 6123783601**Status:** Designated **Designation Date:** 21-Dec-98 Marketing Approval Date:**Generic Name:** 5,6-dihydro-5-azacytidine

Trade Name:

Orphan Indication: Treatment of malignant mesothelioma.**Sponsor:** ILEX Oncology, Inc. **Contact:** Mr. Edward Martinez**Address:** San Antonio, TX **Phone:** (210) 949-8270 **Fax:** (210) 949-8282**Status:** Designated **Designation Date:** 11-May-92 Marketing Approval Date:**Generic Name:** 5-aza-2'-deoxycytidine

Trade Name:

Orphan Indication: Treatment of acute leukemia.**Sponsor:** SuperGen, Inc. **Contact:** Dr. Sam Boddapati**Address:** Dublin, CA **Phone:** 9255600100 **Fax:** 9255516472**Status:** Designated **Designation Date:** 03-Aug-87 Marketing Approval Date:**Generic Name:** 506U78

Trade Name:

Orphan Indication: Treatment of chronic lymphocytic leukemia.**Sponsor:** Glaxo Wellcome, Inc. **Contact:** Ms. Marna Doucette**Address:** Research Triangle Park, NC **Phone:** (919) 483-6222 **Fax:****Status:** Designated **Designation Date:** 02-Sep-99 Marketing Approval Date:**Generic Name:** 5a8, monoclonal antibody to CD4

Trade Name:

Orphan Indication: For use in post-exposure prophylaxis for occupational exposure to human immunodeficiency virus.**Sponsor:** Biogen, Inc. **Contact:** Ms. Sylvie Gregoire**Address:** Cambridge, MA **Phone:** (617) 679-2631 **Fax:** (617) 679-3170**Status:** Designated/Withdrawn **Designation Date:** 20-Dec-93 Marketing Approval Date:

Generic Name: 6-hydroxymethylacylfulvene
Trade Name:

Orphan Indication: Treatment of ovarian cancer.

Sponsor: MGI Pharma, Inc. **Contact:** Dr. Jo Gustafson

Address: Bloomington, MN **Phone:** 9523464722 **Fax:** 9523464800

Status: Designated **Designation Date:** 06-Jul-99 Marketing Approval Date:

Generic Name: 6-hydroxymethylacylfulvene
Trade Name:

Orphan Indication: Treatment of renal cell carcinoma.

Sponsor: MGI Pharma, Inc. **Contact:** Dr. Jo Gustafson

Address: Bloomington, MN **Phone:** 9523464722 **Fax:** (612) 346-4800

Status: Designated **Designation Date:** 27-Jul-99 Marketing Approval Date:

Generic Name: 6-hydroxymethylacylfulvene
Trade Name:

Orphan Indication: Treatment of histologically confirmed advanced or metastatic pancreatic cancer.

Sponsor: MGI Pharma, Inc. **Contact:** Dr. Jo Gustafson

Address: Bloomington, MN **Phone:** 9523464722 **Fax:** 9523464800

Status: Designated **Designation Date:** 06-Apr-99 Marketing Approval Date:

Generic Name: 8 Cyclopentyl 1,3-dipropylxanthine
Trade Name:

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: SciClone Pharmaceuticals, Inc. **Contact:** Mr. David Wilgus

Address: San Mateo, CA **Phone:** 6503583456 **Fax:** (415) 358-3469

Status: Designated **Designation Date:** 24-Mar-97 Marketing Approval Date:

Generic Name: 8-methoxsalen **Trade Name:** Uvadex

Orphan Indication: For use in conjunction with the UVAR photopheresis to treat diffuse systemic sclerosis.

Sponsor: Therakos, Inc. **Contact:** Ms. Roberta Acchione

Address: Exton, PA **Phone:** (610) 280-1008 **Fax:**

Status: Designated **Designation Date:** 22-Jun-93 Marketing Approval Date:

Generic Name: 8-methoxsalen **Trade Name:** Uvadex

Orphan Indication: For the prevention of acute rejection of cardiac allografts.

Sponsor: Therakos, Inc. **Contact:** Ms. Roberta Acchione

Address: Exton, PA **Phone:** (610) 280-1008 **Fax:**

Status: Designated **Designation Date:** 12-May-94 Marketing Approval Date:

Generic Name: 9-cis retinoic acid **Trade Name:** Panretin

Orphan Indication: Treatment of acute promyelocytic leukemia.

Sponsor: Ligand Pharmaceuticals, Inc. **Contact:** Dr. Howard Holden

Address: San Diego, CA **Phone:** (619) 550-7600 **Fax:** (619) 625-9524

Status: Designated **Designation Date:** 10-Apr-92 Marketing Approval Date:

Generic Name: 9-cis-retinoic acid
Trade Name:

Orphan Indication: Prevention of retinal detachment due to proliferative vitreoretinopathy.

Sponsor: Allergan, Inc. **Contact:** Dr. Trudy Rumbaugh

Address: Irvine, CA **Phone:** (714) 246-4292 **Fax:** (714) 246-4272

Status: Designated/Withdrawn **Designation Date:** 02-Jan-97 Marketing Approval Date:

Generic Name: 9-nitro-20-(S)-camptothecin
Trade Name:

Orphan Indication: Treatment of pancreatic cancer.

Sponsor: Stehlin Foundation for Cancer Research **Contact:** Dr. Beppino Giovannella

Address: Houston, TX **Phone:** (713) 659-1336 **Fax:** (713) 659-1503

Status: Designated **Designation Date:** 16-Sep-96 Marketing Approval Date:

Generic Name: 9-nitro-20-(S)-camptothecin **Trade Name:** Camvirex

Orphan Indication: Treatment of pediatric HIV infection/AIDS
Sponsor: NovoMed Pharmaceuticals, Inc. **Contact:** Dr. M. Reza Sadaie
Address: Germantown, MD **Phone:** 3012756625 **Fax:** 5093525349
Status: Designated **Designation Date:** 15-May-01 Marketing Approval Date:

Generic Name: Abetimus
Trade Name:

Orphan Indication: Treatment of lupus nephritis.
Sponsor: La Jolla Pharmaceutical Co. **Contact:** Dr. Andrew Wiseman
Address: San Diego, CA **Phone:** (858) 452-6600 **Fax:**
Status: Designated **Designation Date:** 28-Jul-00 Marketing Approval Date:

Generic Name: acetylcysteine **Trade Name:** Acetadote

Orphan Indication: For the intravenous treatment of moderate to severe acetaminophen overdose
Sponsor: Cumberland Pharmaceuticals Inc. **Contact:** Mr. Peter Vaccari
Address: Nashville, TN **Phone:** 3013091260 **Fax:** 3013098470
Status: Designated **Designation Date:** 19-Oct-01 Marketing Approval Date:

Generic Name: Acetylcysteine **Trade Name:** Mucomyst/Mucomyst 10 IV

Orphan Indication: Intravenous treatment of patients presenting with moderate to severe acetaminophen overdose.
Sponsor: Bristol-Myers Squibb Company **Contact:** Ms. Barbara LoPiccolo
Address: Princeton, NJ **Phone:** 6098972470 **Fax:** (609) 897-5515
Status: Designated **Designation Date:** 13-Aug-87 Marketing Approval Date:

Generic Name: Aconiazide
Trade Name:

Orphan Indication: Treatment of tuberculosis.
Sponsor: Lincoln Diagnostics **Contact:** Mr. Gary Hein
Address: Decatur, IL **Phone:** (800) 537-1336 **Fax:**
Status: Designated **Designation Date:** 20-Jun-88 Marketing Approval Date:

Generic Name: Adeno-associated viral vector containing the gene for human coagulation factor IX **Trade Name:** Coagulin-B

Orphan Indication: Intrahepatic treatment of patients with moderate to severe hemophilia
Sponsor: Avigen, Inc. **Contact:** Ms. Janice Castillo
Address: Alameda, CA **Phone:** 5107487282 **Fax:**
Status: Designated **Designation Date:** 13-Jun-01 Marketing Approval Date:

Generic Name: Adeno-associated viral vector containing the gene for human coagulation factor IX **Trade Name:** Coagulin-B

Orphan Indication: Intramuscular treatment of patients with moderate to severe hemophilia
Sponsor: Avigen, Inc. **Contact:** Ms. Janice Castillo
Address: Alameda, CA **Phone:** 5107487150 **Fax:** 5107487155
Status: Designated **Designation Date:** 13-Jun-01 Marketing Approval Date:

Generic Name: Adeno-associated viral-based vector cystic fibrosis gene therapy
Trade Name:

Orphan Indication: Treatment of cystic fibrosis.
Sponsor: Targeted Genetics Corporation **Contact:** Mr. Barry Polenz
Address: Seattle, WA **Phone:** (206) 521-7818 **Fax:** (206) 223-0288
Status: Designated **Designation Date:** 15-Feb-95 Marketing Approval Date:

Generic Name: Adenosine
Trade Name:

Orphan Indication: For use in conjunction with BCNU in the treatment of brain tumors.
Sponsor: Medco Research, Inc. **Contact:** Dr. Sam Teichman
Address: Los Angeles, CA **Phone:** (213) 966-4155 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 01-Aug-89 Marketing Approval Date:

Generic Name: Adenovirus-based vector Factor VIII complementary DNA to somatic cells **Trade Name:** MiniAdFVIII

Orphan Indication: Treatment of hemophilia A.
Sponsor: GenStar Therapeutics Corporation **Contact:** Dr. Carolyn Sidor

Address: San Diego, CA **Phone:** (919) 361-2286 **Fax:** (919) 361-2290
Status: Designated **Designation Date:** 15-Dec-99 **Marketing Approval Date:**

Generic Name: adenovirus-mediated herpes simplex virus-thymidine kinase gene
Trade Name:

Orphan Indication: Use with gancyclovir in the treatment of malignant glioma
Sponsor: Ark Therapeutics Ltd **Contact:** Dr. James Parker
Address: London W1T6AR, UK **Phone:** 9788978404 **Fax:** 9784610333
Status: Designated **Designation Date:** 31-Jul-01 **Marketing Approval Date:**

Generic Name: Aerosolized pooled immune globulin
Trade Name:

Orphan Indication: Treatment of respiratory syncytial virus lower respiratory tract disease.
Sponsor: Pediatric Pharmaceuticals, Inc. **Contact:** R.C. Stites
Address: Westfield, NJ **Phone:** (908) 225-0989 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 03-Jan-89 **Marketing Approval Date:**

Generic Name: AI-RSA
Trade Name:

Orphan Indication: Treatment of autoimmune uveitis.
Sponsor: AutoImmune, Inc. **Contact:** Dr. Malcolm Fletcher
Address: Lexington, MA **Phone:** (617) 860-0710 **Fax:** (617) 860-0705
Status: Designated/Withdrawn **Designation Date:** 08-Oct-92 **Marketing Approval Date:**

Generic Name: Albendazole **Trade Name:** Albenza

Orphan Indication: 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.
Sponsor: SmithKline Beecham Pharmaceuticals **Contact:** Ms. Debra Hackett
Address: Philadelphia, PA **Phone:** (215) 751-4000 **Fax:** (215) 751-3400
Status: Designated/Approved **Designation Date:** 18-Jan-96 **Marketing Approval Date:** 11-Jun-96

Generic Name: Albendazole **Trade Name:** Albenza

Orphan Indication: Treatment of hydatid disease (cystic echinococcosis due to *E. granulosus* larvae or alveolar echinococcosis due to *E. multilocularis* larvae).
Sponsor: SmithKline Beecham Pharmaceuticals **Contact:** Ms. Debra Hackett
Address: Philadelphia, PA **Phone:** (215) 751-4000 **Fax:** (215) 751-3400
Status: Designated/Approved **Designation Date:** 17-Jan-96 **Marketing Approval Date:** 11-Jun-96

Generic Name: Aldesleukin **Trade Name:** Proleukin

Orphan Indication: For the treatment non-Hodgkin's lymphoma.
Sponsor: Chiron Corporation **Contact:** Ms. Linda FitzGerald
Address: Emeryville, CA **Phone:** 5109233575 **Fax:** 5109233344
Status: Designated **Designation Date:** 24-Nov-98 **Marketing Approval Date:**

Generic Name: Aldesleukin **Trade Name:** Proleukin

Orphan Indication: Treatment of metastatic melanoma.
Sponsor: Chiron Corporation **Contact:** Ms. Linda FitzGerald
Address: Emeryville, CA **Phone:** 5109233575 **Fax:** (510) 923-3344
Status: Designated/Approved **Designation Date:** 10-Sep-96 **Marketing Approval Date:** 09-Jan-98

Generic Name: Aldesleukin **Trade Name:** Proleukin

Orphan Indication: Treatment of acute myelogenous leukemia.
Sponsor: Chiron Corporation **Contact:** Ms. Linda FitzGerald
Address: Emeryville, CA **Phone:** 5109233575 **Fax:** (510) 923-3344
Status: Designated **Designation Date:** 31-Jul-98 **Marketing Approval Date:**

Generic Name: Aldesleukin **Trade Name:** Proleukin

Orphan Indication: Treatment of metastatic renal cell carcinoma.
Sponsor: Chiron Corporation **Contact:** Ms. Linda FitzGerald

Address: Emeryville, CA **Phone:** 5109233575 **Fax:** (510) 923-3344

Status: Designated/Approved **Designation Date:** 14-Sep-88 **Marketing Approval Date:** 05-May-92

Generic Name: Aldesleukin **Trade Name:** Proleukin

Orphan Indication: Treatment of primary immunodeficiency disease associated with T-cell defects.

Sponsor: Chiron Corporation **Contact:** Ms. Mary O'Hara

Address: Emeryville, CA **Phone:** (510) 923-2679 **Fax:** (510) 923-3344

Status: Designated **Designation Date:** 22-Mar-89 **Marketing Approval Date:**

Generic Name: alemtuzumab **Trade Name:** Campath

Orphan Indication: Treatment of chronic lymphocytic leukemia.

Sponsor: Millennium and ILEX Partners, LP **Contact:** Mr. Mike Bernstein

Address: Cambridge, MA **Phone:** 6175513618 **Fax:**

Status: Designated/Approved **Designation Date:** 20-Oct-97 **Marketing Approval Date:** 07-May-01

Generic Name: Alendronate disodium **Trade Name:** Fosamax

Orphan Indication: Treatment of the bone manifestations of Gaucher disease

Sponsor: Richard J. Wenstrup, M.D. **Contact:** Dr. Joseph Fondacaro

Address: Cincinnati, OH **Phone:** 5136367695 **Fax:** 5136368453

Status: Designated **Designation Date:** 13-Feb-01 **Marketing Approval Date:**

Generic Name: Alglucerase injection **Trade Name:** Ceredase

Orphan Indication: For replacement therapy in patients with Gaucher's disease type I.

Sponsor: Genzyme Corporation **Contact:** Ms. Suzanne Sensabaugh

Address: Cambridge, MA **Phone:** (617) 374-7455 **Fax:** (617) 374-7470

Status: Designated/Approved **Designation Date:** 11-Mar-85 **Marketing Approval Date:** 05-Apr-91

Generic Name: Alglucerase injection **Trade Name:** Ceredase

Orphan Indication: Replacement therapy in patients with Type II and III Gaucher's disease.

Sponsor: Genzyme Corporation **Contact:** Ms. Suzanne Sensabaugh

Address: Cambridge, MA **Phone:** (617) 374-7455 **Fax:** (617) 374-7470

Status: Designated **Designation Date:** 21-Jul-95 **Marketing Approval Date:**

Generic Name: Alitretinoin **Trade Name:** Panretin

Orphan Indication: Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.

Sponsor: Ligand Pharmaceuticals Inc. **Contact:** Dr. David Furlano

Address: San Diego, CA **Phone:** (619) 550-7600 **Fax:** (619) 550-1827

Status: Designated/Approved **Designation Date:** 24-Mar-98 **Marketing Approval Date:** 02-Feb-99

Generic Name: Allogeneic human retinal pigment epithelial cells on gelatin microcarriers **Trade Name:** Spheramine

Orphan Indication: Treatment of Hoehn and Yahr stage 3 and 4 Parkinson's disease.

Sponsor: Titan Pharmaceuticals, Inc. **Contact:** Dr. Richard Allen

Address: Somerville, NJ **Phone:** (908) 429-9880 **Fax:** (908) 429-9096

Status: Designated **Designation Date:** 18-Jul-97 **Marketing Approval Date:**

Generic Name: Allogeneic peripheral blood mononuclear cells sensitized against patient alloantigens by mixed lymphocyte culture **Trade Name:** CYTOIMPLANT

Orphan Indication: Treatment of pancreatic cancer.

Sponsor: Applied Immunotherapeutics, LLC **Contact:** Mr. Michael O'Neill

Address: Santa Fe Springs, CA **Phone:** (310) 926-8600 **Fax:** (562) 921-9415

Status: Designated **Designation Date:** 13-Jun-97 **Marketing Approval Date:**

Generic Name: Allopurinol riboside

Trade Name:

Orphan Indication: Treatment of Chagas' disease.

Sponsor: Burroughs Wellcome Company **Contact:** Dr. Michael Dalton

Address: Research Triangle Park, NC **Phone:** (919) 315-4453 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 04-Dec-85 **Marketing Approval Date:**

Generic Name: Allopurinol riboside
Trade Name:

Orphan Indication: Treatment of cutaneous and visceral leishmaniasis.
Sponsor: Burroughs Wellcome Company **Contact:** Dr. Michael Dalton
Address: Research Triangle Park, NC **Phone:** (919) 315-4453 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 04-Dec-85 **Marketing Approval Date:**

Generic Name: Allopurinol sodium **Trade Name:** Zyloprim for Injection

Orphan Indication: 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.
Sponsor: Catalytica Pharmaceuticals, Inc **Contact:** Dr. Greg Little
Address: Greenville, NC **Phone:** (800) 327-7106 **Fax:** () -
Status: Designated/Approved **Designation Date:** 16-Oct-92 **Marketing Approval Date:** 17-May-96

Generic Name: Allopurinol sodium **Trade Name:** Zyloprim

Orphan Indication: Ex-vivo preservation of cadaveric kidneys for transplantation
Sponsor: Burroughs Wellcome Company **Contact:** Dr. Michael Dalton
Address: Research Triangle Pk, NC **Phone:** (919) 248-4453 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 09-Nov-87 **Marketing Approval Date:**

Generic Name: Alpha-1-antitrypsin (recombinant DNA Origin)
Trade Name:

Orphan Indication: As supplementation therapy for alpha-1-antitrypsin deficiency in the ZZ phenotype population.
Sponsor: Chiron Corporation **Contact:** Ms. Mary O'Hara
Address: Emeryville, CA **Phone:** (510) 923-2679 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 01-Jan-84 **Marketing Approval Date:**

Generic Name: Alpha-galactosidase A **Trade Name:** Fabrase

Orphan Indication: Treatment of Fabry's disease.
Sponsor: Desnick, Robert J. M.D. **Contact:** Dr. Robert Desnick
Address: New York, NY **Phone:** (212) 241-6946 **Fax:**
Status: Designated **Designation Date:** 20-Jul-90 **Marketing Approval Date:**

Generic Name: Alpha-galactosidase A **Trade Name:** Replagal

Orphan Indication: Long-term enzyme replacement therapy for the treatment of Fabry disease.
Sponsor: Transkaryotic Therapies Inc. **Contact:** Dr. Kurt Gunter
Address: Cambridge, MA **Phone:** (617) 349-0226 **Fax:** 6175030313
Status: Designated **Designation Date:** 22-Jun-98 **Marketing Approval Date:**

Generic Name: Alpha-galactosidase A **Trade Name:** CC-galactosidase

Orphan Indication: Treatment of alpha-galactosidase A deficiency (Fabry's disease).
Sponsor: Orphan Medical, Inc. **Contact:** Dr. Dayton Reardon
Address: Minnetonka, MN **Phone:** (612) 513-6969 **Fax:** (612) 541-9209
Status: Designated **Designation Date:** 17-Jun-91 **Marketing Approval Date:**

Generic Name: Alpha-melanocyte stimulating hormone
Trade Name:

Orphan Indication: Prevention and treatment of intrinsic acute renal failure due to ischemia.
Sponsor: National Institute of Diabetes, and Digestive and Kidney Diseases **Contact:** Dr. Ira Levin
Address: Bethesda, MD **Phone:** 3014964128 **Fax:** 3014969943
Status: Designated **Designation Date:** 19-Aug-97 **Marketing Approval Date:**

Generic Name: Alpha-1-proteinase inhibitor (human) **Trade Name:** Prolastin

Orphan Indication: For replacement therapy in the alpha-1-proteinase inhibitor congenital deficiency state.
Sponsor: Bayer Corporation **Contact:** Dr. Brian Miller
Address: New Haven, CT **Phone:** (800) 288-8371 **Fax:**
Status: Designated/Approved **Designation Date:** 07-Dec-84 **Marketing Approval Date:** 02-Dec-87

Generic Name: Alpha1-proteinase inhibitor (human)
Trade Name:

Orphan Indication: For slowing the progression of emphysema in alpha1-antitrypsin deficient patients.

Sponsor: Aventis Behring L.L.C. **Contact:** Ms. Denise Rieker

Address: King of Prussia, PA **Phone:** (610) 878-4460 **Fax:** (610) 878-4009

Status: Designated **Designation Date:** 24-Nov-99 **Marketing Approval Date:**

Generic Name: Alprostadil
Trade Name:

Orphan Indication: Treatment of severe peripheral arterial occlusive disease (critical limb ischemia) in patients where other procedures, grafts or angioplasty, are not indicated.

Sponsor: Schwarz Pharma, Inc. **Contact:** Ms. Donna Multhauf

Address: Milwaukee, WI **Phone:** (414) 354-4300 **Fax:** (414) 354-4309

Status: Designated/Withdrawn **Designation Date:** 20-Oct-93 **Marketing Approval Date:**

Generic Name: Alronidase **Trade Name:** Aldurazyme

Orphan Indication: Treatment of patients with mucopolysaccharidosis-I.

Sponsor: BioMarin Pharmaceutical, Inc. **Contact:** Ms. Lily Medina

Address: Novato, CA **Phone:** (415) 884-6722 **Fax:** (415) 382-7889

Status: Designated **Designation Date:** 24-Sep-97 **Marketing Approval Date:**

Generic Name: Altretamine **Trade Name:** Hexalen

Orphan Indication: Treatment of advanced adenocarcinoma of the ovary.

Sponsor: Medimmune Oncology, Inc. **Contact:** Ms. Eve Damiano

Address: West Conshohocken, PA **Phone:** (610) 832-4580 **Fax:** (610) 832-4571

Status: Designated/Approved **Designation Date:** 09-Feb-84 **Marketing Approval Date:** 26-Dec-90

Generic Name: Amifostine **Trade Name:** Ethyol

Orphan Indication: For use as a chemoprotective agent for cisplatin in the treatment of advanced ovarian carcinoma.

Sponsor: Medimmune Oncology, Inc. **Contact:** Ms. Eve Damiano

Address: West Conshohocken, PA **Phone:** (610) 832-4580 **Fax:** 6108324671

Status: Designated/Approved **Designation Date:** 30-May-90 **Marketing Approval Date:** 08-Dec-95

Generic Name: Amifostine **Trade Name:** Ethyol

Orphan Indication: For use as a chemoprotective agent for cisplatin in the treatment of metastatic melanoma.

Sponsor: Medimmune Oncology, Inc. **Contact:** Dr. Hanne Johansen

Address: Gaithersburg, MD **Phone:** 2406324012 **Fax:** 2406324018

Status: Designated **Designation Date:** 30-May-90 **Marketing Approval Date:**

Generic Name: Amifostine **Trade Name:** Ethyol

Orphan Indication: Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer.

Sponsor: Medimmune Oncology, Inc. **Contact:** Ms. Eve Damiano

Address: Conshohocken, PA **Phone:** (610) 832-4580 **Fax:** (610) 832-4571

Status: Designated/Approved **Designation Date:** 12-May-98 **Marketing Approval Date:** 24-Jun-99

Generic Name: Amifostine **Trade Name:** Ethyol

Orphan Indication: For the reduction of the incidence and severity of toxicities associated with cisplatin administration.

Sponsor: Medimmune Oncology, Inc. **Contact:** Dr. Hanne Johansen

Address: Gaithersburg, MD **Phone:** 2406324012 **Fax:** 2406324018

Status: Designated **Designation Date:** 24-Nov-98 **Marketing Approval Date:**

Generic Name: Amifostine **Trade Name:** Ethyol

Orphan Indication: Treatment of myelodysplastic syndromes.

Sponsor: Medimmune Oncology, Inc. **Contact:** Dr. Hanne Johansen

Address: Gaithersburg, MD **Phone:** 2406324012 **Fax:** 2406324018

Status: Designated **Designation Date:** 04-Oct-99 **Marketing Approval Date:**

Generic Name: Amifostine **Trade Name:** Ethyol

Orphan Indication: For use as a chemoprotective agent for cyclophosphamide in the treatment of advanced ovarian carcinoma.

Sponsor: Medimmune Oncology, Inc. **Contact:** Dr. Hanne Johannesen

Address: Gaithersburg, MD **Phone:** 2406324012 **Fax:** 2406324018

Status: Designated **Designation Date:** 30-May-90 **Marketing Approval Date:**

Generic Name: Amiloride HCl solution for inhalation
Trade Name:

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: Glaxo Wellcome Research and Development **Contact:** Dr. John Morgan

Address: Research Triangle Park, NC **Phone:** (919) 483-6894 **Fax:** (919) 315-0033

Status: Designated/Withdrawn **Designation Date:** 18-Jul-90 **Marketing Approval Date:**

Generic Name: Aminocaproic acid **Trade Name:** Caprogel

Orphan Indication: For the topical treatment of traumatic hyphema of the eye.

Sponsor: Eastern Virginia Medical School **Contact:** Dr. Earl Crouch

Address: Norfolk, VA **Phone:** 7574610050 **Fax:** 7574614538

Status: Designated **Designation Date:** 06-Jan-95 **Marketing Approval Date:**

Generic Name: Aminosalicylate sodium
Trade Name:

Orphan Indication: Treatment of Crohn's disease.

Sponsor: Syncom Pharmaceuticals, Inc. **Contact:** Dr. Fred McIlreath

Address: Florham Park, NJ **Phone:** (201) 822-9222 **Fax:** (201) 822-1444

Status: Designated/Withdrawn **Designation Date:** 06-Apr-93 **Marketing Approval Date:**

Generic Name: Aminosalicylic acid **Trade Name:** Paser Granules

Orphan Indication: Treatment of tuberculosis infections.

Sponsor: Jacobus Pharmaceutical Company **Contact:** Dr. Neil Lewis

Address: Princeton, NJ **Phone:** (609) 921-7447 **Fax:**

Status: Designated/Approved **Designation Date:** 19-Feb-92 **Marketing Approval Date:** 30-Jun-94

Generic Name: Aminosidine **Trade Name:** Gabbromicina

Orphan Indication: Treatment of Mycobacterium avium complex.

Sponsor: Kanyok, Thomas P. Pharm.D. **Contact:** Dr. Thomas Kanyok

Address: Chicago, IL **Phone:** (312) 996-6300 **Fax:**

Status: Designated **Designation Date:** 15-Nov-93 **Marketing Approval Date:**

Generic Name: Aminosidine **Trade Name:** Paromomycin

Orphan Indication: Treatment of visceral leishmaniasis (kala-azar).

Sponsor: Kanyok, Thomas P. Pharm.D. **Contact:** Dr. Thomas Kanyok

Address: Chicago, IL **Phone:** (312) 996-6300 **Fax:**

Status: Designated **Designation Date:** 09-Sep-94 **Marketing Approval Date:**

Generic Name: Aminosidine **Trade Name:** Gabbromicina

Orphan Indication: Treatment of tuberculosis.

Sponsor: Kanyok, Thomas P. Pharm.D. **Contact:** Dr. Thomas Kanyok

Address: Chicago, IL **Phone:** (312) 996-6300 **Fax:**

Status: Designated **Designation Date:** 14-May-93 **Marketing Approval Date:**

Generic Name: Amiodarone **Trade Name:** Amio-Aqueous

Orphan Indication: Treatment of incessant ventricular tachycardia.

Sponsor: Wyeth-Ayerst Research **Contact:** Dr. Caroline Henesey

Address: Philadelphia, PA **Phone:** 6109023279 **Fax:** (610) 964-3898

Status: Designated **Designation Date:** 17-Aug-93 **Marketing Approval Date:**

Generic Name: Amiodarone HCl **Trade Name:** Cordarone

Orphan Indication: For the acute treatment and prophylaxis of life-threatening ventricular tachycardia or ventricular fibrillation.

Sponsor: Wyeth-Ayerst Laboratories **Contact:** Dr. Eleanor DeLorme

Address: Philadelphia, PA **Phone:** (215) 341-2239 **Fax:**

Status: Designated/Approved **Designation Date:** 16-Mar-94 **Marketing Approval Date:** 03-Aug-95

Generic Name: Ammonium tetrathiomolybdate

Trade Name:

Orphan Indication: Treatment of Wilson's disease.

Sponsor: Brewer, George J. M.D. **Contact:** Dr. George Brewer

Address: Ann Arbor, MI **Phone:** (734) 764-5499 **Fax:**

Status: Designated **Designation Date:** 31-Jan-94 **Marketing Approval Date:**

Generic Name: Amphotericin B lipid complex **Trade Name:** Abelcet

Orphan Indication: Treatment of invasive protothecosis.

Sponsor: The Liposome Company, Inc. **Contact:** Dr. James Boyle

Address: Princeton, NJ **Phone:** (609) 452-7060 **Fax:** (609) 452-1890

Status: Designated/Withdrawn **Designation Date:** 21-Aug-96 **Marketing Approval Date:**

Generic Name: Amphotericin B lipid complex **Trade Name:** Abelcet

Orphan Indication: Treatment of invasive candidiasis.

Sponsor: The Liposome Company, Inc. **Contact:** Dr. James Boyle

Address: Princeton, NJ **Phone:** (609) 452-7060 **Fax:** (609) 452-1890

Status: Designated/Withdrawn **Designation Date:** 27-Jun-96 **Marketing Approval Date:**

Generic Name: Amphotericin B lipid complex **Trade Name:** Abelcet

Orphan Indication: Treatment of invasive sporotrichosis.

Sponsor: The Liposome Company, Inc. **Contact:** Dr. James Boyle

Address: Princeton, NJ **Phone:** (609) 452-7060 **Fax:** (609) 452-1890

Status: Designated/Withdrawn **Designation Date:** 23-Sep-96 **Marketing Approval Date:**

Generic Name: Amphotericin B lipid complex **Trade Name:** Abelcet

Orphan Indication: Treatment of invasive zygomycosis.

Sponsor: The Liposome Company, Inc. **Contact:** Dr. James Boyle

Address: Princeton, NJ **Phone:** (609) 452-7060 **Fax:** (609) 452-1890

Status: Designated/Withdrawn **Designation Date:** 06-May-96 **Marketing Approval Date:**

Generic Name: Amphotericin B lipid complex **Trade Name:** Abelcet

Orphan Indication: Treatment of invasive coccidioidomycosis.

Sponsor: The Liposome Company, Inc. **Contact:** Dr. James Boyle

Address: Princeton, NJ **Phone:** (609) 452-7060 **Fax:** (609) 452-1890

Status: Designated/Withdrawn **Designation Date:** 06-May-96 **Marketing Approval Date:**

Generic Name: Amphotericin B lipid complex **Trade Name:** Abelcet

Orphan Indication: Treatment of invasive fungal infections.

Sponsor: Liposome Company, Inc. **Contact:** Dr. James Boyle

Address: Princeton, NJ **Phone:** (609) 452-7060 **Fax:** (609) 452-1890

Status: Designated/Approved **Designation Date:** 03-Dec-96 **Marketing Approval Date:** 18-Oct-96

Generic Name: Amsacrine **Trade Name:** Amsidyl

Orphan Indication: Treatment of acute adult leukemia.

Sponsor: Warner-Lambert Company **Contact:** Ms. Janeth Turner

Address: Ann Arbor, MI **Phone:** (313) 996-7000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 07-Dec-84 **Marketing Approval Date:**

Generic Name: Anagrelide **Trade Name:** Agrylin

Orphan Indication: Treatment of thrombocytosis in chronic myelogenous leukemia.

Sponsor: Roberts Pharmaceutical Corp. **Contact:** Mr. Richard Raffa

Address: Eatontown, NJ **Phone:** (732) 389-1182 **Fax:** (732) 389-1014

Status: Designated **Designation Date:** 14-Jul-86 **Marketing Approval Date:**

Generic Name: Anagrelide **Trade Name:** Agrylin

Orphan Indication: Treatment of polycythemia vera.
Sponsor: Roberts Pharmaceutical Corp. **Contact:** Mr. Richard Raffa
Address: Eatontown, NJ **Phone:** (732) 389-1182 **Fax:** (732) 389-1014
Status: Designated **Designation Date:** 11-Jun-85 **Marketing Approval Date:**

Generic Name: Anagrelide **Trade Name:** Agrylin

Orphan Indication: Treatment of essential thrombocythemia.
Sponsor: Roberts Pharmaceutical Corp. **Contact:** Mr. Drew Karlan
Address: Eatontown, NJ **Phone:** (732) 389-1182 **Fax:** () -
Status: Designated/Approved **Designation Date:** 27-Jan-88 **Marketing Approval Date:** 14-Mar-97

Generic Name: Ananain, comosain **Trade Name:** Vianain

Orphan Indication: For the enzymatic debridement of severe burns.
Sponsor: Genzyme Corporation **Contact:** Ms. Patricia Thomas
Address: Cambridge, MA **Phone:** 6177618239 **Fax:** (617) 252-7600
Status: Designated **Designation Date:** 21-Jan-92 **Marketing Approval Date:**

Generic Name: Anaritide acetate **Trade Name:** Auriculin

Orphan Indication: Improvement of early renal allograft function following renal transplantation.
Sponsor: Scios, Inc. **Contact:** Ms. Karen Harder
Address: Mountain View, CA **Phone:** (415) 940-6645 **Fax:** (415) 968-2438
Status: Designated/Withdrawn **Designation Date:** 10-Apr-92 **Marketing Approval Date:**

Generic Name: Anaritide acetate **Trade Name:** Auriculin

Orphan Indication: Treatment of patients with acute renal failure.
Sponsor: Scios, Inc. **Contact:** Ms. Karen Harder
Address: Mountain View, CA **Phone:** (415) 940-6645 **Fax:** (415) 966-2438
Status: Designated/Withdrawn **Designation Date:** 27-Aug-92 **Marketing Approval Date:**

Generic Name: Ancestim **Trade Name:** Stemgen

Orphan Indication: 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.
Sponsor: Amgen, Inc. **Contact:** Mr. Neal Birkett
Address: Thousand Oaks, CA **Phone:** (805) 447-3416 **Fax:** 8054801330
Status: Designated **Designation Date:** 05-Jul-95 **Marketing Approval Date:**

Generic Name: Ancrod **Trade Name:** Viprinex

Orphan Indication: To establish and maintain anticoagulation in heparin-intolerant patients undergoing cardiopulmonary bypass.
Sponsor: Knoll Pharmaceutical Company **Contact:** Dr. Robert Ashworth
Address: Mt. Olive, NJ **Phone:** (973) 426-6012 **Fax:**
Status: Designated **Designation Date:** 20-Oct-89 **Marketing Approval Date:**

Generic Name: Angiotensin 1-7

Trade Name:

Orphan Indication: Treatment of neutropenia associated with autologous bone marrow transplantation.
Sponsor: Maret Pharmaceuticals **Contact:** Dr. Jamie Oliver
Address: Newport Beach, CA **Phone:** (949) 225-0005 **Fax:** (949) 225-0006
Status: Designated **Designation Date:** 16-Feb-00 **Marketing Approval Date:**

Generic Name: Angiotensin 1-7 **Trade Name:** MARstem

Orphan Indication: Treatment of myelodysplastic syndrome
Sponsor: Maret Pharmaceutical Corporation **Contact:** Dr. Jamie Oliver
Address: Newport Beach, CA **Phone:** 9492250005 **Fax:** 9492250006
Status: Designated **Designation Date:** 03-Aug-01 **Marketing Approval Date:**

Generic Name: Anti pan T lymphocyte monoclonal antibody **Trade Name:** Anti-t Lymphocyte Immunotoxin Xmmlly-h65-rt

Orphan Indication: For ex-vivo treatment to eliminate mature T cells from potential bone marrow grafts.
Sponsor: Xoma Corporation **Contact:** Joan Roelands
Address: Berkeley, CA **Phone:** (510) 644-1170 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 29-Jan-86 **Marketing Approval Date:**

Generic Name: Anti pan T lymphocyte monoclonal antibody **Trade Name:** Anti-t Lymphocyte Immunotoxin Xmmyly-h65-rta

Orphan Indication: For in-vivo treatment of bone marrow recipients to prevent graft rejection and graft versus host disease.

Sponsor: Xoma Corporation **Contact:** Joan Roelands

Address: Berkeley, CA **Phone:** (510) 644-1170 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 29-Jan-86 **Marketing Approval Date:**

Generic Name: Anti-CD45 monoclonal antibodies

Trade Name:

Orphan Indication: Prevention of acute graft rejection of human organ transplants.

Sponsor: Baxter Healthcare Corporation **Contact:** Mr. Robert Wilkinson

Address: Mcgaw Park, IL **Phone:** (708) 473-6030 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 10-Sep-90 **Marketing Approval Date:**

Generic Name: Anti-cytomegalovirus monoclonal antibodies

Trade Name:

Orphan Indication: Treatment of human cytomegalovirus infection in patients diagnosed with AIDS.

Sponsor: Biomedical Research Institute **Contact:** Dr. Richard Gehrz

Address: St. Paul, MN **Phone:** (612) 220-6900 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 03-May-90 **Marketing Approval Date:**

Generic Name: Anti-cytomegalovirus monoclonal antibodies

Trade Name:

Orphan Indication: Treatment of human cytomegalovirus infection in bone marrow and organ transplant patients.

Sponsor: Biomedical Research Institute **Contact:** Dr. Richard Gehrz

Address: St. Paul, MN **Phone:** (612) 220-6900 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 02-May-90 **Marketing Approval Date:**

Generic Name: Anti-cytomegalovirus monoclonal antibodies

Trade Name:

Orphan Indication: Prevention of human cytomegalovirus infection in patients diagnosed with AIDS.

Sponsor: Biomedical Research Institute **Contact:** Dr. Richard Gehrz

Address: St. Paul, MN **Phone:** (612) 220-6900 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 03-May-90 **Marketing Approval Date:**

Generic Name: Anti-cytomegalovirus monoclonal antibodies

Trade Name:

Orphan Indication: Prevention of human cytomegalovirus infection in bone marrow and organ transplant patients.

Sponsor: Biomedical Research Institute **Contact:** Dr. Richard Gehrz

Address: St. Paul, MN **Phone:** (612) 220-6900 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 02-May-90 **Marketing Approval Date:**

Generic Name: Anti-tap-72 immunotoxin **Trade Name:** Xomazyme-791

Orphan Indication: Treatment of metastatic colorectal adenocarcinoma.

Sponsor: Xoma Corporation **Contact:** Joan Roelands

Address: Berkeley, CA **Phone:** (510) 644-1170 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 06-Mar-87 **Marketing Approval Date:**

Generic Name: Anti-thymocyte Globulin (Rabbit) **Trade Name:** Thymoglobulin

Orphan Indication: Treatment of myelodysplastic syndrome (MDS)

Sponsor: SangStat Medical Corporation **Contact:** Dr. Elizabeth Squiers

Address: Freemont, CA **Phone:** 5107894300 **Fax:** 5107894400

Status: Designated **Designation Date:** 06-Sep-00 **Marketing Approval Date:**

Generic Name: Anti-thymocyte serum **Trade Name:** Nashville Rabbit Anti-thymocyte Serum

Orphan Indication: Treatment of allograft rejection, including solid organ (kidney, liver, heart, lung, and pancreas) and bone marrow transplantation.

Sponsor: Applied Medical Research **Contact:** Dr. Harold Miller
Address: Nashville, TN **Phone:** (615) 327-0676 **Fax:** (615) 327-3627
Status: Designated **Designation Date:** 02-Jun-93 **Marketing Approval Date:**

Generic Name: Antiepilepsirine
Trade Name:

Orphan Indication: Treatment of drug resistant generalized tonic-clonic epilepsy in children and adults.
Sponsor: Children's Hospital **Contact:** Dr. Philip Walson
Address: Columbus, OH **Phone:** (614) 722-6478 **Fax:** (614) 722-4565
Status: Designated **Designation Date:** 23-Mar-89 **Marketing Approval Date:**

Generic Name: Antihemophilic factor (human) **Trade Name:** Alphanate

Orphan Indication: Treatment of von Willebrand's disease.
Sponsor: Alpha Therapeutic Corporation **Contact:** Ms. M. Sue Preston
Address: Los Angeles, CA **Phone:** (323) 225-7580 **Fax:**
Status: Designated **Designation Date:** 05-Jan-96 **Marketing Approval Date:**

Generic Name: Antihemophilic factor (recombinant) **Trade Name:** ReFacto

Orphan Indication: For the control and prevention of hemorrhagic episodes and for surgical prophylaxis in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia).
Sponsor: Genetics Institute, Inc. **Contact:** Ms. Maryann Krane
Address: Cambridge, MA **Phone:** (617) 665-8737 **Fax:** (617) 498-8838
Status: Designated/Approved **Designation Date:** 08-Feb-96 **Marketing Approval Date:** 06-Mar-00

Generic Name: Antihemophilic factor (recombinant) **Trade Name:** Kogenate

Orphan Indication: Prophylaxis and treatment of bleeding in individuals with hemophilia A or for prophylaxis when surgery is required in individuals with hemophilia A.
Sponsor: Bayer Corporation **Contact:** Ms. Carol Moore
Address: Elkhart, IN **Phone:** (510) 705-5224 **Fax:** (510) 705-5553
Status: Designated/Approved **Designation Date:** 25-Sep-89 **Marketing Approval Date:** 25-Feb-93

Generic Name: Antihemophilic factor/von Willebrand factor complex (human), dried, pasteurized **Trade Name:** Humate-P

Orphan Indication: 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.
Sponsor: Aventis Behring L.L.C. **Contact:** Ms. Carol Marchione
Address: King Of Prussia, PA **Phone:** (610) 878-4026 **Fax:** (610) 878-4009
Status: Designated/Approved **Designation Date:** 16-Oct-92 **Marketing Approval Date:** 01-Apr-99

Generic Name: Antimelanoma Antibody XMMME-001-DTPA 111 Indium **Trade Name:** Antimelanoma Antibody XMMME-001-DTPA 111 Indium

Orphan Indication: Diagnostic use in imaging systemic and nodal melanoma metastasis.
Sponsor: Xoma Corporation **Contact:** Joan Roelands
Address: Berkeley, CA **Phone:** (510) 644-1170 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 14-Nov-84 **Marketing Approval Date:**

Generic Name: Antimelanoma Antibody XMMME-001-RTA **Trade Name:** Antimelanoma Antibody XMMME-001-RTA

Orphan Indication: Treatment of stage III melanoma not amenable to surgical resection.
Sponsor: Xoma Corporation **Contact:** Joan Roelands
Address: Berkeley, CA **Phone:** (510) 644-1170 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 14-Nov-84 **Marketing Approval Date:**

Generic Name: Antipyrine Test
Trade Name:

Orphan Indication: For use as an index of hepatic drug-metabolizing capacity.
Sponsor: Upsher-Smith Laboratories, Inc **Contact:** Dr. Harvey Arbit
Address: Minneapolis, MN **Phone:** (612) 473-4412 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 21-Feb-85 **Marketing Approval Date:**

Generic Name: Antithrombin III (human) **Trade Name:** ATnativ

Orphan Indication: For the treatment of patients with hereditary antithrombin III deficiency in connection with surgical or obstetrical procedures or when they suffer from thromboembolism.

Sponsor: Pharmacia & Upjohn AB **Contact:** Dr. Ronald Leonardi

Address: Sweden, SE **Phone:** (858) 586-0751 **Fax:** () -

Status: Designated/Approved **Designation Date:** 08-Feb-85 **Marketing Approval Date:** 31-Dec-89

Generic Name: Antithrombin III (human) **Trade Name:** Thrombate III

Orphan Indication: For replacement therapy in congenital deficiency of AT-III for prevention and treatment of thrombosis and pulmonary emboli.

Sponsor: Bayer Corporation **Contact:** Ms.

Address: New Haven, CT **Phone:** (203) 937-2000 **Fax:**

Status: Designated/Approved **Designation Date:** 26-Nov-84 **Marketing Approval Date:** 30-Dec-91

Generic Name: Antithrombin III (human) concentrate IV **Trade Name:** Kybernin P

Orphan Indication: For prophylaxis and treatment of thromboembolic episodes in patients with genetic AT-III deficiency.

Sponsor: Aventis Behring L.L.C. **Contact:** Mr. Victor Paulus

Address: King of Prussia, PA **Phone:** (610) 878-4052 **Fax:** (610) 878-4009

Status: Designated **Designation Date:** 02-Jul-85 **Marketing Approval Date:**

Generic Name: Antithrombin III human **Trade Name:** Antithrombin III human

Orphan Indication: 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.

Sponsor: American National Red Cross **Contact:** Dr. Doris Menache-Aronson

Address: Bethesda, MD **Phone:** (301) 530-6040 **Fax:**

Status: Designated **Designation Date:** 02-Jan-86 **Marketing Approval Date:**

Generic Name: Antivenin, crotalidae polyvalent immune Fab (ovine) **Trade Name:** CroFab

Orphan Indication: Treatment of envenomations inflicted by North American crotalid snakes.

Sponsor: Protherics, Inc. **Contact:** Ms. Carol Clark-Evans

Address: Nashville, TN **Phone:** 6153271027 **Fax:** 6153201212

Status: Designated/Approved **Designation Date:** 12-Jan-94 **Marketing Approval Date:** 02-Oct-00

Generic Name: Antivenom (crotalidae) purified (avian)

Trade Name:

Orphan Indication: Treatment of envenomation by poisonous snakes belonging to the Crotalidae family.

Sponsor: Ophidian Pharmaceuticals, Inc. **Contact:** Dr. Douglas Stafford

Address: Madison, WI **Phone:** (608) 271-0878 **Fax:** (608) 277-2395

Status: Designated **Designation Date:** 12-Feb-91 **Marketing Approval Date:**

Generic Name: AP1903

Trade Name:

Orphan Indication: Treatment of acute graft-versus-host disease in patients undergoing bone marrow transplantation.

Sponsor: Ariad Gene Therapeutics, Inc. **Contact:** Dr. John Iulucci

Address: Cambridge, MA **Phone:** (617) 494-0400 **Fax:** (617) 494-1828

Status: Designated **Designation Date:** 24-Nov-99 **Marketing Approval Date:**

Generic Name: APL 400-020 V-Beta DNA vaccine

Trade Name:

Orphan Indication: Treatment of cutaneous T cell lymphoma.

Sponsor: Wyeth-Lederle Vaccines and Pediatrics **Contact:** Mr. Jack Love

Address: West Henrietta, NY **Phone:** (716) 272-9728 **Fax:** (716) 273-7515

Status: Designated **Designation Date:** 08-Mar-95 **Marketing Approval Date:**

Generic Name: Apomorphine

Trade Name:

Orphan Indication: For use as rescue treatment for early morning motor dysfunction in late-stage Parkinson's disease.

Sponsor: Scherer DDS **Contact:** Mr. B. Randall Vestal

Address: Wiltshire, UK **Phone:** (703) 406-0906 **Fax:** (703) 406-9513

Status: Designated/Withdrawn **Designation Date:** 20-Oct-97 **Marketing Approval Date:**

Generic Name: Apomorphine

Trade Name:

Orphan Indication: Treatment of the on-off fluctuations associated with late-stage Parkinson's disease.

Sponsor: Pentech Pharmaceuticals, Inc. **Contact:** Ms. Julie Phillips

Address: Buffalo Grove, IL **Phone:** (847) 215-0971 **Fax:** (847) 215-1370

Status: Designated **Designation Date:** 17-Jul-95 **Marketing Approval Date:**

Generic Name: Apomorphine HCl

Trade Name:

Orphan Indication: Treatment of the on-off fluctuations associated with late-stage Parkinson's disease.

Sponsor: Mylan Pharmaceuticals, Inc. **Contact:** Mr. Frank Sisto

Address: Morgantown, WV **Phone:** (304) 599-2595 **Fax:** (304) 285-6407

Status: Designated **Designation Date:** 22-Apr-93 **Marketing Approval Date:**

Generic Name: Aprotinin **Trade Name:** Trasylol

Orphan Indication: 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.

Sponsor: Bayer Corporation **Contact:** Dr. Christine Miller

Address: West Haven, CT **Phone:** (203) 931-5145 **Fax:**

Status: Designated/Approved **Designation Date:** 17-Nov-93 **Marketing Approval Date:** 29-Dec-93

Generic Name: Arcitumomab **Trade Name:** 99m Tc-labeled CEA-Scan

Orphan Indication: Diagnosis and localization of primary, residual, recurrent and metastatic medullary thyroid carcinoma.

Sponsor: Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz

Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282

Status: Designated **Designation Date:** 10-May-96 **Marketing Approval Date:**

Generic Name: Arginine butyrate

Trade Name:

Orphan Indication: Treatment of beta-hemoglobinopathies and beta-thalassemia.

Sponsor: Perrine, Susan P., M.D. **Contact:** Dr. Susan Perrine

Address: Boston, MA **Phone:** (617) 638-4173 **Fax:**

Status: Designated **Designation Date:** 07-Apr-92 **Marketing Approval Date:**

Generic Name: Arginine butyrate

Trade Name:

Orphan Indication: Treatment of sickle cell disease and beta thalassemia.

Sponsor: Vertex Pharmaceuticals Inc. **Contact:** Dr. William Kelley

Address: Cambridge, MA **Phone:** (617) 577-6000 **Fax:** (617) 577-6680

Status: Designated/Withdrawn **Designation Date:** 25-May-94 **Marketing Approval Date:**

Generic Name: arsenic **Trade Name:** Trisenox

Orphan Indication: Treatment of acute myelocytic leukemia subtypes M0, M1, M2, M4, M5, M6 and M7

Sponsor: Cell Therapeutics, Inc. **Contact:** Ms. Jennie Allewell

Address: Seattle, WA **Phone:** 2062708424 **Fax:** 2062708463

Status: Designated **Designation Date:** 02-Nov-01 **Marketing Approval Date:**

Generic Name: Arsenic trioxide **Trade Name:** Trisenox

Orphan Indication: Treatment of multiple myeloma.

Sponsor: Cell Therapeutics, Inc. **Contact:** Ms. Jennie Allewell

Address: Seattle, WA **Phone:** (206) 282-7100 **Fax:** (206) 284-6206

Status: Designated **Designation Date:** 28-Apr-00 **Marketing Approval Date:**

Generic Name: arsenic trioxide **Trade Name:** Trisenox

Orphan Indication: Treatment of myelodysplastic syndrome.
Sponsor: Cell Therapeutics, Inc. **Contact:** Ms. Jennie Allewell
Address: Seattle, WA **Phone:** (206) 270-8424 **Fax:** (206) 270-8463
Status: Designated/Approved **Designation Date:** 17-Jul-00 **Marketing Approval Date:** 25-Sep-00

Generic Name: Arsenic trioxide **Trade Name:** Trisenox

Orphan Indication: Treatment of acute promyelocytic leukemia.
Sponsor: Cell Therapeutics, Inc. **Contact:** Ms. Jennie Allewell
Address: Seattle, WA **Phone:** 2062708424 **Fax:** 2062708463
Status: Designated/Approved **Designation Date:** 03-Mar-98 **Marketing Approval Date:** 25-Sep-00

Generic Name: arsenic trioxide **Trade Name:** Trisenox

Orphan Indication: Treatment of chronic myeloid leukemia
Sponsor: Cell Therapeutics, Inc. **Contact:** Ms. Jennie Allewell
Address: Seattle, WA **Phone:** 2062708424 **Fax:** 2062708463
Status: Designated **Designation Date:** 18-Oct-01 **Marketing Approval Date:**

Generic Name: Artesunate

Trade Name:

Orphan Indication: Treatment of malaria.
Sponsor: World Health Organisation **Contact:** Dr. Nelle Temple Brown
Address: Switzerland, CH **Phone:** (202) 331-9081 **Fax:** (202) 331-9097
Status: Designated **Designation Date:** 19-Jul-99 **Marketing Approval Date:**

Generic Name: As-101

Trade Name:

Orphan Indication: Treatment of acquired immunodeficiency syndrome.
Sponsor: NPDC-AS101, Inc. **Contact:** Hilary Helmrich
Address: New Brunswick, NJ **Phone:** (908) 249-3232 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 09-Nov-87 **Marketing Approval Date:**

Generic Name: Atovaquone **Trade Name:** Mepron

Orphan Indication: Primary prophylaxis of HIV-infected persons at high risk for developing Toxoplasma gondii encephalitis.
Sponsor: Glaxo Wellcome Inc. **Contact:** Mr. Thomas Shumaker
Address: Research Triangle Park, NC **Phone:** (919) 483-9324 **Fax:** (919) 483-5756
Status: Designated **Designation Date:** 16-Mar-93 **Marketing Approval Date:**

Generic Name: Atovaquone **Trade Name:** Mepron

Orphan Indication: Treatment and suppression of Toxoplasma gondii encephalitis.
Sponsor: Glaxo Wellcome Inc. **Contact:** Mr. Thomas Shumaker
Address: Research Triangle Park, NC **Phone:** (919) 483-9324 **Fax:** (919) 483-5756
Status: Designated **Designation Date:** 16-Mar-93 **Marketing Approval Date:**

Generic Name: Atovaquone **Trade Name:** Mepron

Orphan Indication: 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.
Sponsor: Glaxo Wellcome Research and Development **Contact:** Mr. Thomas Shumaker
Address: Research Triangle Park, NC **Phone:** (919) 483-9324 **Fax:** (919) 483-5756
Status: Designated/Approved **Designation Date:** 14-Aug-91 **Marketing Approval Date:** 05-Jan-99

Generic Name: Atovaquone **Trade Name:** Mepron

Orphan Indication: Treatment of AIDS associated Pneumocystis Carinii Pneumonia.
Sponsor: Glaxo Wellcome Inc. **Contact:** Dr. Michael Dalton
Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**
Status: Designated/Approved **Designation Date:** 10-Sep-90 **Marketing Approval Date:** 25-Nov-92

Generic Name: augmerosen **Trade Name:** Genasense

Orphan Indication: Treatment of multiple myeloma
Sponsor: Genta Incorporated **Contact:** Mr. Paul Manley

Address: Berkeley Heights, NJ **Phone:** 9082863974 **Fax:** 9084641705
Status: Designated **Designation Date:** 28-Aug-01 **Marketing Approval Date:**

Generic Name: augmerosen **Trade Name:** Genasense

Orphan Indication: Treatment of acute myelocytic leukemia
Sponsor: Genta Incorporated **Contact:** Mr. Paul Manley
Address: Berkeley Heights, NJ **Phone:** 9082863974 **Fax:** 9084641705
Status: Designated **Designation Date:** 28-Aug-01 **Marketing Approval Date:**

Generic Name: augmerosen **Trade Name:** Genasense

Orphan Indication: Treatment of chronic lymphocytic leukemia
Sponsor: Genta Incorporated **Contact:** Mr. Paul Manley
Address: Berkeley Heights, NJ **Phone:** 9082863974 **Fax:** 9084641705
Status: Designated **Designation Date:** 28-Aug-01 **Marketing Approval Date:**

Generic Name: Autologous DNP-conjugated tumor vaccine **Trade Name:** M-Vax

Orphan Indication: For adjuvant therapy in melanoma patients with surgically resectable lymph node metastasis (Stage III and limited Stage IV disease).
Sponsor: Avax Technologies, Inc. **Contact:** Mr. Gary Knappenberger
Address: Kansas City, MO **Phone:** (816) 960-1333 **Fax:** (816) 960-1334
Status: Designated **Designation Date:** 23-Feb-99 **Marketing Approval Date:**

Generic Name: Autolymphocyte therapy
Trade Name:

Orphan Indication: Treatment of renal cell carcinoma.
Sponsor: Cytogen Corporation **Contact:** Ms. Ursula Treves
Address: Princeton, NJ **Phone:** (609) 987-8200 **Fax:** (609) 452-2975
Status: Designated **Designation Date:** 12-Jul-94 **Marketing Approval Date:**

Generic Name: Azathioprine **Trade Name:** Imuran

Orphan Indication: Treatment of oral manifestations of graft-versus-host disease.
Sponsor: Oral Solutions, Inc. **Contact:** Mr. Michael Ferrari
Address: New York, NY **Phone:** (212) 554-4293 **Fax:** (212) 554-4338
Status: Designated **Designation Date:** 14-Sep-99 **Marketing Approval Date:**

Generic Name: B Lymphocyte Stimulator **Trade Name:** BLyS

Orphan Indication: Treatment of common variable immunodeficiency (CVID)
Sponsor: Human Genome Sciences, Inc. **Contact:** Dr. Sally Bolmer
Address: Rockville, MD **Phone:** 3016105806 **Fax:** 3013090311
Status: Designated **Designation Date:** 21-Feb-01 **Marketing Approval Date:**

Generic Name: Bacitracin **Trade Name:** Altracin

Orphan Indication: Treatment of antibiotic-associated pseudomembranous enterocolitis caused by toxins A and B elaborated by *Clostridium difficile*.
Sponsor: A. L. Laboratories, Inc. **Contact:** Dr. Bernard Brown
Address: Fort Lee, NJ **Phone:** (201) 947-7774 **Fax:**
Status: Designated **Designation Date:** 13-Mar-84 **Marketing Approval Date:**

Generic Name: Baclofen **Trade Name:** Lioresal Intrathecal

Orphan Indication: Treatment of spasticity associated with cerebral palsy.
Sponsor: Medtronic, Inc. **Contact:** Ms. Diana Salditt
Address: Minneapolis, MN **Phone:** (612) 572-5647 **Fax:**
Status: Designated **Designation Date:** 26-Sep-94 **Marketing Approval Date:**

Generic Name: Baclofen **Trade Name:** Lioresal Intrathecal

Orphan Indication: 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).
Sponsor: Medtronic, Inc. **Contact:** Mr. Darryle Peterson
Address: Minneapolis, MN **Phone:** (612) 572-5000 **Fax:**
Status: Designated/Approved **Designation Date:** 10-Nov-87 **Marketing Approval Date:** 25-Jun-92

Generic Name: Baclofen
Trade Name:

Orphan Indication: Treatment of intractable spasticity due to multiple sclerosis or spinal cord injury.
Sponsor: Infusaid, Inc. **Contact:** Mr. Vincent Bucci
Address: Norwood, MA **Phone:** (617) 769-8330 **Fax:**
Status: Designated **Designation Date:** 16-Dec-91 **Marketing Approval Date:**

Generic Name: Basiliximab **Trade Name:** Simulect

Orphan Indication: Prophylaxis of solid organ rejection.
Sponsor: Novartis Pharmaceuticals Corporation **Contact:** Dr. Inmaculada Esparza
Address: East Hanover, NJ **Phone:** (973) 781-3154 **Fax:** (973) 781-8364
Status: Designated/Approved **Designation Date:** 12-Dec-97 **Marketing Approval Date:** 12-May-98

Generic Name: beclomethasone 17,21-dipropionate
Trade Name:

Orphan Indication: Prevention of gastrointestinal graft-versus-host disease
Sponsor: Enteron Pharmaceuticals, Inc. **Contact:** Mr. Nicholas Stergiopoulos
Address: Miami, FL **Phone:** 3057772258 **Fax:** 3057772249
Status: Designated **Designation Date:** 28-Aug-01 **Marketing Approval Date:**

Generic Name: Beclomethasone dipropionate
Trade Name:

Orphan Indication: For oral administration in the treatment of intestinal graft-versus-host disease.
Sponsor: George B. McDonald, M.D. **Contact:** Dr. George McDonald
Address: Seattle, WA **Phone:** (206) 667-6932 **Fax:** (206) 667-6129
Status: Designated **Designation Date:** 27-Mar-98 **Marketing Approval Date:**

Generic Name: Benzoate and phenylacetate **Trade Name:** Ucephan

Orphan Indication: 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.
Sponsor: B. Braun Medical Inc. **Contact:** Mr. John D'Angelo
Address: Irvine, CA **Phone:** (949) 660-2517 **Fax:**
Status: Designated/Approved **Designation Date:** 21-Jan-86 **Marketing Approval Date:** 23-Dec-87

Generic Name: benzoate/phenylacetate **Trade Name:** Ammonul

Orphan Indication: For the treatment of acute hyperammonemia and associated encephalopathy in patients with deficiencies in enzymes of the urea cycle.
Sponsor: Medicis Pharmaceutical Corp. **Contact:** Ms. Lynn Hansen
Address: Scottsdale, AZ **Phone:** 6028083813 **Fax:** 6028080822
Status: Designated **Designation Date:** 22-Nov-93 **Marketing Approval Date:**

Generic Name: Benzophenone-3, octylmethoxycinnamate, avobenzone, titanium dioxide, zinc oxide **Trade Name:** Total Block VL SPF 75

Orphan Indication: For the prevention of visible light induced skin photosensitivity as a result of porfimer sodium photodynamic therapy
Sponsor: Fallien Cosmeceuticals Ltd. **Contact:** Dr. Harry Fallick
Address: King of Prussia, PA **Phone:** 6103379048 **Fax:**
Status: Designated **Designation Date:** 13-Aug-01 **Marketing Approval Date:**

Generic Name: Benzydamine hydrochloride **Trade Name:** Tantum

Orphan Indication: Prophylactic treatment of oral mucositis resulting from radiation therapy for head and neck cancer.
Sponsor: Angelini Pharmaceuticals, Inc. **Contact:** Dr. Dario Paggiarino
Address: River Edge, NJ **Phone:** (201) 489-4100 **Fax:** (201) 489-9535
Status: Designated **Designation Date:** 18-May-98 **Marketing Approval Date:**

Generic Name: Benzylpenicillin, benzylpenicilloic, benzylpenilloic acid **Trade Name:** Pre-Pen/MDM

Orphan Indication: 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.

Sponsor: Hollister-Stier Laboratories LLC **Contact:** Mr. David Mirabell
Address: Spokane, WA **Phone:** (509) 482-1721 **Fax:** (509) 484-4320
Status: Designated **Designation Date:** 29-Sep-87 **Marketing Approval Date:**

Generic Name: Beractant **Trade Name:** Survanta Intratracheal Suspension

Orphan Indication: Treatment of full-term newborn infants with respiratory failure caused by meconium aspiration syndrome, persistent pulmonary hypertension of the newborn, or pneumonia and sepsis.

Sponsor: Ross Laboratories **Contact:** Ms. Patricia Welch
Address: Columbus, OH **Phone:** (614) 624-7283 **Fax:** (614) 624-3519
Status: Designated **Designation Date:** 20-Dec-93 **Marketing Approval Date:**

Generic Name: Beractant **Trade Name:** Survanta intratracheal suspension

Orphan Indication: Treatment of neonatal respiratory distress syndrome.

Sponsor: Ross Laboratories **Contact:** Ms. Patricia Welch
Address: Columbus, OH **Phone:** (614) 624-7283 **Fax:**
Status: Designated/Approved **Designation Date:** 05-Feb-86 **Marketing Approval Date:** 01-Jul-91

Generic Name: Beractant **Trade Name:** Survanta intratracheal suspension

Orphan Indication: Prevention of neonatal respiratory distress syndrome.

Sponsor: Ross Laboratories **Contact:** Ms. Patricia Welch
Address: Columbus, OH **Phone:** (614) 624-7283 **Fax:**
Status: Designated/Approved **Designation Date:** 05-Feb-86 **Marketing Approval Date:** 01-Jul-91

Generic Name: Beraprost

Trade Name:

Orphan Indication: Treatment of pulmonary arterial hypertension associated with any New York Heart Association classification (Class I, II, III, or IV).

Sponsor: United Therapeutics Corporation **Contact:** Dr. Roger Jeffs
Address: Research Triangle Park, NC **Phone:** (919) 485-8350 **Fax:** (919) 485-8352
Status: Designated **Designation Date:** 29-Apr-99 **Marketing Approval Date:**

Generic Name: Beta alethine **Trade Name:** Betathine

Orphan Indication: Treatment of metastatic melanoma.

Sponsor: Dovetail Technologies, Inc. **Contact:** Dr. Floyd Taub
Address: College Park, MD **Phone:** (301) 405-0608 **Fax:** (301) 405-9187
Status: Designated **Designation Date:** 24-Mar-97 **Marketing Approval Date:**

Generic Name: Beta alethine **Trade Name:** Betathine

Orphan Indication: Treatment of multiple myeloma.

Sponsor: Dovetail Technologies, Inc. **Contact:** Dr. Floyd Taub
Address: College Park, MD **Phone:** (301) 405-0608 **Fax:** (301) 405-9187
Status: Designated **Designation Date:** 24-Mar-97 **Marketing Approval Date:**

Generic Name: Betaine **Trade Name:** Cystadane

Orphan Indication: Treatment of homocystinuria.

Sponsor: Orphan Medical, Inc. **Contact:** Dr. Dayton Reardan
Address: Minnetonka, MN **Phone:** (612) 513-6900 **Fax:** (612) 541-9209
Status: Designated/Approved **Designation Date:** 16-May-94 **Marketing Approval Date:** 25-Oct-96

Generic Name: Bethanidine sulfate

Trade Name:

Orphan Indication: Treatment of primary ventricular fibrillation.

Sponsor: Medco Research, Inc. **Contact:** Dr. Sam Teichman
Address: Los Angeles, CA **Phone:** (213) 966-4155 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 20-Sep-88 **Marketing Approval Date:**

Generic Name: Bethanidine sulfate

Trade Name:

Orphan Indication: Prevention of recurrence of primary ventricular fibrillation.

Sponsor: Medco Research, Inc. **Contact:** Dr. Sam Teichman

Address: Los Angeles, CA **Phone:** (213) 966-4155 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 24-Nov-89 **Marketing Approval Date:**

Generic Name: Bexarotene **Trade Name:** Targretin

Orphan Indication: Treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.

Sponsor: Ligand Pharmaceuticals, Inc. **Contact:** Dr. Howard Holden

Address: San Diego, CA **Phone:** (858) 550-7600 **Fax:** (858) 550-1827

Status: Designated/Approved **Designation Date:** 18-Jun-99 **Marketing Approval Date:** 29-Dec-99

Generic Name: Bindarit

Trade Name:

Orphan Indication: Treatment of lupus nephritis.

Sponsor: Angelini Pharmaceuticals, Inc. **Contact:** Dr. Dario Paggiarino

Address: River Edge, NJ **Phone:** (201) 489-4100 **Fax:** (201) 818-3388

Status: Designated **Designation Date:** 03-Feb-98 **Marketing Approval Date:**

Generic Name: Bis(4-fluorophenyl)phenylacetamide

Trade Name:

Orphan Indication: Treatment of sickle cell disease.

Sponsor: ICAgen Inc. **Contact:** Dr. Greg Rigdon

Address: Durham, NC **Phone:** (919) 941-5206 **Fax:**

Status: Designated **Designation Date:** 02-Mar-00 **Marketing Approval Date:**

Generic Name: Bispecific antibody 520c9x22

Trade Name:

Orphan Indication: For in vivo serotherapy of patients with ovarian cancer.

Sponsor: Medarex, Inc. **Contact:** Dr. Randall Curnow

Address: Annandale, NJ **Phone:** (908) 713-6001 **Fax:** (908) 713-6002

Status: Designated **Designation Date:** 05-Oct-93 **Marketing Approval Date:**

Generic Name: Bleomycin **Trade Name:** Blenoxane

Orphan Indication: Treatment of pancreatic cancer.

Sponsor: Genetronics, Inc. **Contact:** Mr. Albert Snyder

Address: San Diego, CA **Phone:** (619) 597-6006 **Fax:**

Status: Designated **Designation Date:** 09-Feb-99 **Marketing Approval Date:**

Generic Name: Bleomycin sulfate **Trade Name:** Blenoxane

Orphan Indication: Treatment of malignant pleural effusion.

Sponsor: Bristol-Myers Squibb Pharmaceutical Research Institute **Contact:** Dr. Joseph Sonk

Address: Princeton, NJ **Phone:** (609) 252-5710 **Fax:**

Status: Designated/Approved **Designation Date:** 17-Sep-93 **Marketing Approval Date:** 20-Feb-96

Generic Name: BMY-45622

Trade Name:

Orphan Indication: Treatment of ovarian cancer.

Sponsor: Bristol-Myers Squibb **Contact:** Cheryl Anderson

Address: Wallingford, CT **Phone:** (203) 284-6083 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 15-Oct-90 **Marketing Approval Date:**

Generic Name: Bosentan

Trade Name:

Orphan Indication: Treatment of pulmonary arterial hypertension.

Sponsor: Actelion Life Sciences Ltd. **Contact:** Ms. Jean Busch

Address: San Mateo, CA **Phone:** (978) 887-0972 **Fax:** 9788877314

Status: Designated **Designation Date:** 06-Oct-00 **Marketing Approval Date:**

Generic Name: Botulinum toxin type A

Trade Name:

Orphan Indication: Treatment of synkinetic closure of the eyelid associated with VII cranial nerve aberrant regeneration.

Sponsor: Botulinum Toxin Research Associates, Inc. **Contact:** Dr. Gary Borodic
Address: Quincy, MA **Phone:** 6177700011 **Fax:** 6177700030
Status: Designated **Designation Date:** 15-Sep-92 **Marketing Approval Date:**

Generic Name: Botulinum toxin type A **Trade Name:** Botox

Orphan Indication: Treatment of blepharospasm associated with dystonia in adults (patients 12 years of age and above).

Sponsor: Allergan, Inc. **Contact:** Mr. Peter Kresel
Address: Irvine, CA **Phone:** (714) 752-4500 **Fax:**

Status: Designated/Approved **Designation Date:** 22-Mar-84 **Marketing Approval Date:** 29-Dec-89

Generic Name: Botulinum toxin type A **Trade Name:** Dysport

Orphan Indication: Treatment of dynamic muscle contractures in pediatric cerebral palsy patients.

Sponsor: Ipsen Limited **Contact:** Dr. Jill Hillier
Address: England, GB **Phone:** 5084780144 **Fax:** 5084733531

Status: Designated **Designation Date:** 20-Oct-99 **Marketing Approval Date:**

Generic Name: Botulinum toxin type A **Trade Name:** Dysport

Orphan Indication: Treatment of essential blepharospasm.

Sponsor: Porton International, Inc. **Contact:** Dr. Jill Hillier
Address: Washington, DC **Phone:** 5084780144 **Fax:** 5084733531

Status: Designated **Designation Date:** 23-Mar-89 **Marketing Approval Date:**

Generic Name: Botulinum toxin type A **Trade Name:** Botox

Orphan Indication: Treatment of strabismus associated with dystonia in adults (patients 12 years of age and above).

Sponsor: Allergan, Inc. **Contact:** Mr. Peter Kresel
Address: Irvine, CA **Phone:** (714) 752-4500 **Fax:**

Status: Designated/Approved **Designation Date:** 22-Mar-84 **Marketing Approval Date:** 29-Dec-89

Generic Name: Botulinum toxin type A **Trade Name:** Dysport

Orphan Indication: Treatment of spasmodic torticollis (cervical dystonia).

Sponsor: Ipsen Limited **Contact:** Dr. Jill Hillier
Address: U.K. SL6 4UH, GB **Phone:** 5084780144 **Fax:** 5084733531

Status: Designated **Designation Date:** 12-Aug-98 **Marketing Approval Date:**

Generic Name: Botulinum toxin type A **Trade Name:** Botox

Orphan Indication: Treatment of dynamic muscle contracture in pediatric cerebral palsy patients.

Sponsor: Allergan, Inc. **Contact:** Mr. Adelbert Stagg
Address: Irvine, CA **Phone:** (714) 246-6931 **Fax:**

Status: Designated **Designation Date:** 06-Dec-91 **Marketing Approval Date:**

Generic Name: Botulinum toxin type A **Trade Name:** Botox

Orphan Indication: Treatment of cervical dystonia.

Sponsor: Allergan, Inc. **Contact:** Dr. Adelbert Stagg
Address: Irvine, CA **Phone:** 7142466931 **Fax:**

Status: Designated/Approved **Designation Date:** 20-Aug-86 **Marketing Approval Date:** 21-Dec-00

Generic Name: Botulinum toxin type B **Trade Name:** NeuroBloc

Orphan Indication: Treatment of cervical dystonia.

Sponsor: Elan Pharmaceuticals, Inc. **Contact:** Mr. Steven Morrissey
Address: South San Francisco, CA **Phone:** (800) 435-5108 **Fax:** (650) 616-5053

Status: Designated/Approved **Designation Date:** 16-Jan-92 **Marketing Approval Date:** 08-Dec-00

Generic Name: Botulinum toxin type F **Trade Name:** Dysport

Orphan Indication: Treatment of essential blepharospasm.

Sponsor: Ipsen Limited (name changed from Porton International Inc) **Contact:** Dr. Jill Hillier

Address: Milford, MA **Phone:** 5084780144 **Fax:** 5084733531

Status: Designated **Designation Date:** 05-Dec-91 **Marketing Approval Date:**

Generic Name: Botulinum toxin type F **Trade Name:** Dysport

Orphan Indication: Treatment of spasmodic torticollis (cervical dystonia).
Sponsor: Ipsen Limited (name changed from Porton **Contact:** Dr. Jill Hillier International Inc.)
Address: Milford, MA **Phone:** 5084780144 **Fax:** 5084733531
Status: Designated **Designation Date:** 24-Oct-91 Marketing Approval Date:

Generic Name: Botulism immune globulin
Trade Name:

Orphan Indication: Treatment of infant botulism.
Sponsor: California Department of Health Services **Contact:** Dr. Stephen Arnon
Address: Berkeley, CA **Phone:** (510) 540-2646 **Fax:** (510) 540-3205
Status: Designated **Designation Date:** 31-Jan-89 Marketing Approval Date:

Generic Name: Bovine colostrum
Trade Name:

Orphan Indication: Treatment of AIDS-related diarrhea.
Sponsor: Hastings, Donald DVM **Contact:** Dr. Donald Hastings
Address: Bismarck, ND **Phone:** (701) 223-3036 **Fax:**
Status: Designated **Designation Date:** 19-Nov-90 Marketing Approval Date:

Generic Name: Bovine immunoglobulin concentrate, *Cryptosporidium parvum* **Trade Name:** Sporidin-G

Orphan Indication: Treatment and symptomatic relief of *Cryptosporidium parvum* infection of the gastrointestinal tract in immunocompromised patients.
Sponsor: GalaGen, Inc. **Contact:** Ms. Lynda Sutton
Address: Arden Hills, MN **Phone:** (919) 361-2286 **Fax:** (919) 361-2290
Status: Designated **Designation Date:** 01-Mar-94 Marketing Approval Date:

Generic Name: Bovine whey protein concentrate **Trade Name:** Immuno-C

Orphan Indication: Treatment of cryptosporidiosis caused by the presence of *Cryptosporidium parvum* in the gastrointestinal tract of patients who are immunodeficient/immunocompromised or immunocompetent.
Sponsor: Biomune Systems, Inc. **Contact:** Dr. Frank Eldredge
Address: Salt Lake City, UT **Phone:** (801) 582-2345 **Fax:**
Status: Designated **Designation Date:** 30-Sep-93 Marketing Approval Date:

Generic Name: Branched chain amino acids
Trade Name:

Orphan Indication: Treatment of amyotrophic lateral sclerosis.
Sponsor: Mount Sinai Medical Center **Contact:** Dr. Andreas Plaitakis
Address: New York, NY **Phone:** (212) 241-7310 **Fax:**
Status: Designated **Designation Date:** 23-Dec-88 Marketing Approval Date:

Generic Name: Brimonidine **Trade Name:** Alphagan

Orphan Indication: Treatment of anterior ischemic optic neuropathy.
Sponsor: Allergan, Inc. **Contact:** Mr. Peter Kresel
Address: Irvine, CA **Phone:** (714) 246-5882 **Fax:**
Status: Designated **Designation Date:** 07-Feb-00 Marketing Approval Date:

Generic Name: Bromhexine **Trade Name:** Bisolvon

Orphan Indication: Treatment of mild to moderate keratoconjunctivitis sicca in patients with Sjogren's syndrome.
Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc. **Contact:** Dr. C. Richard Tamorria
Address: Ridgefield, CT **Phone:** (203) 798-4344 **Fax:** (203) 791-6262
Status: Designated **Designation Date:** 15-May-89 Marketing Approval Date:

Generic Name: Broxuridine **Trade Name:** Broxine/Neomark

Orphan Indication: Radiation sensitizer in the treatment of primary brain tumors.
Sponsor: NeoPharm, Inc. **Contact:** Dr. William Govier
Address: Lake Forest, IL **Phone:** (708) 295-8678 **Fax:**
Status: Designated **Designation Date:** 18-Sep-95 Marketing Approval Date:

Generic Name: Buffered intrathecal electrolyte/dextrose injection **Trade Name:** Elliotts B Solution

Orphan Indication: For use as a diluent in the intrathecal administration of methotrexate and cytarabine for the prevention or treatment meningeal leukemia and lymphocytic lymphoma.

Sponsor: Orphan Medical, Inc. **Contact:** Dr. Dayton Reardon

Address: Minnetonka, MN **Phone:** (612) 513-6900 **Fax:** (612) 541-9209

Status: Designated/Approved **Designation Date:** 24-Aug-94 **Marketing Approval Date:** 27-Sep-96

Generic Name: Buprenorphine hydrochloride **Trade Name:** Subutex

Orphan Indication: Treatment of opiate addiction in opiate users.

Sponsor: Reckitt & Colman Pharmaceuticals, Inc. **Contact:** Mr. Alan Young

Address: Richmond, VA **Phone:** (804) 379-1090 **Fax:** (804) 379-1215

Status: Designated **Designation Date:** 15-Jun-94 **Marketing Approval Date:**

Generic Name: Buprenorphine in combination with naloxone **Trade Name:** Suboxone

Orphan Indication: Treatment of opiate addiction in opiate users.

Sponsor: Reckitt & Colman Pharmaceuticals, Inc. **Contact:** Mr. Alan Young

Address: Richmond, VA **Phone:** (804) 379-1090 **Fax:** (804) 379-1215

Status: Designated **Designation Date:** 27-Oct-94 **Marketing Approval Date:**

Generic Name: Busulfan **Trade Name:** Spartaject

Orphan Indication: For use as preparative therapy for malignancies treated with bone marrow transplantation.

Sponsor: Sparta Pharmaceuticals, Inc. **Contact:** Ms. Cris Friedman

Address: Horsham, PA **Phone:** (215) 442-1700 **Fax:** (215) 442-1827

Status: Designated **Designation Date:** 21-Apr-94 **Marketing Approval Date:**

Generic Name: Busulfan **Trade Name:** Busulfex

Orphan Indication: As preparative therapy in the treatment of malignancies with bone marrow transplantation.

Sponsor: Orphan Medical, Inc. **Contact:** Ms. Carol Curme

Address: Minnetonka, MN **Phone:** 9525136974 **Fax:** 9525419209

Status: Designated/Approved **Designation Date:** 28-Jul-94 **Marketing Approval Date:** 04-Feb-99

Generic Name: Busulfan **Trade Name:** Spartajet-Busulfan

Orphan Indication: Intrathecal therapy for neoplastic meningitis

Sponsor: SuperGen, Inc. **Contact:** Dr. Sam Boddapati

Address: Dublin, CA **Phone:** 9255600100 **Fax:** 9255516472

Status: Designated **Designation Date:** 05-Mar-01 **Marketing Approval Date:**

Generic Name: Busulfan **Trade Name:** Spartaject

Orphan Indication: Treatment of primary brain malignancies.

Sponsor: SuperGen, Inc. **Contact:** Dr. Sam Boddapati

Address: San Ramon, CA **Phone:** 9253270200 **Fax:** 9259041921

Status: Designated **Designation Date:** 07-Jul-97 **Marketing Approval Date:**

Generic Name: Butyrylcholinesterase

Trade Name:

Orphan Indication: For the reduction and clearance of toxic blood levels of cocaine encountered during a drug overdose.

Sponsor: Shire Laboratories Inc. **Contact:** Ms. Tami Martin

Address: Rockville, MD **Phone:** (301) 838-2500 **Fax:** (301) 838-2501

Status: Designated **Designation Date:** 25-Mar-92 **Marketing Approval Date:**

Generic Name: Butyrylcholinesterase

Trade Name:

Orphan Indication: Treatment of post-surgical apnea.

Sponsor: Shire Laboratories Inc. **Contact:** Tami Martin

Address: Rockville, MD **Phone:** 2404536450 **Fax:** (301) 838-2501

Status: Designated **Designation Date:** 30-Sep-92 **Marketing Approval Date:**

Generic Name: BW 12C

Trade Name:

Orphan Indication: Treatment of sickle cell disease.**Sponsor:** Burroughs Wellcome Company **Contact:** Dr. Michael Dalton**Address:** Research Triangle Pk, NC **Phone:** (919) 248-4453 **Fax:****Status:** Designated **Designation Date:** 23-Oct-87 **Marketing Approval Date:****Generic Name:** C1 esterase inhibitor (human)

Trade Name:

Orphan Indication: Treatment and prevention of angioedema caused by C1-esterase inhibitor deficiency.**Sponsor:** Alpha Therapeutic Corporation **Contact:** Ms. Claudia Miller**Address:** Los Angeles, CA **Phone:** (323) 227-7580 **Fax:****Status:** Designated **Designation Date:** 21-Aug-96 **Marketing Approval Date:****Generic Name:** C1-esterase-inhibitor, human, pasteurized **Trade Name:** Berinert P**Orphan Indication:** Prevention and/or treatment of acute attacks of hereditary angioedema.**Sponsor:** Aventis Behring L.L.C. **Contact:** Mr. Victor Paulus**Address:** King of Prussia, PA **Phone:** (610) 878-4052 **Fax:** (610) 878-4009**Status:** Designated **Designation Date:** 16-Oct-92 **Marketing Approval Date:****Generic Name:** C1-inhibitor **Trade Name:** C1-inhibitor (human) vapor heated, Immuno**Orphan Indication:** Treatment of acute attacks of angioedema.**Sponsor:** Baxter Healthcare Corp. **Contact:** Ms. Arlene Vidor**Address:** Glendale, CA **Phone:** (818) 507-5523 **Fax:** (818) 507-5596**Status:** Designated **Designation Date:** 30-Aug-90 **Marketing Approval Date:****Generic Name:** C1-inhibitor **Trade Name:** C1-inhibitor (human) vapor heated, Immuno**Orphan Indication:** Prevention of acute attacks of angioedema, including short-term prophylaxis for patients requiring dental or other surgical procedures.**Sponsor:** Baxter Healthcare Corp. **Contact:** Ms. Ade Denloye**Address:** Glendale, CA **Phone:** 8185075447 **Fax:** () -**Status:** Designated **Designation Date:** 30-Aug-90 **Marketing Approval Date:****Generic Name:** Caffeine **Trade Name:** Cafcit**Orphan Indication:** Treatment of apnea of prematurity.**Sponsor:** O.P.R. Development, L.P. **Contact:** Mr. Sean Alan F.X. Reade**Address:** Lawrence, KS **Phone:** (614) 241-4131 **Fax:** (614) 276-0321**Status:** Designated/Approved **Designation Date:** 20-Sep-88 **Marketing Approval Date:** 21-Sep-99**Generic Name:** Calcitonin salmon nasal spray **Trade Name:** Miacalcin Nasal Spray**Orphan Indication:** Treatment of symptomatic Paget's disease (osteitis deformans).**Sponsor:** Sandoz Pharmaceuticals Corp. **Contact:** Jerry Klinek**Address:** East Hanover, NJ **Phone:** (201) 503-7646 **Fax:****Status:** Designated/Withdrawn **Designation Date:** 29-Oct-90 **Marketing Approval Date:****Generic Name:** Calcitonin-human for injection **Trade Name:** Cibacalcin**Orphan Indication:** Treatment of symptomatic Paget's disease (osteitis deformans).**Sponsor:** Novartis Pharmaceutical Corporation **Contact:** Ms. Nancy Price**Address:** East Hanover, NJ **Phone:** (201) 503-7500 **Fax:****Status:** Designated/Approved **Designation Date:** 20-Jan-87 **Marketing Approval Date:** 31-Oct-86**Generic Name:** Calcium acetate **Trade Name:** Phos-Lo**Orphan Indication:** Treatment of hyperphosphatemia in end stage renal failure.**Sponsor:** Braintree Laboratories **Contact:** Dr. Mark Cleveland**Address:** Braintree, MA **Phone:** (617) 843-2202 **Fax:****Status:** Designated/Approved **Designation Date:** 22-Dec-88 **Marketing Approval Date:** 10-Dec-90**Generic Name:** Calcium acetate

Trade Name:

Orphan Indication: Treatment of hyperphosphatemia in end stage renal disease.**Sponsor:** Pharmedic Company **Contact:** Ms. Joan Carter

Address: Lake Forest, IL **Phone:** (708) 549-8500 **Fax:**

Status: Designated **Designation Date:** 27-Jun-89 **Marketing Approval Date:**

Generic Name: Calcium carbonate **Trade Name:** R & D calcium carbonate/600

Orphan Indication: Treatment of hyperphosphatemia in patients with end stage renal disease.

Sponsor: R & D Laboratories, Inc. **Contact:** Dr. Rhoda Makoff

Address: Marina Del Rey, CA **Phone:** (310) 305-8053 **Fax:**

Status: Designated **Designation Date:** 06-Jun-90 **Marketing Approval Date:**

Generic Name: Calcium gluconate **Trade Name:** Calgonate

Orphan Indication: For use as a wash for hydrofluoric acid spills on human skin.

Sponsor: Calgonate Corp. **Contact:** Mr. Howard Haronian

Address: Warwick, RI **Phone:** (401) 739-9330 **Fax:** (401) 738-8144

Status: Designated **Designation Date:** 20-Nov-97 **Marketing Approval Date:**

Generic Name: Calcium gluconate gel **Trade Name:** H-F Gel

Orphan Indication: For use in the emergency topical treatment of hydrogen fluoride (hydrofluoric acid) burns.

Sponsor: LTR Pharmaceuticals, Inc. **Contact:** Dr. Louis Luzzi

Address: Narragansett, RI **Phone:** (401) 789-1865 **Fax:** (401) 783-1361

Status: Designated **Designation Date:** 21-May-91 **Marketing Approval Date:**

Generic Name: Calcium gluconate gel 2.5%

Trade Name:

Orphan Indication: Emergency topical treatment of hydrogen fluoride (hydrofluoric acid) burns.

Sponsor: Paddock Laboratories, Inc. **Contact:** Ms. Mary Beth Erstad

Address: Minneapolis, MN **Phone:** (612) 546-4676 **Fax:**

Status: Designated **Designation Date:** 10-Sep-90 **Marketing Approval Date:**

Generic Name: Calfactant **Trade Name:** Infasurf

Orphan Indication: Acute respiratory distress syndrome (ARDS)

Sponsor: ONY, Inc. **Contact:** Dr. Edmund Egan

Address: Amherst, NY **Phone:** 7166369096 **Fax:** 7166363942

Status: Designated **Designation Date:** 05-Sep-00 **Marketing Approval Date:**

Generic Name: Carbamylglutamic acid

Trade Name:

Orphan Indication: Treatment of N-acetylglutamate synthetase deficiency.

Sponsor: Orphan Europe **Contact:** Mr. Milton Ellis

Address: 92046 Paris La Defense, FR **Phone:** (615) 399-0700 **Fax:** (615) 399-2285

Status: Designated **Designation Date:** 20-Jan-98 **Marketing Approval Date:**

Generic Name: Carbovir

Trade Name:

Orphan Indication: Treatment of persons with AIDS and in patients with symptomatic HIV infection and a CD4 count less than 200/mm³.

Sponsor: Glaxo Wellcome Inc. **Contact:** Mr. David Cocchetto

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 13-Dec-89 **Marketing Approval Date:**

Generic Name: Carmustine

Trade Name:

Orphan Indication: Treatment of intracranial malignancies.

Sponsor: Direct Therapeutics, Inc. **Contact:** Ms. Bonnie Horner

Address: San Bruno, CA **Phone:** (650) 917-4142 **Fax:** (650) 320-9650

Status: Designated **Designation Date:** 03-Jul-00 **Marketing Approval Date:**

Generic Name: Cascara sagrada fluid extract

Trade Name:

Orphan Indication: Treatment of oral drug overdose to speed lower bowel evacuation.

Sponsor: Intramed Corporation **Contact:** Dr. John Ward

Address: Augusta, GA **Phone:** (706) 863-2878 **Fax:**

Status: Designated **Designation Date:** 21-Mar-89 **Marketing Approval Date:**

Generic Name: CD4 human truncated 369 AA polypeptide **Trade Name:** Soluble T4

Orphan Indication: Treatment of acquired immunodeficiency syndrome.

Sponsor: SmithKline Beecham **Contact:** Dr. Stella Jones

Address: King Of Prussia, PA **Phone:** (215) 832-3707 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 21-Nov-89 **Marketing Approval Date:**

Generic Name: CD5-T lymphocyte immunotoxin **Trade Name:** Xomazyme-H65

Orphan Indication: Treatment of graft versus host disease and/or rejection in patients who have received bone marrow transplants.

Sponsor: Xoma Corporation **Contact:** Ms. Joan Roelands

Address: Berkeley, CA **Phone:** (510) 644-1170 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 27-Aug-87 **Marketing Approval Date:**

Generic Name: CDP571

Trade Name:

Orphan Indication: Treatment of Crohn's disease.

Sponsor: Celltech Chiroscience Limited **Contact:** Dr. James Parker

Address: Berkshire, UK **Phone:** (978) 897-8404 **Fax:** (508) 461-0333

Status: Designated **Designation Date:** 11-Dec-97 **Marketing Approval Date:**

Generic Name: Centruroides immune F(ab)₂ **Trade Name:** Alacramyn

Orphan Indication: Treatment of scorpion envenomations requiring medical attention.

Sponsor: Silanes Laboratories S.A. de C.V. **Contact:** Mr. Milton Ellis

Address: , **Phone:** 6153990700 **Fax:** 6153991217

Status: Designated **Designation Date:** 12-Jun-00 **Marketing Approval Date:**

Generic Name: Ceramide trihexosidase/alpha-galactosidase A

Trade Name:

Orphan Indication: Treatment of Fabry's disease.

Sponsor: Genzyme Corporation **Contact:** Ms. Nicole Brien

Address: Cambridge, MA **Phone:** (617) 374-7286 **Fax:** (617) 252-7600

Status: Designated **Designation Date:** 19-Jan-88 **Marketing Approval Date:**

Generic Name: Cetiedil citrate injection

Trade Name:

Orphan Indication: Treatment of sickle cell disease crisis.

Sponsor: Baker Cummins Pharmaceuticals, Inc. **Contact:**

Address: , **Phone:** Fax:

Status: Designated/Withdrawn **Designation Date:** 22-Dec-88 **Marketing Approval Date:**

Generic Name: Cetuximab

Trade Name:

Orphan Indication: Treatment of squamous cell cancer of the head and neck in patients who express epidermal growth factor receptor.

Sponsor: ImClone Systems Incorporated **Contact:** Ms. Deborah Lynch

Address: Somerville, NJ **Phone:** (908) 541-8026 **Fax:** (908) 704-8325

Status: Designated **Designation Date:** 03-Jul-00 **Marketing Approval Date:**

Generic Name: Chenodiol **Trade Name:** Chenix

Orphan Indication: 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.

Sponsor: Solvay **Contact:** Mr. George Severn

Address: Marietta, GA **Phone:** (404) 578-9000 **Fax:**

Status: Designated/Approved **Designation Date:** 21-Sep-84 **Marketing Approval Date:** 28-Jul-83

Generic Name: Chimeric (human-murine) G250 IgG monoclonal antibody

Trade Name:

Orphan Indication: Treatment of renal cell carcinoma.
Sponsor: Wilex Biotechnology GmbH **Contact:** Dr. E. Hoffmann
Address: Germany, DE **Phone:** (212) 450-1530 **Fax:** (212) 450-1535
Status: Designated **Designation Date:** 24-Jul-00 **Marketing Approval Date:**

Generic Name: Chimeric M-T412 (human-murine) IgG monoclonal anti-CD4
Trade Name:

Orphan Indication: Treatment of multiple sclerosis.
Sponsor: Centocor, Inc. **Contact:** Mr. Martin Page
Address: Malvern, PA **Phone:** (215) 889-4786 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 05-Jun-91 **Marketing Approval Date:**

Generic Name: Chimeric, humanized monoclonal antibody to staphylococcus
Trade Name:

Orphan Indication: Prophylaxis of Staphylococcus epidermidis sepsis in low birth weight (1500 grams or less) infants.
Sponsor: Biosynexus, Inc. **Contact:** Dr. Gerald Fischer
Address: Rockville, MD **Phone:** (301) 294-8604 **Fax:** (301) 309-0471
Status: Designated **Designation Date:** 03-Aug-00 **Marketing Approval Date:**

Generic Name: Chlorhexidine gluconate mouthrinse **Trade Name:** Peridex

Orphan Indication: For use in the amelioration of oral mucositis associated with cytoreductive therapy used in conditioning patients for bone marrow transplantation therapy.
Sponsor: Procter & Gamble Company **Contact:** Dr. Ronald Downey
Address: Cincinnati, OH **Phone:** (513) 626-2514 **Fax:**
Status: Designated **Designation Date:** 18-Aug-86 **Marketing Approval Date:**

Generic Name: Choline chloride **Trade Name:** Intrachol

Orphan Indication: Treatment of choline deficiency, specifically the choline deficiency, hepatic steatosis, and cholestasis, associated with long-term parenteral nutrition.
Sponsor: Orphan Medical, Inc. **Contact:** Ms. Carol Curme
Address: Minnetonka, MN **Phone:** 9525136974 **Fax:** 9525419209
Status: Designated **Designation Date:** 10-Feb-94 **Marketing Approval Date:**

Generic Name: Chondrocyte-alginate gel suspension
Trade Name:

Orphan Indication: For use in correcting vesicoureteral reflux in the pediatric population.
Sponsor: Curis, Inc. **Contact:** Dr. Frank Gentile
Address: Cambridge, MA **Phone:** 6178760086 **Fax:** 6178760866
Status: Designated **Designation Date:** 01-Dec-97 **Marketing Approval Date:**

Generic Name: Chondroitinase
Trade Name:

Orphan Indication: Treatment of patients undergoing vitrectomy.
Sponsor: Bausch & Lomb Pharmaceuticals, Inc. **Contact:** Mr. Samuel Bohannon
Address: Tampa, FL **Phone:** (813) 975-7700 **Fax:** (813) 975-7770
Status: Designated/Withdrawn **Designation Date:** 09-Feb-95 **Marketing Approval Date:**

Generic Name: Ciliary neurotrophic factor
Trade Name:

Orphan Indication: Treatment of amyotrophic lateral sclerosis.
Sponsor: Regeneron Pharmaceuticals Inc **Contact:** Mr. Stephen Holst
Address: Tarrytown, NY **Phone:** (914) 347-7000 **Fax:**
Status: Designated **Designation Date:** 30-Jan-92 **Marketing Approval Date:**

Generic Name: Ciliary neurotrophic factor, recombinant human
Trade Name:

Orphan Indication: Treatment of spinal muscular atrophies.
Sponsor: Syntex-Synergen Neuroscience **Contact:** Mr. Jeffery Fellows
Address: Boulder, CO **Phone:** (303) 441-5510 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 02-Apr-92 **Marketing Approval Date:**

Generic Name: Ciliary neurotrophic factor, recombinant human
Trade Name:

Orphan Indication: Treatment of motor neuron disease (including amyotrophic lateral sclerosis, progressive muscular atrophy, progressive bulbar palsy, and primary lateral sclerosis).

Sponsor: Syntex-Synergen Neuroscience **Contact:** Mr. Jeffery Fellows

Address: Boulder, CO **Phone:** (303) 441-5510 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 08-May-92 **Marketing Approval Date:**

Generic Name: Cisplatin/epinephrine **Trade Name:** IntraDose

Orphan Indication: Treatment of squamous cell carcinoma of the head and neck.

Sponsor: Matrix Pharmaceutical, Inc. **Contact:** Ms. Luana Staiger

Address: Fremont, CA **Phone:** (510) 742-9900 **Fax:**

Status: Designated **Designation Date:** 03-Apr-00 **Marketing Approval Date:**

Generic Name: Cisplatin/epinephrine **Trade Name:** IntraDose

Orphan Indication: Treatment of metastatic malignant melanoma.

Sponsor: Matrix Pharmaceutical, Inc. **Contact:** Ms. Luana Staiger

Address: Fremont, CA **Phone:** (510) 742-9900 **Fax:**

Status: Designated **Designation Date:** 07-Sep-00 **Marketing Approval Date:**

Generic Name: Citric acid, glucono-delta-lactone and magnesium carbonate **Trade Name:** Renacidin Irrigation

Orphan Indication: Treatment of renal and bladder calculi of the apatite or struvite variety.

Sponsor: United-Guardian, Inc. **Contact:** Mr. Robert Rubinger

Address: Smithtown, NY **Phone:** (516) 273-0900 **Fax:**

Status: Designated/Approved **Designation Date:** 28-Aug-89 **Marketing Approval Date:** 02-Oct-90

Generic Name: Cladribine **Trade Name:** Mylinax

Orphan Indication: Treatment of the chronic progressive form of multiple sclerosis.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Ms. Eileen Hanigan

Address: Raritan, NJ **Phone:** (908) 704-5109 **Fax:**

Status: Designated **Designation Date:** 19-Apr-94 **Marketing Approval Date:**

Generic Name: Cladribine **Trade Name:** Leustatin Injection

Orphan Indication: Treatment of non-Hodgkin's lymphoma.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Mr. William Sisco

Address: Raritan, NJ **Phone:** (908) 704-4301 **Fax:**

Status: Designated **Designation Date:** 19-Apr-93 **Marketing Approval Date:**

Generic Name: Cladribine **Trade Name:** Leustatin Injection

Orphan Indication: Treatment of chronic lymphocytic leukemia.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Mr. William Sisco

Address: Raritan, NJ **Phone:** (908) 704-4301 **Fax:**

Status: Designated **Designation Date:** 31-Dec-90 **Marketing Approval Date:**

Generic Name: Cladribine **Trade Name:** Leustatin

Orphan Indication: Treatment of acute myeloid leukemia.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Mr. Michael Kaufman

Address: Raritan, NJ **Phone:** (908) 704-4600 **Fax:**

Status: Designated **Designation Date:** 20-Jul-90 **Marketing Approval Date:**

Generic Name: Cladribine **Trade Name:** Leustatin Injection

Orphan Indication: Treatment of hairy cell leukemia.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Ms. Jacqueline Coelln

Address: Raritan, NJ **Phone:** (908) 704-5829 **Fax:**

Status: Designated/Approved **Designation Date:** 15-Nov-90 **Marketing Approval Date:** 26-Feb-93

Generic Name: Clindamycin **Trade Name:** Cleocin

Orphan Indication: Treatment of Pneumocystis carinii pneumonia associated with AIDS patients.

Sponsor: Pharmacia & Upjohn **Contact:** Ms. Rebecca Tong

Address: Kalamazoo, MI **Phone:** (616) 833-8542 **Fax:** (616) 833-8237

Status: Designated **Designation Date:** 28-Oct-88 **Marketing Approval Date:**

Generic Name: Clindamycin **Trade Name:** Cleocin**Orphan Indication:** Prevention of Pneumocystis carinii pneumonia in AIDS patients.**Sponsor:** Pharmacia & Upjohn **Contact:** Ms. Rebecca Tong**Address:** Kalamazoo, MI **Phone:** (616) 833-8542 **Fax:** (616) 833-8237**Status:** Designated **Designation Date:** 28-Oct-88 **Marketing Approval Date:****Generic Name:** Clofazimine **Trade Name:** Lamprène**Orphan Indication:** Treatment of lepromatous leprosy, including dapsone-resistant lepromatous leprosy and lepromatous leprosy complicated by erythema nodosum leprosum.**Sponsor:** Novartis Pharmaceutical Corporation **Contact:** Ms. Nancy Price**Address:** East Hanover, NJ **Phone:** (201) 503-7500 **Fax:****Status:** Designated/Approved **Designation Date:** 11-Jun-84 **Marketing Approval Date:** 15-Dec-86**Generic Name:** Clonazepam **Trade Name:** Klonopin**Orphan Indication:** Treatment of hyperekplexia (startle disease).**Sponsor:** Hoffmann-La Roche, Inc. **Contact:** Mr. Thomas Watson**Address:** Nutley, NJ **Phone:** (201) 812-3724 **Fax:** (201) 812-3700**Status:** Designated **Designation Date:** 04-Aug-94 **Marketing Approval Date:****Generic Name:** Clonidine **Trade Name:** Duraclon**Orphan Indication:** 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.**Sponsor:** Roxane Laboratories, Inc. **Contact:** Mr. Sean Alan F.X. Reade**Address:** Columbus, OH **Phone:** (614) 241-4131 **Fax:** (614) 276-0321**Status:** Designated/Approved **Designation Date:** 24-Jan-89 **Marketing Approval Date:** 02-Oct-96**Generic Name:** Clostridial collagenase

Trade Name:

Orphan Indication: Treatment of advanced (involitional or residual stage) Dupuytren's disease.**Sponsor:** Hurst, L. M.D. & Badalamente, M. Ph.D. **Contact:** Dr. Lawrence Hurst**Address:** Stony Brook, NY **Phone:** 6314447830 **Fax:** 6314447671**Status:** Designated **Designation Date:** 23-May-96 **Marketing Approval Date:****Generic Name:** Clotrimazole

Trade Name:

Orphan Indication: Treatment of sickle cell disease.**Sponsor:** Brugnara, Carlo M.D. **Contact:** Dr. Carlo Brugnara**Address:** Boston, MA **Phone:** (617) 735-6347 **Fax:****Status:** Designated **Designation Date:** 24-Apr-95 **Marketing Approval Date:****Generic Name:** Coagulation factor IX **Trade Name:** Mononine**Orphan Indication:** Replacement treatment and prophylaxis of the hemorrhagic complications of hemophilia B.**Sponsor:** Armour Pharmaceutical Company **Contact:** Mr. Stewart Mueller**Address:** Collegeville, PA **Phone:** (215) 540-8139 **Fax:****Status:** Designated/Approved **Designation Date:** 27-Jun-89 **Marketing Approval Date:** 20-Aug-92**Generic Name:** Coagulation Factor IX (human) **Trade Name:** AlphaNine**Orphan Indication:** 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.**Sponsor:** Alpha Therapeutic Corporation **Contact:** Ms. M. Sue Preston**Address:** Los Angeles, CA **Phone:** (213) 225-2221 **Fax:****Status:** Designated/Approved **Designation Date:** 05-Jul-90 **Marketing Approval Date:** 31-Dec-90**Generic Name:** Coagulation Factor IX (recombinant) **Trade Name:** BeneFix**Orphan Indication:** Treatment of hemophilia B.**Sponsor:** Genetics Institute, Inc. **Contact:** Dr. Frederick Gates**Address:** Cambridge, MA **Phone:** (617) 503-7332 **Fax:****Status:** Designated/Approved **Designation Date:** 03-Oct-94 **Marketing Approval Date:** 11-Feb-97

Generic Name: Coagulation factor VIIa (recombinant)	Trade Name: NovoSeven
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Orphan Indication: Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.

Sponsor: Novo Nordisk Pharmaceuticals, Inc. **Contact:** Dr. Barry Reit

Address: Princeton, NJ **Phone:** (609) 987-5877 **Fax:** (609) 921-8082

Status: Designated/Approved **Designation Date:** 06-Jun-88 **Marketing Approval Date:** 25-Mar-99

Generic Name: Coenzyme Q10

Trade Name:

Orphan Indication: For the treatment of Huntington's disease

Sponsor: Vitaline Corporation **Contact:** Mr. Frank Sasinowski

Address: Ashland, OR **Phone:** 2027375600 **Fax:** 2027379329

Status: Designated **Designation Date:** 05-Mar-01 **Marketing Approval Date:**

Generic Name: Colchicine

Trade Name:

Orphan Indication: For arresting the progression of neurologic disability caused by chronic progressive multiple sclerosis.

Sponsor: Pharmacontrol Corporation **Contact:** Dr. Laszlo Darko

Address: Englewood Cliffs, NJ **Phone:** (212) 249-0221 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 09-Dec-85 **Marketing Approval Date:**

Generic Name: Colfosceril palmitate, cetyl alcohol, tyloxapol	Trade Name: Exosurf
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Orphan Indication: Treatment of adult respiratory distress syndrome.

Sponsor: Glaxo Wellcome Research and Development **Contact:** Sara Nelson

Address: Research Triangle Park, NC **Phone:** 9194835140 **Fax:** (919) 315-0033

Status: Designated **Designation Date:** 11-Jan-93 **Marketing Approval Date:**

Generic Name: Colfosceril palmitate, cetyl alcohol, tyloxapol	Trade Name: Exosurf Neonatal for Intratracheal Suspension
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Orphan Indication: Prevention of hyaline membrane disease, also known as respiratory distress syndrome, in infants born at 32 weeks gestation or less.

Sponsor: Glaxo Wellcome Inc. **Contact:** Dr. Michael Dalton

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Designated/Approved **Designation Date:** 20-Oct-89 **Marketing Approval Date:** 02-Aug-90

Generic Name: Colfosceril palmitate, cetyl alcohol, tyloxapol	Trade Name: Exosurf Neonatal for Intratracheal Suspension
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Orphan Indication: Treatment of established hyaline membrane disease at all gestational ages.

Sponsor: Glaxo Wellcome Inc. **Contact:** Dr. Michael Dalton

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Designated/Approved **Designation Date:** 20-Oct-89 **Marketing Approval Date:** 02-Aug-90

Generic Name: Collagenase (lyophilized) for injection	Trade Name: Plaquase
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Orphan Indication: Treatment of Peyronie's disease.

Sponsor: Advance Biofactures Corporation **Contact:** Mr. Thomas Wegman

Address: Lynbrook, NY **Phone:** (516) 593-7000 **Fax:** (516) 593-7039

Status: Designated **Designation Date:** 12-Mar-96 **Marketing Approval Date:**

Generic Name: Corticorelin ovine triflutate	Trade Name: Acthrel
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Orphan Indication: For use in differentiating pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushings syndrome.

Sponsor: Ferring Laboratories, Inc. **Contact:** Mr. Isidoro Nudelman

Address: Suffern, NY **Phone:** (888) 793-6367 **Fax:** () -

Status: Designated/Approved **Designation Date:** 24-Nov-89 **Marketing Approval Date:** 23-May-96

Generic Name: Corticotropin-releasing factor, human	Trade Name: Xerecept
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Orphan Indication: Treatment of peritumoral brain edema.

Sponsor: Neurobiological Technologies, Inc. **Contact:** Ms. Jian Johnson

Address: Richmond, CA **Phone:** (510) 215-8000 **Fax:** (510) 215-8100

Status: Designated **Designation Date:** 06-Apr-98 **Marketing Approval Date:**

Generic Name: Coumarin **Trade Name:** Onkolox**Orphan Indication:** Treatment of renal cell carcinoma.**Sponsor:** Drossapharm LTD **Contact:** Dr. Sam Boddapati**Address:** Switzerland, CH **Phone:** 9255600100 **Fax:** 9255600101**Status:** Designated **Designation Date:** 22-Dec-94 **Marketing Approval Date:****Generic Name:** Cromolyn sodium **Trade Name:** Gastrocrom**Orphan Indication:** Treatment of mastocytosis.**Sponsor:** Fisons Corporation **Contact:** Ms. Susan Raymond**Address:** Rochester, NY **Phone:** (716) 475-9000 **Fax:****Status:** Designated/Approved **Designation Date:** 08-Mar-84 **Marketing Approval Date:** 22-Dec-89**Generic Name:** Cromolyn sodium 4% ophthalmic solution **Trade Name:** Opticrom 4% ophthalmic solution**Orphan Indication:** Treatment of vernal keratoconjunctivitis.**Sponsor:** Fisons Corporation **Contact:** Ms. Susan Raymond**Address:** Rochester, NY **Phone:** (716) 475-9000 **Fax:****Status:** Designated/Approved **Designation Date:** 24-Jul-85 **Marketing Approval Date:** 03-Oct-84**Generic Name:** Cryptosporidium hyperimmune bovine colostrum IgG concentrate**Trade Name:****Orphan Indication:** Treatment of diarrhea in AIDS patients caused by infection with *Cryptosporidium parvum*.**Sponsor:** ImmuCell Corporation **Contact:** Dr. Joseph Crabb**Address:** Portland, ME **Phone:** (207) 878-2770 **Fax:****Status:** Designated **Designation Date:** 30-Dec-91 **Marketing Approval Date:****Generic Name:** CT-2584 mesylate**Trade Name:****Orphan Indication:** Treatment of malignant mesothelioma.**Sponsor:** Cell Therapeutics, Inc. **Contact:** Ms. Jennie Allewell**Address:** Seattle, WA **Phone:** (206) 282-7100 **Fax:****Status:** Designated **Designation Date:** 16-Apr-99 **Marketing Approval Date:****Generic Name:** CT-2584 mesylate**Trade Name:****Orphan Indication:** Treatment of adult soft tissue sarcoma.**Sponsor:** Cell Therapeutics, Inc. **Contact:** Ms. Jennie Allewell**Address:** Seattle, WA **Phone:** (206) 270-8424 **Fax:** (206)284-6206**Status:** Designated **Designation Date:** 16-Apr-99 **Marketing Approval Date:****Generic Name:** CY-1503 **Trade Name:** Cylexin**Orphan Indication:** Treatment of post-ischemic pulmonary reperfusion edema following surgical treatment for chronic thromboembolic pulmonary hypertension.**Sponsor:** Cytel Corporation **Contact:** Dr. Robert Roe**Address:** San Diego, CA **Phone:** (619) 552-3062 **Fax:** (619) 552-8801**Status:** Designated **Designation Date:** 22-Dec-93 **Marketing Approval Date:****Generic Name:** CY-1503 **Trade Name:** Cylexin**Orphan Indication:** Treatment of neonates and infants undergoing cardiopulmonary bypass during surgical repair of congenital heart lesions.**Sponsor:** Cytel Corporation **Contact:** Dr. Robert Roe**Address:** San Diego, CA **Phone:** (619) 552-3062 **Fax:** (619) 552-8801**Status:** Designated **Designation Date:** 18-Jul-97 **Marketing Approval Date:****Generic Name:** CY-1899**Trade Name:****Orphan Indication:** Treatment of chronic active hepatitis B infection in HLA-A2 positive patients.**Sponsor:** Cytel Corporation **Contact:** Dr. Robert Roe**Address:** San Diego, CA **Phone:** (619) 552-3062 **Fax:** (619) 552-8801**Status:** Designated **Designation Date:** 16-Mar-94 **Marketing Approval Date:**

Generic Name: Cyclosporine 2% ophthalmic ointment
Trade Name:

Orphan Indication: Treatment of patients at high risk of graft rejection following penetrating keratoplasty.

Sponsor: Allergan, Inc. **Contact:** Ms. Elizabeth Bancroft

Address: Irvine, CA **Phone:** (714) 246-4391 **Fax:**

Status: Designated **Designation Date:** 01-Aug-91 **Marketing Approval Date:**

Generic Name: Cyclosporine 2% ophthalmic ointment
Trade Name:

Orphan Indication: For use in corneal melting syndromes of known or presumed immunologic etiopathogenesis, including Mooren's ulcer.

Sponsor: Allergan, Inc. **Contact:** Ms. Elizabeth Bancroft

Address: Irvine, CA **Phone:** (714) 246-4391 **Fax:**

Status: Designated **Designation Date:** 01-Aug-91 **Marketing Approval Date:**

Generic Name: Cyclosporine in combination with omega-3 polyunsaturated fatty acids
Trade Name:

Orphan Indication: Prevention of solid organ graft rejection.

Sponsor: RTP Pharma Corporation **Contact:** Mr. Peter Vaccari

Address: Durham, NC **Phone:** 3013091260 **Fax:** 3013098470

Status: Designated **Designation Date:** 06-Dec-00 **Marketing Approval Date:**

Generic Name: Cyclosporine ophthalmic **Trade Name:** Optimmune

Orphan Indication: Treatment of severe keratoconjunctivitis sicca associated with Sjogren's syndrome.

Sponsor: University Of Georgia **Contact:** Dr. Renee Kaswan

Address: Athens, GA **Phone:** (706) 542-3221 **Fax:**

Status: Designated **Designation Date:** 09-Nov-88 **Marketing Approval Date:**

Generic Name: Cyproterone acetate **Trade Name:** Androcur

Orphan Indication: Treatment of severe hirsutism.

Sponsor: Berlex Laboratories, Inc. **Contact:** Dr. Suzanne Hampton

Address: Wayne, NJ **Phone:** (201) 305-5288 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 26-Oct-84 **Marketing Approval Date:**

Generic Name: Cysteamine **Trade Name:** Cystagon

Orphan Indication: Treatment of nephropathic cystinosis.

Sponsor: Mylan Laboratories, Inc. **Contact:** Dr. John O'Donnell

Address: Morgantown, WV **Phone:** (304) 599-2595 **Fax:**

Status: Designated/Approved **Designation Date:** 25-Jan-91 **Marketing Approval Date:** 15-Aug-94

Generic Name: Cysteamine
Trade Name:

Orphan Indication: Treatment of nephropathic cystinosis.

Sponsor: Thoene, Jess G., M.D. **Contact:** Dr. Jess Thoene

Address: Ann Arbor, MI **Phone:** (734) 763-3427 **Fax:** (734) 764-0463

Status: Designated **Designation Date:** 01-May-86 **Marketing Approval Date:**

Generic Name: Cysteamine hydrochloride
Trade Name:

Orphan Indication: Treatment of corneal cystine crystal accumulation in cystinosis patients.

Sponsor: Sigma-Tau Pharmaceuticals, Inc. **Contact:** Mr. A Hanzas

Address: Gaithersburg, MD **Phone:** 3016702192 **Fax:** (301) 948-3194

Status: Designated **Designation Date:** 19-Aug-97 **Marketing Approval Date:**

Generic Name: Cystic fibrosis gene therapy
Trade Name:

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: Genzyme Corporation **Contact:** Mr. Robert Martin

Address: Framingham, MA **Phone:** 5082713772 **Fax:** 5082712692

Status: Designated **Designation Date:** 30-Jun-92 **Marketing Approval Date:**

Generic Name: Cystic fibrosis Tr gene therapy (recombinant adenovirus) **Trade Name:** AdGVCFTR.10

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: GenVec, Inc. **Contact:** Mr. Thomas D'Alonzo

Address: Rockville, MD **Phone:** (301) 816-0396 **Fax:** (301) 816-0085

Status: Designated **Designation Date:** 09-Mar-95 **Marketing Approval Date:**

Generic Name: Cystic fibrosis transmembrane conductance regulator

Trade Name:

Orphan Indication: For cystic fibrosis transmembrane conductance regulator protein replacement therapy in cystic fibrosis patients.

Sponsor: Genzyme Corporation **Contact:** Ms. Christine Boisclair

Address: Framingham, MA **Phone:** (508) 270-2314 **Fax:** (508) 872-9080

Status: Designated/Withdrawn **Designation Date:** 14-Jan-92 **Marketing Approval Date:**

Generic Name: Cystic fibrosis transmembrane conductance regulator gene

Trade Name:

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: Genetic Therapy, Inc. **Contact:** Mr. Jeffrey Carey

Address: Gaithersburg, MD **Phone:** (301) 208-2451 **Fax:** (301) 948-0097

Status: Designated **Designation Date:** 08-Jan-93 **Marketing Approval Date:**

Generic Name: Cytarabine liposomal **Trade Name:** DepoCyt

Orphan Indication: Treatment of neoplastic meningitis.

Sponsor: DepoTech Corporation **Contact:** Mr. Raymond Lamy

Address: San Diego, CA **Phone:** (619) 625-2414 **Fax:** (619) 558-6617

Status: Designated/Approved **Designation Date:** 02-Jun-93 **Marketing Approval Date:** 01-Apr-99

Generic Name: Cytomegalovirus immune globulin (human) **Trade Name:** CytoGam

Orphan Indication: Prevention or attenuation of primary cytomegalovirus disease in immunosuppressed recipients of organ transplants.

Sponsor: Massachusetts Public Health Biologic Laboratories **Contact:** Dr. Jeanne Leszczynski

Address: Boston, MA **Phone:** (617) 983-6400 **Fax:**

Status: Designated/Approved **Designation Date:** 03-Aug-87 **Marketing Approval Date:** 04-Dec-98

Generic Name: Cytomegalovirus immune globulin intravenous (human)

Trade Name:

Orphan Indication: For use in conjunction with ganciclovir sodium for the treatment of cytomegalovirus pneumonia in bone marrow transplant patients.

Sponsor: Bayer Corporation **Contact:** Ms.

Address: New Haven, CT **Phone:** (203) 937-2000 **Fax:**

Status: Designated **Designation Date:** 28-Jan-91 **Marketing Approval Date:**

Generic Name: Daclizumab **Trade Name:** Zenapax

Orphan Indication: Prevention of acute renal allograft rejection.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Ileana Leon Brown

Address: Nutley, NJ **Phone:** (201) 812-3720 **Fax:** (201) 812-3700

Status: Designated/Approved **Designation Date:** 05-Mar-93 **Marketing Approval Date:** 10-Dec-97

Generic Name: Dantrolene sodium **Trade Name:** Dantrium

Orphan Indication: Treatment of the neuroleptic malignant syndrome.

Sponsor: Norwich Eaton Pharmaceuticals **Contact:** Steven Salerno

Address: Norwich, NY **Phone:** **Fax:**

Status: Designated/Withdrawn **Designation Date:** 14-Dec-87 **Marketing Approval Date:**

Generic Name: Dapsone

Trade Name:

Orphan Indication: Prophylaxis of toxoplasmosis in severely immunocompromised patients with CD4 counts below 100.

Sponsor: Jacobus Pharmaceutical Company, Inc. **Contact:** Mr. David Jacobus

Address: Princeton, NJ **Phone:** (609) 921-7447 **Fax:** (609) 799-1176

Status: Designated **Designation Date:** 07-Nov-94 **Marketing Approval Date:**

Generic Name: Dapsone USP **Trade Name:** Dapsone

Orphan Indication: Prophylaxis for Pneumocystis carinii pneumonia.

Sponsor: Jacobus Pharmaceutical Company **Contact:** Dr. Neil Lewis

Address: Princeton, NJ **Phone:** (609) 921-7447 **Fax:**

Status: Designated **Designation Date:** 24-Dec-91 **Marketing Approval Date:**

Generic Name: Dapsone USP **Trade Name:** Dapsone

Orphan Indication: For the combination treatment of Pneumocystis carinii pneumonia in conjunction with trimethoprim.

Sponsor: Jacobus Pharmaceutical Company **Contact:** Dr. Neil Lewis

Address: Princeton, NJ **Phone:** (609) 921-7447 **Fax:**

Status: Designated **Designation Date:** 08-Jan-92 **Marketing Approval Date:**

Generic Name: Daunorubicin citrate liposome injection **Trade Name:** DaunoXome

Orphan Indication: Treatment of patients with advanced HIV-associated Kaposi's sarcoma.

Sponsor: NeXstar Pharmaceuticals, Inc. **Contact:** Mr. Stephen Campbell

Address: San Dimas, CA **Phone:** (909) 592-8530 **Fax:**

Status: Designated/Approved **Designation Date:** 14-May-93 **Marketing Approval Date:** 08-Apr-96

Generic Name: Decitabine

Trade Name:

Orphan Indication: Treatment of myelodysplastic syndromes.

Sponsor: SuperGen, Inc. **Contact:** Dr. Sam Boddapati

Address: Dublin, CA **Phone:** 9255600100 **Fax:** 9255516472

Status: Designated **Designation Date:** 08-Mar-99 **Marketing Approval Date:**

Generic Name: Decitabine

Trade Name:

Orphan Indication: Treatment of chronic myelogenous leukemia.

Sponsor: SuperGen, Inc. **Contact:** Dr. Sam Boddapati

Address: Dublin, CA **Phone:** 9255600100 **Fax:** 9255516472

Status: Designated **Designation Date:** 08-Mar-99 **Marketing Approval Date:**

Generic Name: Defibrotide

Trade Name:

Orphan Indication: Treatment of thrombotic thrombocytopenic purpura.

Sponsor: Crinos International **Contact:** Mr. Romano Becatti

Address: Villa Guardia, Italy, **Phone:** () - **Fax:**

Status: Designated **Designation Date:** 05-Jul-85 **Marketing Approval Date:**

Generic Name: Dehydroepiandrosterone

Trade Name:

Orphan Indication: Treatment of systemic lupus erythematosus (SLE) and the reduction in the use of steroids in steroid-dependent SLE patients.

Sponsor: Genelabs Technologies, Inc. **Contact:** Ms. Kerry Maurer

Address: Redwood City, CA **Phone:** (650) 562-1428 **Fax:** (650) 368-0709

Status: Designated **Designation Date:** 13-Jul-94 **Marketing Approval Date:**

Generic Name: Dehydroepiandrosterone sulfate sodium

Trade Name:

Orphan Indication: To accelerate the re-epithelialization of donor sites in those hospitalized burn patients who must undergo autologous skin grafting.

Sponsor: Pharmadigm, Inc. **Contact:** Ms. Catherine Hamilton

Address: Salt Lake City, UT **Phone:** (801) 464-6103 **Fax:** (801) 464-6116

Status: Designated **Designation Date:** 28-Jan-97 **Marketing Approval Date:**

Generic Name: Dehydroepiandrosterone sulfate sodium

Trade Name:

Orphan Indication: Treatment of serious burns requiring hospitalization.

Sponsor: Pharmadigm, Inc. **Contact:** Mr. Timothy DiLiberti

Address: Salt Lake City, UT **Phone:** (801) 464-6103 **Fax:** (801) 464-6116

Status: Designated **Designation Date:** 29-Jan-97 **Marketing Approval Date:**

Generic Name: Denileukin diftitox **Trade Name:** Ontak**Orphan Indication:** Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.**Sponsor:** Seragen, Inc. **Contact:** Dr. Jill Hillier**Address:** Hopkinton, MA **Phone:** (508) 435-2331 **Fax:** (508) 435-0558**Status:** Designated/Approved **Designation Date:** 21-Aug-96 **Marketing Approval Date:** 05-Feb-99**Generic Name:** Deoxyribose, phosphorothioate
Trade Name:**Orphan Indication:** Treatment of advanced malignant melanoma (Stages II,III, IV).**Sponsor:** Genta, Inc. **Contact:** Dr. Howard Fingert**Address:** Lexington, MA **Phone:** (781) 860-5149 **Fax:** (781) 860-5137**Status:** Designated **Designation Date:** 31-Jul-00 **Marketing Approval Date:****Generic Name:** Deslorelin **Trade Name:** Somagard**Orphan Indication:** Treatment of central precocious puberty.**Sponsor:** Roberts Pharmaceutical Corp. **Contact:** Mr. Richard Raffa**Address:** Eatontown, NJ **Phone:** (732) 389-1182 **Fax:** (732) 389-1014**Status:** Designated **Designation Date:** 05-Nov-87 **Marketing Approval Date:****Generic Name:** Desmopressin acetate
Trade Name:**Orphan Indication:** Treatment of mild hemophilia A and von Willebrand's disease.**Sponsor:** Aventis Behring L.L.C. **Contact:** Ms. Carol Marchione**Address:** King of Prussia, PA **Phone:** 6108784026 **Fax:****Status:** Designated/Approved **Designation Date:** 22-Jan-91 **Marketing Approval Date:** 07-Mar-94**Generic Name:** Dexamethasone
Trade Name:**Orphan Indication:** For use in posterior segment drug delivery system in the treatment of idiopathic intermediate uveitis.**Sponsor:** Oculex Pharmaceuticals, Inc. **Contact:** Ms. Jill Findlay**Address:** Sunnyvale, CA **Phone:** (408) 481-0424 **Fax:** (408) 481-0662**Status:** Designated **Designation Date:** 11-Sep-98 **Marketing Approval Date:****Generic Name:** Dexrazoxane **Trade Name:** Zinecard**Orphan Indication:** For the prevention of cardiomyopathy associated with doxorubicin administration.**Sponsor:** Pharmacia & Upjohn **Contact:** Mr. Robert Paarlberg**Address:** Kalamazoo, MI **Phone:** (616) 833-0646 **Fax:** (616) 833-8237**Status:** Designated/Approved **Designation Date:** 17-Dec-91 **Marketing Approval Date:** 26-May-95**Generic Name:** Dextran 70 **Trade Name:** Dehydrex**Orphan Indication:** Treatment of recurrent corneal erosion unresponsive to conventional therapy.**Sponsor:** Holles Laboratories, Inc. **Contact:** Mr. Peter Lelecas**Address:** Cohasset, MA **Phone:** (781) 383-0741 **Fax:** (781) 383-0005**Status:** Designated **Designation Date:** 05-Mar-90 **Marketing Approval Date:****Generic Name:** Dextran and deferoxamine **Trade Name:** Bio-Rescue**Orphan Indication:** Treatment of acute iron poisoning.**Sponsor:** Biomedical Frontiers, Inc. **Contact:** Dr. Bo Hedlund**Address:** Minneapolis, MN **Phone:** (612) 378-0228 **Fax:****Status:** Designated **Designation Date:** 08-Mar-91 **Marketing Approval Date:****Generic Name:** Dextran sulfate (inhaled, aerosolized) **Trade Name:** Uendex**Orphan Indication:** For use as an adjunct to the treatment of cystic fibrosis.**Sponsor:** Kennedy & Hoidal, M.D.'s **Contact:** Dr. John Hoidal**Address:** Salt Lake City, UT **Phone:** (801) 581-7806 **Fax:****Status:** Designated **Designation Date:** 05-Oct-90 **Marketing Approval Date:****Generic Name:** Dextran sulfate sodium
Trade Name:

Orphan Indication: Treatment of aquired immunodeficiency syndrome.
Sponsor: Ueno Fine Chemicals Industry, Ltd. **Contact:** Mr. Armond Welch
Address: Osaka 541, Japan, **Phone:** (202) 452-8666 **Fax:**
Status: Designated **Designation Date:** 19-Nov-87 **Marketing Approval Date:**

Generic Name: DHA-paclitaxel **Trade Name:** Taxoprexin

Orphan Indication: Treatment of pancreatic cancer
Sponsor: Protarga, Inc. **Contact:** Dr. Forrest Anthony
Address: King of Prussia, PA **Phone:** 6105924000 **Fax:** 6105924001
Status: Designated **Designation Date:** 25-Sep-01 **Marketing Approval Date:**

Generic Name: Dianeal peritoneal dialysis solution with 1.1% amino acids **Trade Name:** Nutrineal (Peritoneal Dialysis Solution with 1.1% Amino Acid)

Orphan Indication: For use as a nutritional supplement for the treatment of malnourishment in patients undergoing continuous ambulatory peritoneal dialysis.
Sponsor: Baxter Healthcare Corporation **Contact:** Dr. David Ross
Address: McGaw Park, IL **Phone:** (847) 473-6081 **Fax:**
Status: Designated **Designation Date:** 11-Jun-92 **Marketing Approval Date:**

Generic Name: Diazepam viscous solution for rectal administration
Trade Name:

Orphan Indication: 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.
Sponsor: Athena Neurosciences, Inc. **Contact:** Ms. Kathleen Dumas
Address: South San Francisco, CA **Phone:** (415) 877-0900 **Fax:** (415) 877-8370
Status: Designated/Approved **Designation Date:** 25-Feb-92 **Marketing Approval Date:** 29-Jul-97

Generic Name: Diaziquone
Trade Name:

Orphan Indication: Treatment of primary brain malignancies (grade III and IV astrocytomas).
Sponsor: Warner-Lambert Company **Contact:** Ms. Julia Meyer
Address: Ann Arbor, MI **Phone:** (313) 996-2838 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 10-Nov-83 **Marketing Approval Date:**

Generic Name: Dideoxyinosine
Trade Name:

Orphan Indication: Treatment of acquired immunodeficiency syndrome.
Sponsor: Bristol-Myers Squibb **Contact:**
Address: , **Phone:** **Fax:**
Status: Designated/Withdrawn **Designation Date:** 22-Jun-88 **Marketing Approval Date:**

Generic Name: Diethyldithiocarbamate **Trade Name:** Imuthiol

Orphan Indication: Treatment of AIDS.
Sponsor: Connaught Laboratories **Contact:** Dr. Pinya Cohen
Address: Swiftwater, PA **Phone:** (717) 839-4590 **Fax:**
Status: Designated/Approved **Designation Date:** 03-Apr-86 **Marketing Approval Date:**

Generic Name: digitoxin
Trade Name:

Orphan Indication: Treatment of soft tissue sarcomas
Sponsor: PrimeCyte, Inc. **Contact:** Dr. Irwin Braude
Address: Seattle, WA **Phone:** 2067281575 **Fax:** 2067280256
Status: Designated **Designation Date:** 18-Oct-01 **Marketing Approval Date:**

Generic Name: digitoxin
Trade Name:

Orphan Indication: Treatment of ovarian cancer
Sponsor: PrimeCyte, Inc. **Contact:** Dr. Irwin Braude
Address: Seattle, WA **Phone:** 2067281575 **Fax:** 2067280256
Status: Designated **Designation Date:** 02-Nov-01 **Marketing Approval Date:**

Generic Name: Digoxin immune FAB (Ovine) **Trade Name:** Digibind

Orphan Indication: Treatment of potentially life threatening digitalis intoxication in patients who are refractory to management by conventional therapy.

Sponsor: Glaxo Wellcome Inc. **Contact:** Dr. Michael Dalton

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Designated/Approved **Designation Date:** 01-Nov-84 **Marketing Approval Date:** 22-Apr-86

Generic Name: Digoxin immune fab(ovine) **Trade Name:** Digidote

Orphan Indication: Treatment of life-threatening acute cardiac glycoside intoxication manifested by conduction disorders, ectopic ventricular activity and (in some cases) hyperkalemia.

Sponsor: Boehringer Mannheim Corp. **Contact:** J. Richard Crout

Address: Rockville, MD **Phone:** (301) 360-6700 **Fax:**

Status: Designated **Designation Date:** 11-Mar-85 **Marketing Approval Date:**

Generic Name: Dihydrotestosterone **Trade Name:** Androgel -DHT

Orphan Indication: Treatment of weight loss in AIDS patients with HIV-associated wasting.

Sponsor: Unimed Pharmaceuticals, Inc. **Contact:** Dr. Margaret Hurley

Address: Deerfield, IL **Phone:** 9737011596 **Fax:** 9736359881

Status: Designated **Designation Date:** 05-Feb-96 **Marketing Approval Date:**

Generic Name: Dimethyl sulfoxide

Trade Name:

Orphan Indication: 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.

Sponsor: Pharma 21 **Contact:** Dr. Jack de la Torre

Address: La Jolla, CA **Phone:** (619) 822-3182 **Fax:** () -

Status: Designated **Designation Date:** 22-Nov-94 **Marketing Approval Date:**

Generic Name: Dimethyl sulfoxide

Trade Name:

Orphan Indication: Treatment of cutaneous manifestations of scleroderma.

Sponsor: Research Industries Corp. **Contact:**

Address: , **Phone:** Fax:

Status: Designated/Withdrawn **Designation Date:** 06-Jun-86 **Marketing Approval Date:**

Generic Name: Dimethylsulfoxide

Trade Name:

Orphan Indication: Treatment of palmar-plantar erythrodysesthesia syndrome.

Sponsor: Cancer Technologies, Inc. **Contact:** Mr. Tim Alberts

Address: Tucson, AZ **Phone:** (520) 296-8150 **Fax:** (520) 722-0312

Status: Designated **Designation Date:** 06-Apr-98 **Marketing Approval Date:**

Generic Name: Dimethylsulfoxide

Trade Name:

Orphan Indication: Topical treatment for the prevention of soft tissue injury following extravastion of cytotoxic drugs.

Sponsor: Cancer Technologies, Inc. **Contact:** Mr. Tim Alberts

Address: Tucson, AZ **Phone:** 5205716029 **Fax:** (520) 722-0312

Status: Designated **Designation Date:** 15-Apr-97 **Marketing Approval Date:**

Generic Name: Dipalmitoylphosphatidylcholine /phosphatidylglycerol **Trade Name:** ALEC

Orphan Indication: Prevention and treatment of neonatal respiratory distress syndrome.

Sponsor: Forum Products, Inc. **Contact:** Mr. Christopher Remkus

Address: Southampton, NY **Phone:** (516) 283-5980 **Fax:**

Status: Designated **Designation Date:** 28-Jul-88 **Marketing Approval Date:**

Generic Name: Disaccharide tripeptide glycerol dipalmitoyl **Trade Name:** Immther

Orphan Indication: Treatment of pulmonary and hepatic metastases in patients with colorectal adenocarcinoma.

Sponsor: ImmunoTherapeutics, Inc. **Contact:** Dr. Gerald Vosika

Address: Moorhead, MN **Phone:** (701) 239-3775 **Fax:**

Status: Designated **Designation Date:** 01-Mar-90 **Marketing Approval Date:**

Generic Name: Disodium clodronate
Trade Name:

Orphan Indication: Treatment of hypercalcemia of malignancy.
Sponsor: Discovery Experimental & Development, Inc. **Contact:** Mr. James Kimball
Address: Wesley Chapel, FL **Phone:** (813) 973-7200 **Fax:**
Status: Designated **Designation Date:** 16-Jun-93 **Marketing Approval Date:**

Generic Name: Disodium clodronate tetrahydrate **Trade Name:** Bonefos

Orphan Indication: Treatment of increased bone resorption due to malignancy.
Sponsor: Anthra Pharmaceuticals, Inc. **Contact:** Ms. Nabila Turjman
Address: Princeton, NJ **Phone:** 6095141060 **Fax:**
Status: Designated **Designation Date:** 05-Mar-90 **Marketing Approval Date:**

Generic Name: Disodium silibinin dihemisuccinate **Trade Name:** Legalon

Orphan Indication: Treatment of hepatic intoxication by Amanita phalloides (mushroom poisoning).
Sponsor: Pharmaquest Corporation **Contact:** Mr. Richard D'Agostino
Address: San Rafael, CA **Phone:** (415) 491-6460 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 10-Jul-86 **Marketing Approval Date:**

Generic Name: DMP 777
Trade Name:

Orphan Indication: Therapeutic management of patients with lung disease attributable to cystic fibrosis.
Sponsor: DuPont Pharmaceuticals Company **Contact:** Dr. Judith Hoglund
Address: Wilmington, DE **Phone:** (302) 992-3593 **Fax:** (302) 892-0712
Status: Designated **Designation Date:** 04-Jun-96 **Marketing Approval Date:**

Generic Name: DNA-lipid complex (DMRIE/DOPE)/plasmid vector (VCL-1102, Vical) expressing human interleukin-2 **Trade Name:** Leuvectin

Orphan Indication: Treatment of renal cell carcinoma.
Sponsor: Vical Incorporated **Contact:** Mr. Steven Kradjian
Address: San Diego, CA **Phone:** (858) 646-1117 **Fax:** (858) 646-1151
Status: Designated **Designation Date:** 28-Apr-00 **Marketing Approval Date:**

Generic Name: DNP-Modified autologous tumor vaccine **Trade Name:** O-Vax

Orphan Indication: Adjuvant therapy for the treatment of ovarian cancer
Sponsor: AVAX Technologies, Inc. **Contact:** Mr. Gary Knappenberger
Address: Kansas City, MO **Phone:** 8169601333 **Fax:** 8169604832
Status: Designated **Designation Date:** 21-Sep-00 **Marketing Approval Date:**

Generic Name: docosahexanoic acid-paclitaxel **Trade Name:** Taxoprexin

Orphan Indication: Treatment of hormone-refractory prostate cancer.
Sponsor: Protarga, Inc. **Contact:** Dr. Forrest Anthony
Address: Conshohocken, PA **Phone:** 6102604000 **Fax:** 6102606868
Status: Designated **Designation Date:** 05-Mar-01 **Marketing Approval Date:**

Generic Name: Dornase alfa **Trade Name:** Pulmozyme

Orphan Indication: To reduce mucous viscosity and enable the clearance of airway secretions in patients with cystic fibrosis.
Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane
Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000
Status: Designated/Approved **Designation Date:** 16-Jan-91 **Marketing Approval Date:** 30-Dec-93

Generic Name: Doxorubicin liposome **Trade Name:** Doxil

Orphan Indication: Treatment of ovarian cancer.
Sponsor: Alza Corporation **Contact:** Mr. Thomas Tarlow
Address: Mountain View, CA **Phone:** (650) 494-5000 **Fax:** (650) 321-2417
Status: Designated/Approved **Designation Date:** 04-Nov-98 **Marketing Approval Date:** 28-Jun-99

Generic Name: Dronabinol **Trade Name:** Marinol

Orphan Indication: For the stimulation of appetite and prevention of weight loss in patients with a confirmed diagnosis of AIDS.

Sponsor: Unimed Pharmaceuticals, Inc. **Contact:** Dr. Margaret Hurley
Address: Buffalo Grove, IL **Phone:** 9737011596 **Fax:** 9736359881
Status: Designated/Approved **Designation Date:** 15-Jan-91 **Marketing Approval Date:** 22-Dec-92

Generic Name: Duramycin
Trade Name:

Orphan Indication: Treatment of cystic fibrosis.
Sponsor: MoliChem Medicines Inc. **Contact:** Dr. Luis Molina
Address: Chapel Hill, NC **Phone:** (919) 967-9704 **Fax:**
Status: Designated **Designation Date:** 11-Dec-97 **Marketing Approval Date:**

Generic Name: Dynamine
Trade Name:

Orphan Indication: Treatment of Lambert Eaton myasthenic syndrome.
Sponsor: Mayo Foundation **Contact:** Dr. Anthony Windebank
Address: Rochester, MN **Phone:** (507) 284-2511 **Fax:**
Status: Designated **Designation Date:** 05-Feb-90 **Marketing Approval Date:**

Generic Name: Dynamine
Trade Name:

Orphan Indication: Treatment of hereditary motor and sensory neuropathy type I (Charcot-Marie-Tooth disease).
Sponsor: Mayo Foundation **Contact:** Dr. Anthony Windebank
Address: Rochester, MN **Phone:** (507) 284-2511 **Fax:**
Status: Designated **Designation Date:** 16-Oct-91 **Marketing Approval Date:**

Generic Name: Eflornithine HCl **Trade Name:** Ornidyl

Orphan Indication: Treatment of Pneumocystis carinii pneumonia in AIDS patients.
Sponsor: Marion Merrell Dow, Inc. **Contact:** Gillian Ivers-read
Address: Kansas City, MO **Phone:** (816) 966-5000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 18-Apr-86 **Marketing Approval Date:**

Generic Name: Eflornithine HCl **Trade Name:** Ornidyl

Orphan Indication: Treatment of Trypanosoma brucei gambiense infection (sleeping sickness).
Sponsor: Hoechst Marion Roussel **Contact:** Dr. Jack Dunn
Address: Kansas City, MO **Phone:** (816) 966-5000 **Fax:**
Status: Designated/Approved **Designation Date:** 23-Apr-86 **Marketing Approval Date:** 28-Nov-90

Generic Name: Elcatonin
Trade Name:

Orphan Indication: Intrathecal treatment of intractable pain.
Sponsor: Innapharma, Inc. **Contact:** Dr. Mary Lou Zett
Address: Upper Saddle River, NJ **Phone:** (201) 818-1160 **Fax:** (201) 818-3388
Status: Designated **Designation Date:** 25-Sep-95 **Marketing Approval Date:**

Generic Name: Enadoline hydrochloride
Trade Name:

Orphan Indication: Treatment of severe head injury.
Sponsor: Warner-Lambert Company **Contact:** Ms. Margaret Uprichard
Address: Ann Arbor, MI **Phone:** (313) 996-7000 **Fax:** (313) 998-3283
Status: Designated **Designation Date:** 28-Jan-97 **Marketing Approval Date:**

Generic Name: Encapsulated porcine islet preparation **Trade Name:** BetaRx

Orphan Indication: Treatment of type I diabetic patients who are already on immunosuppression.
Sponsor: VivoRx **Contact:** Ms. Marcia Schmehl
Address: Santa Monica, CA **Phone:** (310) 264-7768 **Fax:** (310) 453-5409
Status: Designated **Designation Date:** 05-Jul-95 **Marketing Approval Date:**

Generic Name: Enisoprost
Trade Name:

Orphan Indication: For use with cyclosporine in organ transplant recipients to reduce acute transplant rejection.

Sponsor: G.D. Searle & Company **Contact:** Dr. Stacy Suberg

Address: Skokie, IL **Phone:** (708) 982-8164 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 20-Oct-89 **Marketing Approval Date:**

Generic Name: Enisoprost

Trade Name:

Orphan Indication: For use in organ transplant patients to diminish the nephrotoxicity induced by cyclosporine.

Sponsor: G.D. Searle & Company **Contact:** Dr. Stacy Suberg

Address: Skokie, IL **Phone:** (708) 982-8164 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 20-Oct-89 **Marketing Approval Date:**

Generic Name: Epidermal growth factor (human)

Trade Name:

Orphan Indication: For promotion of cutaneous wound healing in extreme burn treatment protocols.

Sponsor: Ethicon, Inc. **Contact:** Jacqueline Coelln

Address: Somerville, NJ **Phone:** (908) 253-6162 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 06-Mar-85 **Marketing Approval Date:**

Generic Name: Epidermal growth factor (human)

Trade Name:

Orphan Indication: For acceleration of corneal epithelial regeneration and the healing of stromal tissue in the condition of non-healing corneal defects.

Sponsor: Chiron Vision **Contact:** Mr. Mark Stavro

Address: Claremont, CA **Phone:** (909) 399-1343 **Fax:**

Status: Designated **Designation Date:** 05-Oct-87 **Marketing Approval Date:**

Generic Name: Epirubicin **Trade Name:** Ellence

Orphan Indication: Treatment of breast cancer.

Sponsor: Pharmacia & Upjohn Company **Contact:** Ms. Denise Tindle

Address: Kalamazoo, MI **Phone:** (616) 833-3825 **Fax:** (616) 833-8237

Status: Designated/Approved **Designation Date:** 14-Sep-99 **Marketing Approval Date:** 15-Sep-99

Generic Name: Epoetin alfa **Trade Name:** Epogen

Orphan Indication: Treatment of anemia associated with end stage renal disease.

Sponsor: Amgen, Inc. **Contact:** Mr. Ralph Smalling

Address: Thousand Oaks, CA **Phone:** (805) 447-1000 **Fax:** (805) 499-8670

Status: Designated/Approved **Designation Date:** 10-Apr-86 **Marketing Approval Date:** 01-Jun-89

Generic Name: Epoetin alfa

Trade Name:

Orphan Indication: Treatment of myelodysplastic syndrome.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Ms. Alysia Baldwin-Ferro

Address: Raritan, NJ **Phone:** (908) 704-4966 **Fax:**

Status: Designated **Designation Date:** 20-Dec-93 **Marketing Approval Date:**

Generic Name: Epoetin alfa **Trade Name:** Epogen

Orphan Indication: Treatment of anemia associated with HIV infection or HIV treatment.

Sponsor: Amgen, Inc. **Contact:** Mr. Ralph Smalling

Address: Thousand Oaks, CA **Phone:** (805) 447-1000 **Fax:** (805) 499-8670

Status: Designated/Approved **Designation Date:** 01-Jul-91 **Marketing Approval Date:** 31-Dec-90

Generic Name: Epoetin alpha **Trade Name:** Procrit

Orphan Indication: Treatment of anemia of prematurity in preterm infants.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Ms. Carmella Pascale

Address: Raritan, NJ **Phone:** (908) 704-4595 **Fax:**

Status: Designated **Designation Date:** 21-Jul-88 **Marketing Approval Date:**

Generic Name: Epoetin alpha **Trade Name:** Procrit

Orphan Indication: Treatment of HIV associated anemia related to HIV infection or HIV treatment.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Ms. Jean O'Connor

Address: Raritan, NJ **Phone:** (908) 704-5121 **Fax:**

Status: Designated **Designation Date:** 07-Mar-89 **Marketing Approval Date:**

Generic Name: Epoetin alpha **Trade Name:** Procrit

Orphan Indication: Treatment of anemia associated with end stage renal disease.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Dr. Linda Dujack

Address: Raritan, NJ **Phone:** (908) 704-5057 **Fax:**

Status: Designated **Designation Date:** 27-Aug-87 **Marketing Approval Date:**

Generic Name: Epoetin beta **Trade Name:** Marogen

Orphan Indication: Treatment of anemia associated with end stage renal disease.

Sponsor: Chugai-USA, Inc. **Contact:** Mr. Joseph Sobota

Address: Waukegan, IL **Phone:** (708) 244-6025 **Fax:**

Status: Designated **Designation Date:** 22-Oct-87 **Marketing Approval Date:**

Generic Name: Epoprostenol **Trade Name:** Flolan

Orphan Indication: Replacement of heparin in patients requiring hemodialysis and who are at increased risk of hemorrhage.

Sponsor: Glaxo Wellcome Inc. **Contact:** Dr. Elizabeth Nies

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 29-Mar-84 **Marketing Approval Date:**

Generic Name: Epoprostenol **Trade Name:** Flolan

Orphan Indication: Treatment of primary pulmonary hypertension.

Sponsor: Glaxo Wellcome Inc. **Contact:** Mr. Roger Gaby

Address: Research Triangle Park, NC **Phone:** (919) 483-9035 **Fax:** (919) 315-0033

Status: Designated/Approved **Designation Date:** 25-Sep-85 **Marketing Approval Date:** 20-Sep-95

Generic Name: Epoprostenol **Trade Name:** Cycloprostin

Orphan Indication: Replacement of heparin in patients requiring hemodialysis and who are at increased risk of hemorrhage.

Sponsor: Upjohn Company **Contact:** Dr. J.R. Ishler

Address: Kalamazoo, MI **Phone:** (616) 329-8216 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 29-Oct-84 **Marketing Approval Date:**

Generic Name: Epoprostenol **Trade Name:** Flolan

Orphan Indication: Treatment of secondary pulmonary hypertension due to intrinsic precapillary pulmonary vascular disease.

Sponsor: GlaxoSmithKline **Contact:** Mr. Roger Gaby

Address: Research Triangle Park, NC **Phone:** (919) 483-9035 **Fax:**

Status: Designated/Approved **Designation Date:** 22-Mar-99 **Marketing Approval Date:** 14-Apr-00

Generic Name: Erwinia L-asparaginase

Trade Name:

Orphan Indication: For use as an alternative to E. coli asparaginase in those situations where repeat courses of asparaginase therapy for acute lymphoblastic leukemia are required or where allergic reactions force the discontinuance of the E. coli preparation.

Sponsor: Lyphomed, Inc. **Contact:**

Address: , **Phone:** **Fax:**

Status: Designated/Withdrawn **Designation Date:** 25-Jan-85 **Marketing Approval Date:**

Generic Name: Erwinia L-asparaginase **Trade Name:** Erwinase

Orphan Indication: Treatment of acute lymphocytic leukemia.

Sponsor: Porton International, Inc. **Contact:** Dr. Jill Hillier

Address: Spotsylvania, VA **Phone:** 5084780144 **Fax:** 5084733531

Status: Designated **Designation Date:** 30-Jul-86 **Marketing Approval Date:**

Generic Name: Erythropoietin (human, recombinant)

Trade Name:

Orphan Indication: Treatment of anemia associated with end stage renal disease.

Sponsor: Organon Teknika Corporation **Contact:**

Address: , **Phone:** Fax:

Status: Designated/Withdrawn **Designation Date:** 19-Nov-87 **Marketing Approval Date:**

Generic Name: Erythropoietin (recombinant human)

Trade Name:

Orphan Indication: Treatment of anemia associated with end stage renal disease.

Sponsor: McDonnell Douglas Corp **Contact:** Mr. Norbert Burlis

Address: St. Louis, MO **Phone:** (314) 233-2203 **Fax:**

Status: Designated **Designation Date:** 19-Aug-87 **Marketing Approval Date:**

Generic Name: Etanercept **Trade Name:** Enbrel

Orphan Indication: 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.

Sponsor: Immunex Corporation **Contact:** Ms. Sally Gould

Address: Seattle, WA **Phone:** (206) 389-4097 **Fax:**

Status: Designated/Approved **Designation Date:** 27-Oct-98 **Marketing Approval Date:** 27-May-99

Generic Name: Etanercept **Trade Name:** Enbrel

Orphan Indication: Treatment of Wegener's granulomatosis.

Sponsor: Immunex Corporation **Contact:** Ms. Sally Gould

Address: Seattle, WA **Phone:** (206) 389-4097 **Fax:**

Status: Designated **Designation Date:** 06-Apr-99 **Marketing Approval Date:**

Generic Name: Ethanolamine oleate **Trade Name:** Ethamolol

Orphan Indication: Treatment of patients with esophageal varices that have recently bled, to prevent rebleeding.

Sponsor: Block Drug Company, Inc. **Contact:** Dr. Richard Bourne

Address: Jersey City, NJ **Phone:** (201) 434-3000 **Fax:**

Status: Designated/Approved **Designation Date:** 22-Mar-84 **Marketing Approval Date:** 22-Dec-88

Generic Name: Ethinyl Estradiol, USP

Trade Name:

Orphan Indication: Treatment of Turner's syndrome.

Sponsor: Bio-Technology General Corp. **Contact:** Ms. Briti Kundu

Address: Iselin, NJ **Phone:** (732) 632-8800 **Fax:** (732) 632-8844

Status: Designated/Withdrawn **Designation Date:** 22-Jun-88 **Marketing Approval Date:**

Generic Name: Ethiofos

Trade Name:

Orphan Indication: Use as a chemoprotective agent for cisplatin and cyclophosphamide in the treatment of ovarian cancer.

Sponsor: U.S. Bioscience **Contact:**

Address: , **Phone:** Fax:

Status: Designated/Withdrawn **Designation Date:** 01-Aug-89 **Marketing Approval Date:**

Generic Name: Ethyl eicosapentaenoate

Trade Name:

Orphan Indication: Treatment of Huntington's disease.

Sponsor: Laxdale Ltd. **Contact:** Mr. Frank Sasinowski

Address: United Kingdom, UK **Phone:** (202) 737-5600 **Fax:** (202) 737-9329

Status: Designated **Designation Date:** 06-Apr-00 **Marketing Approval Date:**

Generic Name: Etidronate disodium **Trade Name:** Didronel IV Infusion

Orphan Indication: Treatment of degenerative metabolic bone disease occurring in patients who require long term (6 months or greater) total parenteral nutrition.

Sponsor: MGI Pharma, Inc. **Contact:** Dr. Jo Gustafson

Address: Bloomington, MN **Phone:** (612) 346-4722 **Fax:** (612) 346-4800

Status: Designated/Withdrawn **Designation Date:** 02-May-91 **Marketing Approval Date:**

Generic Name: Etidronate disodium **Trade Name:** Didronel

Orphan Indication: Treatment of hypercalcemia of malignancy inadequately managed by dietary modification and/or oral hydration.

Sponsor: MGI Pharma, Inc. **Contact:** Dr. Jo Gustafson

Address: Bloomington, MN **Phone:** (612) 346-4722 **Fax:** (612) 346-4800

Status: Designated/Approved **Designation Date:** 21-Mar-86 **Marketing Approval Date:** 21-Apr-87

Generic Name: Etidronate disodium **Trade Name:** Didronel IV infusion

Orphan Indication: Prevention of degenerative metabolic bone disease occurring in patients who require long term (6 months or greater) total parenteral nutrition.

Sponsor: MGI Pharma, Inc. **Contact:** Dr. Jo Gustafson

Address: Bloomington, MN **Phone:** (612) 346-4722 **Fax:** (612) 346-4800

Status: Designated/Withdrawn **Designation Date:** 02-May-91 **Marketing Approval Date:**

Generic Name: Etiocholanedione
Trade Name:

Orphan Indication: Treatment of aplastic anemia.

Sponsor: SuperGen, Inc. **Contact:** Dr. Sam Boddapati

Address: San Ramon, CA **Phone:** (510) 327-0200 **Fax:** (510) 327-7347

Status: Designated **Designation Date:** 03-Nov-95 **Marketing Approval Date:**

Generic Name: Etiocholanedione
Trade Name:

Orphan Indication: Treatment of Prader-Willi syndrome.

Sponsor: SuperGen, Inc. **Contact:** Dr. Sam Boddapati

Address: San Ramon, CA **Phone:** (510) 327-0200 **Fax:** (510) 327-7347

Status: Designated **Designation Date:** 07-May-96 **Marketing Approval Date:**

Generic Name: Exemestane **Trade Name:** Aromasin

Orphan Indication: Treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.

Sponsor: Pharmacia & Upjohn **Contact:** Ms. Cecilia Blomqvist

Address: Kalamazoo, MI **Phone:** (616) 833-0774 **Fax:** (616) 833-8237

Status: Designated/Approved **Designation Date:** 19-Sep-91 **Marketing Approval Date:** 21-Oct-99

Generic Name: Exisulind
Trade Name:

Orphan Indication: For the suppression and control of colonic adenomatous polyps in the inherited disease adenomatous polyposis coli.

Sponsor: Cell Pathways, Inc. **Contact:** Ms. Katherine Tsokas

Address: Horsham, PA **Phone:** (215) 706-3827 **Fax:** (215) 706-3801

Status: Designated **Designation Date:** 14-Feb-94 **Marketing Approval Date:**

Generic Name: Factor XIII concentrate (human) pasteurized **Trade Name:** Fibrogammin P

Orphan Indication: Treatment of congenital factor XIII deficiency.

Sponsor: Aventis Behring L.L.C. **Contact:** Mr. Victor Paulus

Address: King of Prussia, PA **Phone:** (610) 878-4052 **Fax:** (610) 878-4009

Status: Designated **Designation Date:** 16-Jan-85 **Marketing Approval Date:**

Generic Name: Factor XIII, recombinant
Trade Name:

Orphan Indication: Treatment of congenital factor XIII deficiency.

Sponsor: Zymogenetics, Inc. **Contact:** Alan Upshall

Address: Seattle, WA **Phone:** (206) 547-8080 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 22-Apr-93 **Marketing Approval Date:**

Generic Name: Fampridine **Trade Name:** Neurelan

Orphan Indication: Relief of symptoms of multiple sclerosis.

Sponsor: Acorda Therapeutics **Contact:** Ms. Veronica Mallon

Address: Hawthorne, NY **Phone:** (914) 347-4300 **Fax:** (914) 347-4560

Status: Designated **Designation Date:** 02-Jun-87 **Marketing Approval Date:**

Generic Name: Fampridine **Trade Name:** Neurelan**Orphan Indication:** Treatment of chronic, incomplete spinal cord injury.**Sponsor:** Acorda Therapeutics, Inc. **Contact:** Ms. Veronica Mallon**Address:** Hawthorne, NY **Phone:** (914) 347-4300 **Fax:** (914) 347-4560**Status:** Designated **Designation Date:** 02-Jun-97 **Marketing Approval Date:****Generic Name:** Felbamate **Trade Name:** Felbatol**Orphan Indication:** Treatment of Lennox-Gastaut syndrome.**Sponsor:** Wallace Laboratories **Contact:** Dr. Monroe Klein**Address:** Princeton, NJ **Phone:** (609) 951-2079 **Fax:****Status:** Designated/Approved **Designation Date:** 24-Jan-89 **Marketing Approval Date:** 29-Jul-93**Generic Name:** FIAU

Trade Name:

Orphan Indication: Adjunctive treatment of chronic active hepatitis B.**Sponsor:** Oclassen Pharmaceuticals, Inc. **Contact:** Mr. Ross Dileo**Address:** San Rafael, CA **Phone:** (415) 258-4556 **Fax:** (415) 258-4550**Status:** Designated **Designation Date:** 24-Jul-92 **Marketing Approval Date:****Generic Name:** Fibrinogen (human)

Trade Name:

Orphan Indication: For the control of bleeding and prophylactic treatment of patients deficient in fibrinogen.**Sponsor:** Alpha Therapeutic Corporation **Contact:** Ms. M. Sue Preston**Address:** Los Angeles, CA **Phone:** (213) 225-2221 **Fax:****Status:** Designated **Designation Date:** 23-Aug-95 **Marketing Approval Date:****Generic Name:** Fibronectin (human plasma derived)

Trade Name:

Orphan Indication: Treatment of non-healing corneal ulcers or epithelial defects which have been unresponsive to conventional therapy and the underlying cause has been eliminated.**Sponsor:** Melville Biologics, Inc. **Contact:** Dr. Joan Pehta**Address:** New York, NY **Phone:** (212) 570-3255 **Fax:** (212) 879-5922**Status:** Designated **Designation Date:** 05-Sep-88 **Marketing Approval Date:****Generic Name:** Fibronectin (plasma derived)

Trade Name:

Orphan Indication: Treatment of non-healing corneal ulcers or epithelial defects which are unresponsive to conventional therapy and for which any infectious cause of the defect has been eliminated.**Sponsor:** Chiron Vision **Contact:** Judy Gordon**Address:** Irvine, CA **Phone:** (714) 768-4690 **Fax:****Status:** Designated/Withdrawn **Designation Date:** 05-Dec-88 **Marketing Approval Date:****Generic Name:** Filgrastim **Trade Name:** Neupogen**Orphan Indication:** For use in the mobilization of peripheral blood progenitor cells for collection in patients who will receive myeloablative or myelosuppressive chemotherapy.**Sponsor:** Amgen, Inc. **Contact:** Mr. Ralph Smalling**Address:** Thousand Oaks, CA **Phone:** (805) 447-1000 **Fax:** (805) 499-8670**Status:** Designated/Approved **Designation Date:** 17-Jul-95 **Marketing Approval Date:** 28-Dec-95**Generic Name:** Filgrastim **Trade Name:** Neupogen**Orphan Indication:** Treatment of myelodysplastic syndrome.**Sponsor:** Amgen, Inc. **Contact:** Mr. Ralph Smalling**Address:** Thousand Oaks, CA **Phone:** (805) 447-1000 **Fax:** (805) 499-8670**Status:** Designated/Withdrawn **Designation Date:** 30-Aug-90 **Marketing Approval Date:****Generic Name:** Filgrastim **Trade Name:** Neupogen**Orphan Indication:** Treatment of patients with AIDS who, in addition, are afflicted with cytomegalovirus retinitis and are being treated with ganciclovir.**Sponsor:** Amgen, Inc. **Contact:** Mr. Jeff Fellows**Address:** Thousand Oaks, CA **Phone:** (805) 447-8972 **Fax:** (805) 499-8670**Status:** Designated **Designation Date:** 03-Sep-91 **Marketing Approval Date:**

Generic Name: Filgrastim **Trade Name:** Neupogen**Orphan Indication:** Treatment of patients with severe chronic neutropenia (absolute neutrophil count less than 500/mm³).**Sponsor:** Amgen, Inc. **Contact:** Mr. Ralph Smalling**Address:** Thousand Oaks, CA **Phone:** (805) 447-1000 **Fax:** (805) 499-8670**Status:** Designated/Approved **Designation Date:** 07-Nov-90 **Marketing Approval Date:** 19-Dec-94**Generic Name:** Filgrastim **Trade Name:** Neupogen**Orphan Indication:** Reduction in the duration of neutropenia, fever, antibiotic use, and hospitalization, following induction and consolidation treatment for acute myeloid leukemia.**Sponsor:** Amgen, Inc. **Contact:** Mr. Jeff Fellows**Address:** Thousand Oaks, CA **Phone:** (805) 447-8972 **Fax:** (805) 498-9377**Status:** Designated/Approved **Designation Date:** 07-Nov-96 **Marketing Approval Date:** 02-Apr-98**Generic Name:** Filgrastim **Trade Name:** Neupogen**Orphan Indication:** Treatment of neutropenia associated with bone marrow transplants.**Sponsor:** Amgen, Inc. **Contact:** Mr. Ralph Smalling**Address:** Thousand Oaks, CA **Phone:** (805) 447-1000 **Fax:** (805) 499-8670**Status:** Designated/Approved **Designation Date:** 01-Oct-90 **Marketing Approval Date:** 15-Jun-94**Generic Name:** Flucinolone

Trade Name:

Orphan Indication: Treatment uveitis involving the posterior segment of the eye.**Sponsor:** Bausch & Lomb Pharmaceuticals, Inc. **Contact:** Mr. Samuel Bohannon**Address:** Tampa, FL **Phone:** (813) 975-7700 **Fax:** (813) 975-7757**Status:** Designated **Designation Date:** 31-Jul-00 **Marketing Approval Date:****Generic Name:** Fludarabine phosphate **Trade Name:** Fludara**Orphan Indication:** Treatment and management of patients with non-Hodgkins lymphoma.**Sponsor:** Berlex Laboratories, Inc. **Contact:** Mr. Anthony Bourdakis**Address:** Richmond, CA **Phone:** (510) 669-4469 **Fax:** (510) 669-4190**Status:** Designated **Designation Date:** 18-Apr-89 **Marketing Approval Date:****Generic Name:** Fludarabine phosphate **Trade Name:** Fludara**Orphan Indication:** Treatment of chronic lymphocytic leukemia (CLL), including refractory CLL.**Sponsor:** Berlex Laboratories, Inc. **Contact:** Mr. Anthony Bourdakis**Address:** Richmond, CA **Phone:** (510) 262-5000 **Fax:** (510) 262-7053**Status:** Designated/Approved **Designation Date:** 18-Apr-89 **Marketing Approval Date:** 18-Apr-91**Generic Name:** Flumecinol **Trade Name:** Zixoryn**Orphan Indication:** Treatment of hyperbilirubinemia in newborn infants unresponsive to phototherapy.**Sponsor:** Farmacon, Inc. **Contact:** Dr. Laszlo Darko**Address:** Westport, CT **Phone:** (203) 255-8898 **Fax:** (203) 255-3888**Status:** Designated/Withdrawn **Designation Date:** 15-Jan-85 **Marketing Approval Date:****Generic Name:** Flunarizine **Trade Name:** Sibelium**Orphan Indication:** Treatment of alternating hemiplegia.**Sponsor:** Janssen Research Foundation **Contact:** Ms. Ruth Wasserman**Address:** Titusville, NJ **Phone:** (609) 730-2000 **Fax:****Status:** Designated **Designation Date:** 06-Jan-86 **Marketing Approval Date:****Generic Name:** Fluorouracil

Trade Name:

Orphan Indication: For use in combination with interferon alpha-2a, recombinant, for the treatment of advanced colorectal carcinoma.**Sponsor:** Hoffmann-La Roche, Inc. **Contact:** Ms. Deborah Savuto**Address:** Nutley, NJ **Phone:** (973) 562-3705 **Fax:** (973) 562-3700**Status:** Designated **Designation Date:** 18-Apr-90 **Marketing Approval Date:****Generic Name:** Fluorouracil **Trade Name:** Adrucil

Orphan Indication: For use in combination with leucovorin for therapy of metastatic adenocarcinoma of the colon and rectum.

Sponsor: Lederle Laboratories **Contact:** Dr. Vern DeVries

Address: Pearl River, NY **Phone:** (914) 732-5000 **Fax:**

Status: Designated **Designation Date:** 06-Feb-89 **Marketing Approval Date:**

Generic Name: Fluorouracil

Trade Name:

Orphan Indication: Treatment of glioblastoma multiforme.

Sponsor: Ethypharm SA **Contact:** Dr. J. Kay Noel

Address: France, FR **Phone:** (510) 525-4250 **Fax:** (510) 528-0374

Status: Designated **Designation Date:** 29-Jun-00 **Marketing Approval Date:**

Generic Name: Fluorouracil

Trade Name:

Orphan Indication: For use in combination with interferon alpha-2a, recombinant, for the treatment of esophageal carcinoma.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Deborah Savuto

Address: Nutley, NJ **Phone:** (973) 562-3705 **Fax:** (973) 562-3700

Status: Designated **Designation Date:** 27-Oct-89 **Marketing Approval Date:**

Generic Name: Fluoxetine **Trade Name:** Prozac

Orphan Indication: Treatment of autism.

Sponsor: Hollander, MD, Eric **Contact:** Dr. Eric Hollander

Address: New York, NY **Phone:** (212) 241-3623 **Fax:**

Status: Designated **Designation Date:** 30-Apr-99 **Marketing Approval Date:**

Generic Name: Follitropin alfa, recombinant **Trade Name:** Gonal-F

Orphan Indication: For the initiation and re-initiation of spermatogenesis in adult males with reproductive failure due to hypothalamic or pituitary dysfunction, hypogonadotropic hypogonadism.

AMENDED indication 6/27/00: For the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

Sponsor: Serono Laboratories, Inc. **Contact:** Ms. Pamela Williamson Joyce

Address: Norwell, MA **Phone:** 7816812298 **Fax:** (781) 871-6754

Status: Designated/Approved **Designation Date:** 21-Dec-98 **Marketing Approval Date:** 24-May-00

Generic Name: Fomepizole **Trade Name:** Antizole

Orphan Indication: Treatment of methanol or ethylene glycol poisoning.

Sponsor: Orphan Medical, Inc. **Contact:** Ms. Carol Curme

Address: Minnetonka, MN **Phone:** 9525136974 **Fax:** 9525419209

Status: Designated/Approved **Designation Date:** 22-Dec-88 **Marketing Approval Date:** 08-Dec-00

Generic Name: Fomepizole **Trade Name:** Antizole

Orphan Indication: Treatment of methanol or ethylene glycol poisoning.

Sponsor: Orphan Medical, Inc. **Contact:** Ms. Carol Curme

Address: Minnetonka, MN **Phone:** 9525136974 **Fax:** 9525419209

Status: Designated/Approved **Designation Date:** 22-Dec-88 **Marketing Approval Date:** 04-Dec-97

Generic Name: Fosphenytoin **Trade Name:** Cerebyx

Orphan Indication: For the acute treatment of patients with status epilepticus of the grand mal type.

Sponsor: Warner-Lambert Company **Contact:** Ms. Janeth Turner

Address: Ann Arbor, MI **Phone:** (313) 996-7000 **Fax:** (313) 998-3283

Status: Designated/Approved **Designation Date:** 04-Jun-91 **Marketing Approval Date:** 05-Aug-96

Generic Name: Fructose-1,6-diphosphate **Trade Name:** Cordox

Orphan Indication: Treatment of painful vaso-occlusive episodes associated with sickle cell disease.

Sponsor: Questcor Pharmaceuticals, Inc. **Contact:** Mr. Charles Casamento

Address: Union City, CA **Phone:** 5107000700 **Fax:** 5104000799

Status: Designated **Designation Date:** 29-May-98 **Marketing Approval Date:**

Generic Name: Gabapentin **Trade Name:** Neurontin**Orphan Indication:** Treatment of amyotrophic lateral sclerosis.**Sponsor:** Warner-Lambert Company **Contact:** Ms. Janeth Turner**Address:** Ann Arbor, MI **Phone:** (734) 622-7426 **Fax:** (313) 998-3283**Status:** Designated **Designation Date:** 05-Jul-95 **Marketing Approval Date:****Generic Name:** Gallium nitrate injection **Trade Name:** Ganite**Orphan Indication:** Treatment of hypercalcemia of malignancy.**Sponsor:** Solopak Pharmaceutical Co. **Contact:** Mr. Jeffrey Ferguson**Address:** Elk Grove Village, IL **Phone:** (847) 806-0080 **Fax:****Status:** Designated/Approved/With **Designation Date:** 05-Dec-88 **Marketing Approval Date:** 17-Jan-91
drawn**Generic Name:** Gamma hydroxybutyrate

Trade Name:

Orphan Indication: Treatment of narcolepsy and the auxiliary symptoms of cataplexy, sleep paralysis, hypnagogic hallucinations and automatic behavior.**Sponsor:** Biocraft Laboratories, Inc. **Contact:** Ms. Debbie Parker**Address:** Fair Lawn, NJ **Phone:** (201) 703-0400 **Fax:****Status:** Designated **Designation Date:** 03-Dec-87 **Marketing Approval Date:****Generic Name:** Gamma-hydroxybutyric acid

Trade Name:

Orphan Indication: Treatment of narcolepsy and the auxiliary symptoms of cataplexy, sleep paralysis, hypnagogic hallucinations, and automatic behavior.**Sponsor:** Sigma Chemical Company **Contact:****Address:** , **Phone:** **Fax:****Status:** Designated/Withdrawn **Designation Date:** 22-Jan-85 **Marketing Approval Date:****Generic Name:** Gammalinolenic acid

Trade Name:

Orphan Indication: Treatment of juvenile rheumatoid arthritis.**Sponsor:** Zurier, Robert B. M.D. **Contact:** Dr. Robert Zurier**Address:** Worcester, MA **Phone:** (508) 856-6246 **Fax:****Status:** Designated **Designation Date:** 27-Jul-94 **Marketing Approval Date:****Generic Name:** Ganaxolone

Trade Name:

Orphan Indication: Treatment of infantile spasms.**Sponsor:** Purdue Pharma L.P. **Contact:** Mr. Michael Harlow**Address:** Norwalk, CT **Phone:** (203) 854-7561 **Fax:** (203) 851-5229**Status:** Designated **Designation Date:** 25-May-94 **Marketing Approval Date:****Generic Name:** Ganciclovir intravitreal implant **Trade Name:** Vitrasert Implant**Orphan Indication:** Treatment of cytomegalovirus retinitis.**Sponsor:** Bausch & Lomb Surgical, Chiron Vision Products **Contact:** Dr. Judy Gordon**Address:** Irvine, CA **Phone:** (714) 768-4690 **Fax:** (714) 468-4882**Status:** Designated/Approved **Designation Date:** 07-Jun-95 **Marketing Approval Date:** 04-Mar-96**Generic Name:** Ganciclovir sodium **Trade Name:** Cytovene**Orphan Indication:** Treatment of cytomegalovirus retinitis in immunocompromised patients with AIDS.**Sponsor:** Syntex (USA), Inc. **Contact:** Michael Perry**Address:** Palo Alto, CA **Phone:** (415) 354-7453 **Fax:****Status:** Designated/Approved/With **Designation Date:** 31-Oct-85 **Marketing Approval Date:** 23-Jun-89
drawn**Generic Name:** Gancyclovir

Trade Name:

Orphan Indication: Treatment of severe human cytomegalovirus infections in specific immunosuppressed patient populations.**Sponsor:** Burroughs Wellcome Company **Contact:****Address:** , **Phone:** **Fax:****Status:** Designated/Withdrawn **Designation Date:** 07-Jun-85 **Marketing Approval Date:**

Generic Name: Gangliosides as sodium salts	Trade Name: Cronassial
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Orphan Indication: Treatment of retinitis pigmentosa.

Sponsor: Fidia Pharmaceutical Corp. **Contact:** Jeanne Wadsworth

Address: Washington, DC **Phone:** (202) 371-9898 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 17-Nov-88 **Marketing Approval Date:**

Generic Name: Gavilimomab
Trade Name:

Orphan Indication: Acute graft-versus-host disease (aGVHD)

Sponsor: Abgenix, Inc. **Contact:** Mr. Lionel Boudrel

Address: Fremont, CA **Phone:** 5106086500 **Fax:** 5106086511

Status: Designated **Designation Date:** 20-Nov-00 **Marketing Approval Date:**

Generic Name: Gemtuzumab zogamicin	Trade Name: Mylotarg
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Orphan Indication: Treatment of CD33-positive acute myeloid leukemia.

Sponsor: Wyeth-Ayerst Laboratories **Contact:** Mr. Barry Sickels

Address: Philadelphia, PA **Phone:** (610) 902-3742 **Fax:** (610) 964-5973

Status: Designated/Approved **Designation Date:** 24-Nov-99 **Marketing Approval Date:** 17-May-00

Generic Name: Gene plasmid hVEGF165 driven by human cytomegalovirus, and [2,3-bis(oleoyl)propyl]trimethyl ammonium and dioleoyl phosphatidyl	Trade Name: Trinam
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Orphan Indication: Prevention of complications due to neointimal hyperplasia disease in certain vascular anastomoses.

Sponsor: Ark Therapeutics Ltd. **Contact:** Dr. James Parker

Address: London W1P 5DJ, UK **Phone:** (978) 897-5613 **Fax:** (978) 461-0333

Status: Designated **Designation Date:** 24-Oct-00 **Marketing Approval Date:**

Generic Name: Gentamicin impregnated PMMA beads on surgical wire	Trade Name: Septopal
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Orphan Indication: Treatment of chronic osteomyelitis of post-traumatic, postoperative, or hematogenous origin.

Sponsor: Lipha Pharmaceuticals, Inc. **Contact:** Mr. Bruce Goddard

Address: New York, NY **Phone:** (212) 223-1280 **Fax:** (212) 223-1398

Status: Designated **Designation Date:** 31-Jan-91 **Marketing Approval Date:**

Generic Name: Gentamicin liposome injection	Trade Name: Maitec
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Orphan Indication: Treatment of disseminated Mycobacterium avium-intracellulare infection.

Sponsor: Liposome Company, Inc. **Contact:** Dr. James Boyle

Address: Princeton, NJ **Phone:** (609) 452-7060 **Fax:** (609) 452-1890

Status: Designated **Designation Date:** 10-Jul-90 **Marketing Approval Date:**

Generic Name: Glatiramer acetate	Trade Name: Copaxone
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Orphan Indication: Treatment of multiple sclerosis.

Sponsor: Teva Pharmaceuticals USA **Contact:** Dr. Stanley Scheindlin

Address: Kulpville, PA **Phone:** (800) 999-8382 **Fax:**

Status: Designated/Approved **Designation Date:** 09-Nov-87 **Marketing Approval Date:** 20-Dec-96

Generic Name: Glatiramer acetate for injection	Trade Name: Copaxone
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Orphan Indication: Treatment of primary-progressive multiple sclerosis

Sponsor: TEVA Pharmaceuticals, USA **Contact:** Dr. Scott Grossman

Address: North Wales, PA **Phone:** 2155918526 **Fax:**

Status: Designated **Designation Date:** 05-Jun-01 **Marketing Approval Date:**

Generic Name: Glutamine
Trade Name:

Orphan Indication: 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).

Sponsor: Nutritional Restart Pharmaceutical, L.P. **Contact:** Ms. Lynda Sutton

Address: Durham, NC **Phone:** (919) 361-2286 **Fax:** (919) 361-2290

Status: Designated **Designation Date:** 06-Mar-95 **Marketing Approval Date:**

Generic Name: Glyceol
Trade Name:

Orphan Indication: To decrease intracranial hypertension and/or alleviate cerebral edema in patients who may benefit from osmotherapy.

Sponsor: Chugai Pharmaceutical Co., Ltd. **Contact:**

Address: , **Phone:** Fax:

Status: Designated/Withdrawn **Designation Date:** 22-Feb-90 **Marketing Approval Date:**

Generic Name: Glyceryl trioleate and glyceryl trierucate
Trade Name:

Orphan Indication: Treatment of adrenoleukodystrophy.

Sponsor: Moser, Hugo W. M.D. **Contact:** Dr. Hugo Moser

Address: Baltimore, MD **Phone:** (410) 550-9405 **Fax:**

Status: Designated **Designation Date:** 14-Feb-95 **Marketing Approval Date:**

Generic Name: Gonadorelin acetate **Trade Name:** Lutrepulse

Orphan Indication: 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.

Sponsor: Ferring Laboratories, Inc. **Contact:** Mr. Isidoro Nudelman

Address: Suffern, NY **Phone:** (888) 793-6367 **Fax:**

Status: Designated/Approved **Designation Date:** 22-Apr-87 **Marketing Approval Date:** 10-Oct-89

Generic Name: Gossypol
Trade Name:

Orphan Indication: Treatment of cancer of the adrenal cortex.

Sponsor: Reidenberg, Marcus M. M.D. **Contact:** Dr. Marcus Reidenberg

Address: New York, NY **Phone:** (212) 746-6227 **Fax:**

Status: Designated **Designation Date:** 22-Oct-90 **Marketing Approval Date:**

Generic Name: Gp100 adenoviral gene therapy
Trade Name:

Orphan Indication: Treatment of metastatic melanoma.

Sponsor: Genzyme Corporation **Contact:** Mr. Robert Martin

Address: Framingham, MA **Phone:** 5082713961 **Fax:** 5082712692

Status: Designated **Designation Date:** 25-Mar-97 **Marketing Approval Date:**

Generic Name: Granulocyte macrophage-colony stimulating factor **Trade Name:** Leucomax

Orphan Indication: Treatment of myelodysplastic syndrome.

Sponsor: Schering Corporation **Contact:** Dr. Alexander Giaquinto

Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 07-Aug-89 **Marketing Approval Date:**

Generic Name: Granulocyte macrophage-colony stimulating factor **Trade Name:** Leucomax

Orphan Indication: Treatment of neutropenia associated with bone marrow transplants.

Sponsor: Schering Corporation **Contact:** Dr. Douglass Given

Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 12-Dec-89 **Marketing Approval Date:**

Generic Name: Granulocyte macrophage-colony stimulating factor **Trade Name:** Leucomax

Orphan Indication: Treatment of chronic lymphocytic leukemia to increase granulocyte count.

Sponsor: Schering Corporation **Contact:** Dr. Douglass Given

Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 04-May-90 **Marketing Approval Date:**

Generic Name: Granulocyte macrophage-colony stimulating factor **Trade Name:** Leucomax

Orphan Indication: Treatment of severe thermal injuries in patients with greater than 40% full or partial thickness burns.

Sponsor: Schering Corporation **Contact:** Dr. Douglass Given

Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 06-Jun-89 **Marketing Approval Date:**

Generic Name: Granulocyte macrophage-colony stimulating factor	Trade Name: Leucomax
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Orphan Indication: Treatment of neutropenia due to hairy cell leukemia.

Sponsor: Schering Corporation **Contact:** Dr. Douglass Given

Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 03-May-90 Marketing Approval Date:

Generic Name: Group B streptococcus immune globulin
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Trade Name:

Orphan Indication: Treatment of neonates for disseminated group B streptococcal infection.

Sponsor: North American Biologicals, Inc. **Contact:** Dr. Lewis Pollack

Address: Rockville, MD **Phone:** (301) 230-3422 **Fax:** (301) 770-0155

Status: Designated/Withdrawn **Designation Date:** 08-May-90 Marketing Approval Date:

Generic Name: Growth hormone releasing factor
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Trade Name:

Orphan Indication: For the long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.

Sponsor: ICN Pharmaceuticals, Inc. **Contact:** Mr. Anil Hiteshi

Address: Costa Mesa, CA **Phone:** (714) 545-0100 **Fax:** (714) 556-0131

Status: Designated **Designation Date:** 07-Aug-89 Marketing Approval Date:

Generic Name: Guanethidine monosulfate	Trade Name: Ismelin
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Orphan Indication: Treatment of moderate to severe reflex sympathetic dystrophy and causalgia.

Sponsor: Novartis Pharmaceuticals Corporation **Contact:** Ms. Nancy Price

Address: East Hanover, NJ **Phone:** (973) 781-3591 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 06-Jan-86 Marketing Approval Date:

Generic Name: Guanfacine	Trade Name: Tenex
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Orphan Indication: Treatment of fragile X syndrome.

Sponsor: Watson Laboratories, Inc. **Contact:** Dr. Ron Browne

Address: Corona, CA **Phone:** (909) 270-1400 **Fax:** (909) 270-1428

Status: Designated **Designation Date:** 05-Aug-99 Marketing Approval Date:

Generic Name: Gusperimus	Trade Name: Spanidin
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Orphan Indication: Treatment of acute renal graft rejection episodes.

Sponsor: Bristol-Myers Squibb Pharmaceutical Research **Contact:** Mr. John Joseph III
Institute

Address: Wallingford, CT **Phone:** (203) 677-6065 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 27-Jun-96 Marketing Approval Date:

Generic Name: h5G1.1-mAb

Trade Name:

Orphan Indication: Treatment of dermatomyositis

Sponsor: Alexion Pharmaceuticals, Inc. **Contact:** Dr. Nancy Motola

Alexion Pharmaceuticals, Inc.

Address: Cheshire, CT **Phone:** 2032722596 **Fax:** 2032718198

Status: Designated **Designation Date:** 21-Sep-00 Marketing Approval Date:

Generic Name: h5G1.1mAb

Trade Name:

Orphan Indication: Idiopathic membranous glomerular nephropathy

Sponsor: Alexion Pharmaceuticals, Inc. **Contact:** Dr. Nancy Motola

Address: Cheshire, CT **Phone:** 2032722596 **Fax:** 2032718198

Status: Designated **Designation Date:** 05-Mar-01 Marketing Approval Date:

Generic Name: Halofantrine	Trade Name: Halfan
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Orphan Indication: Treatment of mild to moderate acute malaria caused by susceptible strains of *P. falciparum* and *P. vivax*.

Sponsor: SmithKline Beecham Pharmaceuticals **Contact:** Dr. Paula Goldberg
Address: Philadelphia, PA **Phone:** (215) 751-4000 **Fax:** (215) 751-3400
Status: Designated/Approved **Designation Date:** 04-Nov-91 **Marketing Approval Date:** 24-Jul-92

Generic Name: Halofuginone **Trade Name:** Stenorol

Orphan Indication: Treatment of systemic sclerosis.
Sponsor: Collgard Biopharmaceuticals Ltd. **Contact:** Dr. Neal Farber
Address: Israel, IL **Phone:** 6179650872 **Fax:**
Status: Designated **Designation Date:** 07-Feb-00 **Marketing Approval Date:**

Generic Name: Heme arginate **Trade Name:** Normosang

Orphan Indication: Treatment of symptomatic stage of acute porphyria.
Sponsor: Berlex Laboratories, Inc. **Contact:** Ms. Patricia Murphy
Address: Richmond, CA **Phone:** 5102625022 **Fax:** () -
Status: Designated **Designation Date:** 10-Mar-88 **Marketing Approval Date:**

Generic Name: Heme arginate **Trade Name:** Normosang

Orphan Indication: Treatment of myelodysplastic syndromes.
Sponsor: Berlex Laboratories, Inc. **Contact:** Ms. Patricia Murphy
Address: Richmond, CA **Phone:** 5102625022 **Fax:** () -
Status: Designated **Designation Date:** 01-Mar-94 **Marketing Approval Date:**

Generic Name: Hemin **Trade Name:** Panhematin

Orphan Indication: 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 coproporphyrin.
Sponsor: Abbott Laboratories **Contact:** Medical Information
Address: Abbott Park, IL **Phone:** 8006339110 **Fax:**
Status: Designated/Approved **Designation Date:** 16-Mar-84 **Marketing Approval Date:** 20-Jul-83

Generic Name: Hemin and zinc mesoporphyrin **Trade Name:** Hemex

Orphan Indication: Treatment of acute porphyric syndromes.
Sponsor: Bonkovsky, Herbert L. M.D. **Contact:** Dr. Herbert Bonkovsky
Address: Worcester, MA **Phone:** (508) 856-3068 **Fax:**
Status: Designated **Designation Date:** 20-Dec-93 **Marketing Approval Date:**

Generic Name: Hepatitis B immune globulin intravenous (human) **Trade Name:** Nabi-HB

Orphan Indication: Prophylaxis against hepatitis B virus reinfection in liver transplant patients.
Sponsor: NABI **Contact:** Dr. Lewis Pollack
Address: Rockville, MD **Phone:** (301) 770-3099 **Fax:** (301) 770-3097
Status: Designated **Designation Date:** 08-Mar-95 **Marketing Approval Date:**

Generic Name: Herpes simplex virus gene

Trade Name:

Orphan Indication: Treatment of primary and metastatic brain tumors.
Sponsor: Genetic Therapy, Inc. **Contact:** Mr. Jeffrey Carey
Address: Gaithersburg, MD **Phone:** (301) 208-2451 **Fax:** (301) 948-0097
Status: Designated **Designation Date:** 16-Oct-92 **Marketing Approval Date:**

Generic Name: Histamine **Trade Name:** Maxamine

Orphan Indication: For use as an adjunct to cytokine therapy in the treatment of malignant melanoma.
Sponsor: Maxim Pharmaceuticals, Inc. **Contact:** Mr. Charles Davis
Address: San Diego, CA **Phone:** 8584534040 **Fax:**
Status: Designated **Designation Date:** 01-Feb-00 **Marketing Approval Date:**

Generic Name: Histamine **Trade Name:** Maxamine

Orphan Indication: Adjunct to cytokine therapy in the treatment of acute myeloid leukemia.
Sponsor: Maxim Pharmaceuticals, Inc. **Contact:** Mr. Charles Davis
Address: San Diego, CA **Phone:** 8584534040 **Fax:**
Status: Designated **Designation Date:** 15-Dec-99 **Marketing Approval Date:**

Generic Name: Histrelin
Trade Name:

Orphan Indication: Treatment of acute intermittent porphyria, hereditary coproporphyria, and variegate porphyria.

Sponsor: Anderson, Karl E., M.D. **Contact:** Dr. Karl Anderson

Address: Galveston, TX **Phone:** (409) 772-4661 **Fax:**

Status: Designated **Designation Date:** 03-May-91 **Marketing Approval Date:**

Generic Name: Histrelin acetate **Trade Name:** Supprelin Injection

Orphan Indication: Treatment of central precocious puberty.

Sponsor: Roberts Pharmaceutical Corp. **Contact:** Mr. Drew Karlan

Address: Eatontown, NJ **Phone:** (732) 389-1182 **Fax:**

Status: Designated/Approved **Designation Date:** 10-Aug-88 **Marketing Approval Date:** 24-Dec-91

Generic Name: HIV neutralizing antibodies **Trade Name:** Immupath

Orphan Indication: Treatment of acquired immunodeficiency syndrome.

Sponsor: Hemacare Corporation **Contact:** Dr. Joshua Levy

Address: Sherman Oaks, CA **Phone:** (818) 986-3883 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 24-Mar-92 **Marketing Approval Date:**

Generic Name: HLA-B7/Beta2M DNA Lipid (DMRIE/DOPE) Complex **Trade Name:** Allovectin-7

Orphan Indication: Treatment of invasive and metastatic melanoma (Stages II, III, and IV).

Sponsor: Vical Incorporated **Contact:** Mr. Steven Kradjian

Address: San Diego, CA **Phone:** (858) 646-1117 **Fax:** (858) 646-1151

Status: Designated **Designation Date:** 30-Sep-99 **Marketing Approval Date:**

Generic Name: HPA-23
Trade Name:

Orphan Indication: Treatment of acquired immunodeficiency syndrome.

Sponsor: Rhone-Poulenc Rorer Pharm. **Contact:** Judith Plon

Address: Collegeville, PA **Phone:** (610) 454-3024 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 17-Jul-85 **Marketing Approval Date:**

Generic Name: Hsp E7
Trade Name:

Orphan Indication: Treatment of recurrent respiratory papillomatosis (RRP)

Sponsor: StressGen Biotechnologies, Inc. **Contact:** Dr. Richard Currano

Address: Collegeville, PA **Phone:** 4105432738 **Fax:**

Status: Designated **Designation Date:** 19-Mar-01 **Marketing Approval Date:**

Generic Name: Human acid precursor alpha-glucosidase, recombinant
Trade Name:

Orphan Indication: Treatment of glycogen storage disease type II.

Sponsor: Pharming/Genzyme LLC **Contact:** Ms. Betty Wiley

Address: Framingham, MA **Phone:** (508) 270-2132 **Fax:** (508) 271-2692

Status: Designated **Designation Date:** 10-Sep-96 **Marketing Approval Date:**

Generic Name: human gammaglobulin
Trade Name:

Orphan Indication: Treatment for juvenile rheumatoid arthritis

Sponsor: Protein Therapeutics, Inc **Contact:** Dr. Leon Barstow

Address: Tucson, AZ **Phone:** 5205741632 **Fax:** 5206633593

Status: Designated **Designation Date:** 25-May-01 **Marketing Approval Date:**

Generic Name: Human IgM monoclonal antibody (C-58) To CMV **Trade Name:** Centovir

Orphan Indication: Prophylaxis of cytomegalovirus infections in bone marrow transplant patients.

Sponsor: Centocor, Inc. **Contact:** Jon Case

Address: Malvern, PA **Phone:** (215) 889-4509 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 07-Aug-89 **Marketing Approval Date:**

Generic Name: Human IgM monoclonal antibody (C-58) To CMV **Trade Name:** Centovir

Orphan Indication: Treatment of cytomegalovirus infections in allogenic bone marrow transplant patients.

Sponsor: Centocor, Inc. **Contact:** Jon Case

Address: Malvern, PA **Phone:** (215) 889-4509 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 07-Aug-89 Marketing Approval Date:

Generic Name: Human immunodeficiency virus immune globulin

Trade Name:

Orphan Indication: Treatment of HIV-infected pregnant women and infants of HIV-infected mothers.

Sponsor: NABI **Contact:** Dr. Pinya Cohen

Address: Boca Raton, FL **Phone:** (561) 989-5730 **Fax:** (561) 989-5801

Status: Designated/Withdrawn **Designation Date:** 25-Mar-92 Marketing Approval Date:

Generic Name: Human immunodeficiency virus immune globulin

Trade Name:

Orphan Indication: Treatment of AIDS.

Sponsor: NABI **Contact:** Dr. Pinya Cohen

Address: Boca Raton, FL **Phone:** (561) 989-5730 **Fax:** (561) 989-5801

Status: Designated/Withdrawn **Designation Date:** 21-Nov-89 Marketing Approval Date:

Generic Name: Human immunodeficiency virus immune globulin **Trade Name:** Hivig

Orphan Indication: Treatment of HIV-infected pediatric patients.

Sponsor: NABI **Contact:** Dr. Pinya Cohen

Address: Boca Raton, FL **Phone:** (561) 989-5730 **Fax:** (561) 989-5801

Status: Designated/Withdrawn **Designation Date:** 04-Jan-95 Marketing Approval Date:

Generic Name: Human T-lymphotropic virus type III Gp160 antigens **Trade Name:** Vaxsyn HIV-1

Orphan Indication: Treatment of AIDS.

Sponsor: MicroGeneSys, Inc. **Contact:** Ms. Carol Cherry

Address: Meriden, CT **Phone:** (203) 686-0800 **Fax:** (203) 686-0268

Status: Designated **Designation Date:** 20-Nov-89 Marketing Approval Date:

Generic Name: Humanized anti-CD2 monoclonal antibody

Trade Name:

Orphan Indication: Treatment of graft-versus-host disease.

Sponsor: MedImmune, Inc. **Contact:** Dr. Peter Patriarca

Address: Gaithersburg, MD **Phone:** 2406324229 **Fax:** (301) 527-4200

Status: Designated **Designation Date:** 13-Nov-98 Marketing Approval Date:

Generic Name: Humanized anti-human CD2 MAb **Trade Name:** MEDI-507

Orphan Indication: 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.

Sponsor: Biotransplant, Inc. **Contact:** Dr. Robert Kauffman

Address: Charlestown, MA **Phone:** (617) 241-5200 **Fax:** (617) 241-8780

Status: Designated **Designation Date:** 17-Sep-98 Marketing Approval Date:

Generic Name: Humanized anti-tac **Trade Name:** Zenapax

Orphan Indication: Prevention of acute graft-vs-host disease following bone marrow transplantation.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Dr. David Smith

Address: Nutley, NJ **Phone:** (201) 812-3720 **Fax:** (201) 812-3700

Status: Designated **Designation Date:** 05-Mar-93 Marketing Approval Date:

Generic Name: Humanized MAb (IDEC-131) to CD40L

Trade Name:

Orphan Indication: Treatment of systemic lupus erythematosus.

Sponsor: Idex Pharmaceuticals Corporation **Contact:** Ms. Alice Wei

Address: San Diego, CA **Phone:** (858) 431-8920 **Fax:** (858) 431-8889

Status: Designated **Designation Date:** 09-Feb-99 Marketing Approval Date:

Generic Name: humanized monoclonal antibody against Shiga-like toxin II

Trade Name:

Orphan Indication: To prevent the development of or to decrease the incidence and severity of hemolytic uremic syndrome and associated sequelae of Shiga-like toxin-producing E. coli.

Sponsor: Teijin America, Inc. **Contact:** Mr. Peter Vaccari

Address: Princeton, NJ **Phone:** 3013091260 **Fax:** 3013098470

Status: Designated **Designation Date:** 12-Sep-01 **Marketing Approval Date:**

Generic Name: Hydroxocobalamin **Trade Name:** CYANOKIT

Orphan Indication: Treatment of acute cyanide poisoning

Sponsor: Orphan Medical, Inc. **Contact:** Dr. Dayton Reardon

Address: Minnetonka, MN **Phone:** 9525136974 **Fax:** 9525419209

Status: Designated **Designation Date:** 22-Sep-00 **Marketing Approval Date:**

Generic Name: Hydroxycobalamin/sodium thiosulfate

Trade Name:

Orphan Indication: Treatment of severe acute cyanide poisoning.

Sponsor: Hall, Alan H., M.D. **Contact:** Dr. Alan Hall

Address: Elk Mountain, WY **Phone:** (307) 348-7371 **Fax:** (307) 348-7372

Status: Designated/Withdrawn **Designation Date:** 04-Oct-85 **Marketing Approval Date:**

Generic Name: Hydroxyurea **Trade Name:** Droxia

Orphan Indication: Treatment of patients with sickle cell anemia as shown by the presence of hemoglobin S.

Sponsor: Bristol-Myers Squibb Pharmaceutical Research Institute **Contact:** Dr. Joseph Linkewich

Address: Princeton, NJ **Phone:** (609) 252-5761 **Fax:**

Status: Designated/Approved **Designation Date:** 01-Oct-90 **Marketing Approval Date:** 25-Feb-98

Generic Name: Hypericin

Trade Name:

Orphan Indication: Treatment of glioblastoma multiforme.

Sponsor: Nexell Therapeutics **Contact:** Dr. John Todhunter

Address: Wilmington, DE **Phone:** (202) 223-0157 **Fax:** (202) 835-8970

Status: Designated **Designation Date:** 03-Aug-00 **Marketing Approval Date:**

Generic Name: Hypericin

Trade Name:

Orphan Indication: Treatment of cutaneous T-cell lymphoma.

Sponsor: Nexell Therapeutics, Inc. **Contact:** Dr. John Todhunter

Address: Wilmington, DE **Phone:** (202) 223-0157 **Fax:** (202) 835-8970

Status: Designated **Designation Date:** 07-Feb-00 **Marketing Approval Date:**

Generic Name: Ibuprofen i.v. solution

Trade Name:

Orphan Indication: Treatment of patent ductus arteriosus.

Sponsor: Farmacon-IL-LLC **Contact:** Dr. Laszlo Darko

Address: Westport, CT **Phone:** (203) 255-8898 **Fax:** (203) 255-3888

Status: Designated **Designation Date:** 29-Oct-96 **Marketing Approval Date:**

Generic Name: Ibuprofen i.v. solution **Trade Name:** Salprofen

Orphan Indication: Prevention of patent ductus arteriosus.

Sponsor: Farmacon-IL, LLC **Contact:** Dr. Laszlo Darko

Address: Westport, CT **Phone:** (203) 255-8898 **Fax:** (203) 255-3888

Status: Designated **Designation Date:** 29-Oct-96 **Marketing Approval Date:**

Generic Name: Icodextrin 7.5% with Electrolytes Peritoneal Dialysis Solution **Trade Name:** Extraneal (with 7.5% Icodextrin) Peritoneal Dialysis Solution

Orphan Indication: Treatment of those patients having end stage renal disease and requiring peritoneal dialysis treatment.

Sponsor: Baxter Healthcare Corporation **Contact:** Dr. Steven Hoff

Address: McGaw Park, IL **Phone:** (847) 473-6359 **Fax:** (847) 473-6952

Status: Designated **Designation Date:** 18-Jul-97 **Marketing Approval Date:**

Generic Name: Idarubicin **Trade Name:** Idamycin

Orphan Indication: Treatment of chronic myelogenous leukemia.

Sponsor: Pharmacia & Upjohn **Contact:** Ms. Marcia Greko

Address: Kalamazoo, MI **Phone:** (616) 833-7520 **Fax:** (616) 833-8237

Status: Designated/Withdrawn **Designation Date:** 02-Dec-92 **Marketing Approval Date:**

Generic Name: Idarubicin **Trade Name:** Idamycin

Orphan Indication: Treatment of myelodysplastic syndromes.

Sponsor: Pharmacia & Upjohn **Contact:** Ms. Marcia Greko

Address: Kalamazoo, MI **Phone:** (616) 833-7520 **Fax:** (616) 833-8237

Status: Designated/Withdrawn **Designation Date:** 01-Dec-92 **Marketing Approval Date:**

Generic Name: Idarubicin HCl for injection **Trade Name:** Idamycin

Orphan Indication: Treatment of acute myelogenous leukemia, also referred to as acute nonlymphocytic leukemia.

Sponsor: Adria Laboratories, Inc. **Contact:** Mr. Douglas Jones

Address: Columbus, OH **Phone:** (614) 764-8100 **Fax:** (614) 764-8102

Status: Designated/Approved **Designation Date:** 25-Jul-88 **Marketing Approval Date:** 27-Sep-90

Generic Name: Idarubicin HCl for injection **Trade Name:** Idamycin

Orphan Indication: Treatment of acute lymphoblastic leukemia in pediatric patients.

Sponsor: Pharmacia & Upjohn **Contact:** Ms. Marcia Greko

Address: Kalamazoo, MI **Phone:** (616) 833-7520 **Fax:** (616) 833-8237

Status: Designated **Designation Date:** 12-Feb-91 **Marketing Approval Date:**

Generic Name: Idoxuridine

Trade Name:

Orphan Indication: Treatment of nonparenchymatous sarcomas.

Sponsor: NeoPharm, Inc. **Contact:** Dr. William Govier

Address: Lake Forest, IL **Phone:** (708) 295-8678 **Fax:** (708) 295-8680

Status: Designated **Designation Date:** 08-Apr-96 **Marketing Approval Date:**

Generic Name: Ifosfamide **Trade Name:** Ifex

Orphan Indication: Treatment of soft tissue sarcomas.

Sponsor: Bristol-Myers Squibb Pharmaceutical Research **Contact:** Dr. Joseph Sonk
Institute

Address: Princeton, NJ **Phone:** (609) 252-5710 **Fax:**

Status: Designated **Designation Date:** 07-Aug-85 **Marketing Approval Date:**

Generic Name: Ifosfamide **Trade Name:** Ifex

Orphan Indication: Treatment of testicular cancer.

Sponsor: Bristol-Myers Squibb Pharmaceutical Research **Contact:** Dr. Douglas Kriesel
Institute

Address: Wallingford, CT **Phone:** (203) 284-6051 **Fax:**

Status: Designated/Approved **Designation Date:** 20-Jan-87 **Marketing Approval Date:** 30-Dec-88

Generic Name: Ifosfamide **Trade Name:** Ifex

Orphan Indication: Treatment of bone sarcomas.

Sponsor: Bristol-Myers Squibb Pharmaceutical Research **Contact:** Dr. Joseph Linkewich
Institute

Address: Princeton, NJ **Phone:** (609) 252-5761 **Fax:** (609) 252-6000

Status: Designated **Designation Date:** 07-Aug-85 **Marketing Approval Date:**

Generic Name: IL-4 Pseudomonas Toxin Fusion Protein (IL-4(38-37)-PE38KDEL)

Trade Name:

Orphan Indication: Treatment of astrocytic glioma.

Sponsor: Neurocrine Biosciences, Inc. **Contact:** Ms. Margaret Valeur-Jensen

Address: San Diego, CA **Phone:** (858) 658-7670 **Fax:** (858) 658-7605

Status: Designated **Designation Date:** 06-Apr-00 **Marketing Approval Date:**

Generic Name: IL13-PE38QQR

Trade Name:

Orphan Indication: Treatment of malignant glioma
Sponsor: NeoPharm, Inc. **Contact:** Mr. Kirk Rosemark
Address: Lake Forest, IL **Phone:** 8472958678 **Fax:** 8472958854
Status: Designated **Designation Date:** 02-Nov-01 **Marketing Approval Date:**

Generic Name: Iloprost solution for infusion
Trade Name:

Orphan Indication: Treatment of heparin-associated thrombocytopenia.
Sponsor: Berlex Laboratories, Inc. **Contact:** Dr. Suzanne Hampton
Address: Wayne, NJ **Phone:** (201) 305-5288 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 14-May-90 **Marketing Approval Date:**

Generic Name: Iloprost solution for infusion
Trade Name:

Orphan Indication: Treatment of Raynaud's phenomenon secondary to systemic sclerosis.
Sponsor: Berlex Laboratories, Inc. **Contact:** Dr. Suzanne Hampton
Address: Wayne, NJ **Phone:** (201) 305-5288 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 21-Sep-89 **Marketing Approval Date:**

Generic Name: Imatinib **Trade Name:** Gleevec

Orphan Indication: Treatment of chronic myelogenous leukemia
Sponsor: Novartis Pharmaceuticals Corporation **Contact:** Ms. Ellen Cutler
Address: East Hanover, NJ **Phone:** 9737818180 **Fax:** 9737816325
Status: Designated/Approved **Designation Date:** 31-Jan-01 **Marketing Approval Date:** 10-May-01

Generic Name: imatinib mesylate **Trade Name:** Gleevec

Orphan Indication: Treatment of gastrointestinal stromal tumors
Sponsor: Novartis Pharmaceuticals Corp. **Contact:** Mr. Robert Miranda
Address: East Hanover, NJ **Phone:** 9737812282 **Fax:** 9737816325
Status: Designated **Designation Date:** 01-Nov-01 **Marketing Approval Date:**

Generic Name: Imciromab pentetate **Trade Name:** Myoscint

Orphan Indication: Detecting early necrosis as an indication of rejection of orthotopic cardiac transplants.
Sponsor: Centocor, Inc. **Contact:** Mr. Martin Page
Address: Malvern, PA **Phone:** (215) 889-4786 **Fax:**
Status: Designated **Designation Date:** 25-Jan-89 **Marketing Approval Date:**

Generic Name: Imexon **Trade Name:** n/a

Orphan Indication: Treatment of metastatic malignant melanoma
Sponsor: AmpliMed Corporation **Contact:** Dr. Evan Hersh
Address: Tucson, AZ **Phone:** 5206262250 **Fax:** 5206262225
Status: Designated **Designation Date:** 03-Aug-01 **Marketing Approval Date:**

Generic Name: Imexon
Trade Name:

Orphan Indication: Treatment of multiple myeloma.
Sponsor: AmpliMed Corporation **Contact:** Dr. Evan Hersh
Address: Tucson, AZ **Phone:** (520) 577-1011 **Fax:** (520) 626-2225
Status: Designated **Designation Date:** 08-Nov-96 **Marketing Approval Date:**

Generic Name: Imiglucerase **Trade Name:** Cerezyme

Orphan Indication: Replacement therapy in patients with types I, II, and III Gaucher's disease.
Sponsor: Genzyme Corporation **Contact:** Ms. Suzanne Sensabaugh
Address: Cambridge, MA **Phone:** (617) 374-7455 **Fax:** (617) 374-7470
Status: Designated/Approved **Designation Date:** 05-Nov-91 **Marketing Approval Date:** 23-May-94

Generic Name: Immune globulin intravenous (human) **Trade Name:** Iivegam, Immuno

Orphan Indication: Treatment of juvenile rheumatoid arthritis.
Sponsor: Immuno Clinical Research Corp. **Contact:** Ms. Marianne Kunschak
Address: New York, NY **Phone:** (212) 759-3875 **Fax:** (212) 751-4971
Status: Designated/Withdrawn **Designation Date:** 16-Dec-92 **Marketing Approval Date:**

Generic Name: Immune globulin intravenous (human)	Trade Name: Iveegam, Immuno
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Orphan Indication: Treatment of polymyositis/dermatomyositis.

Sponsor: Immuno Clinical Research Corp. **Contact:** Marianne Kunschak

Address: New York, NY **Phone:** (212) 759-4260 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 13-Oct-92 **Marketing Approval Date:**

Generic Name: Immune globulin intravenous (human)	Trade Name: Immune Globulin Intravenous (human) Immuno, Iveegam
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Orphan Indication: Treatment of patients with acute myocarditis.

Sponsor: Immuno Clinical Research Corp. **Contact:** Ms. Marianne Kunschak

Address: New York, NY **Phone:** (212) 759-3875 **Fax:** (212) 751-4971

Status: Designated/Withdrawn **Designation Date:** 22-Nov-93 **Marketing Approval Date:**

Generic Name: Immune globulin intravenous, human	Trade Name: Gamimune N
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Orphan Indication: Infection prophylaxis in pediatric patients affected with the human immunodeficiency virus.

Sponsor: Bayer Corporation **Contact:** Ms.

Address: New Haven, CT **Phone:** (203) 937-2000 **Fax:**

Status: Designated/Approved **Designation Date:** 18-Feb-93 **Marketing Approval Date:** 27-Dec-93

Generic Name: Imported fire ant venom, allergenic extract
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Trade Name:

Orphan Indication: 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.

Sponsor: ALK Laboratories, Inc. **Contact:** Mr. John Shumway

Address: Wallingford, CT **Phone:** (800) 325-7354 **Fax:**

Status: Designated **Designation Date:** 12-May-92 **Marketing Approval Date:**

Generic Name: Indium In 111 murine monoclonal antibody FAB to myosin	Trade Name: Myoscint
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Orphan Indication: To aid in the diagnosis of myocarditis.

Sponsor: Centocor, Inc. **Contact:** Mr. Martin Page

Address: Malvern, PA **Phone:** (215) 889-4786 **Fax:**

Status: Designated **Designation Date:** 07-Aug-89 **Marketing Approval Date:**

Generic Name: Indium In-111 altumomab pentetate	Trade Name: Hybri-ceaker
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Orphan Indication: Detection of suspected and previously unidentified tumor foci of recurrent colorectal carcinoma.

Sponsor: Hybritech, Inc. **Contact:** Dr. Joanne Martinis

Address: San Diego, CA **Phone:** (619) 455-6700 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 06-Feb-90 **Marketing Approval Date:**

Generic Name: Indium-In-111 murine MAb(2B8-MX-DTPA) & Yttrium-Y90 murine MAb(2B8-MX-DTPA)	Trade Name: Melimmune
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Orphan Indication: Treatment of B-cell non-Hodgkin's lymphoma.

Sponsor: IDEC Pharmaceuticals Corporation **Contact:** Ms. Alice Wei

Address: San Diego, CA **Phone:** 8584318920 **Fax:** (619) 458-8889

Status: Designated **Designation Date:** 06-Sep-94 **Marketing Approval Date:**

Generic Name: Infliximab	Trade Name: Remicade
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Orphan Indication: 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).

Sponsor: Centocor, Inc. **Contact:** Ms. Wan Yin Jung

Address: Malvern, PA **Phone:** (610) 889-4523 **Fax:** (610) 651-6123

Status: Designated/Approved **Designation Date:** 14-Nov-95 **Marketing Approval Date:** 24-Aug-98

Generic Name: INH-A00021

Trade Name:

Orphan Indication: Reduction (prevention) of nosocomial bacteremia caused by staphylococci in very low birth weight infants.

Sponsor: Inhibitex, Inc. **Contact:** Ms. M. Lorie Stewart

Address: Alpharetta, GA **Phone:** 8167676605 **Fax:** 8167677369

Status: Designated **Designation Date:** 13-Jun-01 **Marketing Approval Date:**

Generic Name: Inosine pranobex **Trade Name:** Isoprinosine

Orphan Indication: Treatment of subacute sclerosing panencephalitis.

Sponsor: Newport Pharmaceuticals **Contact:** Dr. Gordon Schooley

Address: Newport Beach, CA **Phone:** (714) 642-7511 **Fax:**

Status: Designated **Designation Date:** 20-Sep-88 **Marketing Approval Date:**

Generic Name: Interferon alfa-2a **Trade Name:** Roferon A

Orphan Indication: Treatment of chronic myelogenous leukemia.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Loni da Silva

Address: Nutley, NJ **Phone:** (201) 812-3674 **Fax:** (201) 812-3700

Status: Designated/Approved **Designation Date:** 06-Jun-89 **Marketing Approval Date:** 19-Oct-95

Generic Name: Interferon alfa-2a (recombinant) **Trade Name:** Roferon-A

Orphan Indication: Treatment of renal cell carcinoma.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Deborah Savuto

Address: Nutley, NJ **Phone:** (973) 562-3705 **Fax:** (973) 562-3700

Status: Designated **Designation Date:** 18-Apr-88 **Marketing Approval Date:**

Generic Name: Interferon alfa-2a (recombinant) **Trade Name:** Roferon-A

Orphan Indication: For the concomitant administration with fluorouracil for the treatment of advanced colorectal cancer.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Deborah Savuto

Address: Nutley, NJ **Phone:** (973) 562-3705 **Fax:** (973) 562-3700

Status: Designated **Designation Date:** 14-May-90 **Marketing Approval Date:**

Generic Name: Interferon alfa-2a (recombinant) **Trade Name:** Roferon-A

Orphan Indication: Treatment of AIDS related Kaposi's sarcoma.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Loni da Silva

Address: Nutley, NJ **Phone:** (201) 812-3674 **Fax:** (201) 812-3700

Status: Designated/Approved **Designation Date:** 14-Dec-87 **Marketing Approval Date:** 21-Nov-88

Generic Name: Interferon alfa-2a (recombinant) **Trade Name:** Roferon-A

Orphan Indication: For use in combination with fluorouracil for the treatment of esophageal carcinoma.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Deborah Savuto

Address: Nutley, NJ **Phone:** (973) 562-3705 **Fax:** (973) 562-3700

Status: Designated **Designation Date:** 27-Oct-89 **Marketing Approval Date:**

Generic Name: Interferon alfa-2a (recombinant) **Trade Name:** Roferon-A

Orphan Indication: For the concomitant administration with Teceleukin for the treatment of metastatic renal cell carcinoma.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Ileana Leon

Address: Nutley, NJ **Phone:** (201) 812-3720 **Fax:** (201) 812-3700

Status: Designated **Designation Date:** 02-May-90 **Marketing Approval Date:**

Generic Name: Interferon alfa-2a (recombinant) **Trade Name:** Roferon-A

Orphan Indication: For the treatment of metastatic malignant melanoma in combination with Teceleukin.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Ileana Leon

Address: Nutley, NJ **Phone:** (201) 812-3720 **Fax:** (201) 812-3700

Status: Designated **Designation Date:** 11-May-90 **Marketing Approval Date:**

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of ovarian carcinoma.

Sponsor: Schering Corporation **Contact:** Dr. Douglass Given

Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 03-Aug-87 **Marketing Approval Date:**

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of invasive carcinoma of the cervix.
Sponsor: Schering Corporation **Contact:** Dr. Douglass Given
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 18-Apr-88 **Marketing Approval Date:**

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of chronic delta hepatitis.
Sponsor: Schering Corporation **Contact:** Dr. Douglass Given
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 04-May-90 **Marketing Approval Date:**

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of carcinoma in situ of the urinary bladder.
Sponsor: Schering Corporation **Contact:** Dr. Douglass Given
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 10-Aug-88 **Marketing Approval Date:**

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of metastatic renal cell carcinoma.
Sponsor: Schering Corporation **Contact:** Dr. Alexander Giaquinto
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 22-Jun-87 **Marketing Approval Date:**

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of primary malignant brain tumors.
Sponsor: Schering Corporation **Contact:** Dr. Douglass Given
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 13-May-88 **Marketing Approval Date:**

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of acute hepatitis B.
Sponsor: Schering Corporation **Contact:** Dr. Alexander Giaquinto
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 17-Nov-88 **Marketing Approval Date:**

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of laryngeal (respiratory) papillomatosis.
Sponsor: Schering Corporation **Contact:** Dr. Douglass Given
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 17-Aug-88 **Marketing Approval Date:**

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of AIDS-related Kaposi's sarcoma.
Sponsor: Schering Corporation **Contact:** Dr. Alexander Giaquinto
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Approved **Designation Date:** 24-Jun-87 **Marketing Approval Date:** 21-Nov-88

Generic Name: Interferon alfa-2b (recombinant) **Trade Name:** Intron A

Orphan Indication: Treatment of chronic myelogenous leukemia.
Sponsor: Schering Corporation **Contact:** Dr. Alexander Giaquinto
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 22-Jun-87 **Marketing Approval Date:**

Generic Name: Interferon alfa-n1 **Trade Name:** Wellferon

Orphan Indication: Treatment of human papillomavirus in patients with severe resistant/recurrent respiratory (laryngeal) papillomatosis.
Sponsor: Glaxo Wellcome Inc. **Contact:** Ms. Mary Martinson
Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 16-Oct-87 **Marketing Approval Date:**

Generic Name: Interferon alfa-n1 **Trade Name:** Wellferon

Orphan Indication: Treatment of AIDS related Kaposi's sarcoma.

Sponsor: Burroughs Wellcome Company **Contact:** Dr. Michael Dalton

Address: Research Triangle Pk, NC **Phone:** (919) 315-4453 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 25-Aug-86 **Marketing Approval Date:**

Generic Name: Interferon beta (recombinant human) **Trade Name:** Avonex

Orphan Indication: Treatment of primary brain tumors.

Sponsor: Biogen, Inc. **Contact:** Dr. Nadine Cohen

Address: Cambridge, MA **Phone:** 6176793783 **Fax:** (617) 676-3170

Status: Designated **Designation Date:** 13-Jan-93 **Marketing Approval Date:**

Generic Name: Interferon beta (recombinant) **Trade Name:** r-HuIFN-beta

Orphan Indication: For the systemic treatment of cutaneous T-cell lymphoma.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvie Gregoire

Address: Cambridge, MA **Phone:** (617) 679-2631 **Fax:** (617) 679-3170

Status: Designated/Withdrawn **Designation Date:** 18-Apr-91 **Marketing Approval Date:**

Generic Name: Interferon beta (recombinant) **Trade Name:** r-HuIFN-beta

Orphan Indication: For the intralesional and/or systemic treatment of AIDS-related Kaposi's sarcoma.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvie Gregoire

Address: Cambridge, MA **Phone:** (617) 679-2631 **Fax:** (617) 679-3170

Status: Designated/Withdrawn **Designation Date:** 09-May-91 **Marketing Approval Date:**

Generic Name: Interferon beta (recombinant) **Trade Name:** R-IFN-beta

Orphan Indication: For the systemic treatment of metastatic renal cell carcinoma.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvia Gregoire

Address: Cambridge, MA **Phone:** (617) 679-2631 **Fax:** (617) 679-3170

Status: Designated/Withdrawn **Designation Date:** 12-Feb-91 **Marketing Approval Date:**

Generic Name: Interferon beta, recombinant human **Trade Name:** Betaseron

Orphan Indication: Treatment of acquired immunodeficiency syndrome.

Sponsor: Berlex Laboratories, Inc. **Contact:** Donald Gay

Address: Richmond, CA **Phone:** (510) 262-5000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 15-Nov-88 **Marketing Approval Date:**

Generic Name: Interferon beta-1a **Trade Name:** Rebif

Orphan Indication: Treatment of patients with secondary progressive multiple sclerosis.

Sponsor: Serono Laboratories, Inc. **Contact:** Pamela Williamson Joyce

Address: Norwell, MA **Phone:** (781) 982-9000 **Fax:** (617) 871-6754

Status: Designated **Designation Date:** 11-Mar-96 **Marketing Approval Date:**

Generic Name: Interferon Beta-1a **Trade Name:** Avonex

Orphan Indication: Treatment of juvenile rheumatoid arthritis.

Sponsor: Biogen, Inc. **Contact:** Dr. Nadine Cohen

Address: Cambridge, MA **Phone:** 6176793783 **Fax:**

Status: Designated **Designation Date:** 14-Oct-98 **Marketing Approval Date:**

Generic Name: Interferon beta-1a **Trade Name:** Avonex

Orphan Indication: Treatment of multiple sclerosis.

Sponsor: Biogen, Inc. **Contact:** Dr. Burt Adelman

Address: Cambridge, MA **Phone:** (617) 679-2000 **Fax:** (617) 679-2617

Status: Designated/Approved **Designation Date:** 16-Dec-91 **Marketing Approval Date:** 16-May-96

Generic Name: Interferon beta-1a (recombinant human)
Trade Name:

Orphan Indication: Treatment of acute non-A, non-B hepatitis.

Sponsor: Biogen, Inc. **Contact:** Dr. Nadine Cohen

Address: Cambridge, MA **Phone:** 6176793783 **Fax:** (617) 679-3170

Status: Designated **Designation Date:** 24-Jul-92 **Marketing Approval Date:**

Generic Name: Interferon beta-1a (recombinant human)	Trade Name: Avonex
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Orphan Indication: Treatment of pulmonary fibrosis.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvie Gregoire

Address: Cambridge, MA **Phone:** (617) 679-2631 **Fax:** (617) 679-3170

Status: Designated **Designation Date:** 07-Jan-99 **Marketing Approval Date:**

Generic Name: Interferon beta-1a (recombinant)	Trade Name: r-HuIFN-beta
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Orphan Indication: For the systemic treatment of cutaneous malignant melanoma.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvie Gregoire

Address: Cambridge, MA **Phone:** (617) 679-2631 **Fax:** (617) 679-3170

Status: Designated/Withdrawn **Designation Date:** 03-Apr-91 **Marketing Approval Date:**

Generic Name: Interferon beta-1a (recombinant)	Trade Name: Rebif
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Orphan Indication: Treatment of symptomatic patients with AIDS including all patients with CD4 T-cell counts less than 200 cells per mm³.

Sponsor: Sero Laboratories, Inc. **Contact:** Ms. Pamela Williamson Joyce

Address: Norwell, MA **Phone:** (800) 283-8088 **Fax:** (781) 871-6754

Status: Designated **Designation Date:** 02-Dec-92 **Marketing Approval Date:**

Generic Name: Interferon beta-1b	Trade Name: Betaseron
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Orphan Indication: Treatment of multiple sclerosis.

Sponsor: Chiron Corp. & Berlex Laboratories **Contact:** Mr. Dana Redhair

Address: Emeryville, CA **Phone:** (510) 923-2786 **Fax:** (510) 923-3344

Status: Designated/Approved **Designation Date:** 17-Nov-88 **Marketing Approval Date:** 23-Jul-93

Generic Name: Interferon gamma 1-b	Trade Name: Actimmune
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Orphan Indication: Treatment of chronic granulomatous disease.

Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane

Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000

Status: Designated/Approved **Designation Date:** 30-Sep-88 **Marketing Approval Date:** 20-Dec-90

Generic Name: Interferon gamma-1b	Trade Name: Actimmune
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Orphan Indication: Delaying time to disease progression in patients with severe, malignant osteopetrosis.

Sponsor: InterMune, Inc. **Contact:** Ms. Staci Ellis

Address: Brisbane, CA **Phone:** 4154662211 **Fax:** 4155080453

Status: Designated/Approved **Designation Date:** 30-Sep-96 **Marketing Approval Date:** 10-Feb-00

Generic Name: Interferon gamma-1b	Trade Name: Actimmune
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Orphan Indication: Treatment of renal cell carcinoma.

Sponsor: Genentech, Inc. **Contact:** Dr. Robert Garnick

Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (650) 225-6000

Status: Designated **Designation Date:** 04-Dec-95 **Marketing Approval Date:**

Generic Name: Interferon-alfa-1b	Trade Name:
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Orphan Indication: Treatment of multiple myeloma

Sponsor: Ernest C.Borden **Contact:** Dr. Ernest Borden

Address: Cleveland, OH **Phone:** 2164448183 **Fax:** 2166362498

Status: Designated **Designation Date:** 17-Apr-01 **Marketing Approval Date:**

Generic Name: Interleukin-1 alpha, human recombinant	Trade Name:
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Orphan Indication: For the promotion of early engraftment in bone marrow transplantation.

Sponsor: Immunex Corporation **Contact:** Bogdan Dziurzynski

Address: Seattle, WA **Phone:** (206) 587-0430 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 17-Jun-91 **Marketing Approval Date:**

Generic Name: Interleukin-1 alpha, human recombinant	Trade Name:
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Orphan Indication: For hematopoietic potentiation in aplastic anemia.

Sponsor: Immunex Corporation **Contact:** Bogdan Dziurzynski

Address: Seattle, WA **Phone:** (206) 587-0430 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 17-Jun-91 **Marketing Approval Date:**

Generic Name: Interleukin-1 receptor antagonist, human recombinant **Trade Name:** Antril

Orphan Indication: Treatment of juvenile rheumatoid arthritis.

Sponsor: Amgen, Inc. **Contact:** Ms. Adele Shoustal

Address: Thousand Oaks, CA **Phone:** 8054473785 **Fax:** 8054998703

Status: Designated **Designation Date:** 23-Sep-91 **Marketing Approval Date:**

Generic Name: Interleukin-1 receptor antagonist, human recombinant **Trade Name:** Antril

Orphan Indication: Prevention and treatment of graft versus host disease in transplant recipients.

Sponsor: Amgen, Inc. **Contact:** Ms. Donna Kraft

Address: Thousand Oaks, CA **Phone:** (805) 447-6698 **Fax:** 8054996296

Status: Designated **Designation Date:** 16-Oct-92 **Marketing Approval Date:**

Generic Name: Interleukin-2 **Trade Name:** Teleleukin

Orphan Indication: Treatment of metastatic malignant melanoma.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Ileana Leon

Address: Nutley, NJ **Phone:** (201) 812-3720 **Fax:** (201) 812-3700

Status: Designated **Designation Date:** 06-Feb-90 **Marketing Approval Date:**

Generic Name: Interleukin-2 **Trade Name:** Teceleukin

Orphan Indication: Treatment of metastatic renal cell carcinoma.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Ileana Leon

Address: Nutley, NJ **Phone:** (201) 812-3720 **Fax:** (201) 812-3700

Status: Designated **Designation Date:** 05-Feb-90 **Marketing Approval Date:**

Generic Name: Interleukin-2 **Trade Name:** Teceleukin

Orphan Indication: In combination with interferon alfa-2a for the treatment of metastatic renal cell carcinoma.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Ileana Leon

Address: Nutley, NJ **Phone:** (201) 812-3720 **Fax:** (201) 812-3700

Status: Designated **Designation Date:** 03-May-90 **Marketing Approval Date:**

Generic Name: Interleukin-2 **Trade Name:** Teceleukin

Orphan Indication: In combination with interferon alfa-2a for the treatment of metastatic malignant melanoma.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Ileana Leon

Address: Nutley, NJ **Phone:** (201) 812-3720 **Fax:** (201) 812-3700

Status: Designated **Designation Date:** 11-May-90 **Marketing Approval Date:**

Generic Name: Interleukin-3 human (recombinant)

Trade Name:

Orphan Indication: Promotion of erythropoiesis in Diamond-Blackfan anemia (congenital pure red cell aplasia).

Sponsor: Immunex Corporation **Contact:** Ms. Sally Gould

Address: Seattle, WA **Phone:** (206) 587-0430 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 20-May-91 **Marketing Approval Date:**

Generic Name: Interleukin-3, human, recombinant

Trade Name:

Orphan Indication: For sequential administration with sargramostim to accelerate neutrophil and platelet recovery in patients undergoing autologous bone marrow transplantation for the treatment of Hodgkin's disease or non-Hodgkin's lymphoma.

Sponsor: Sandoz Pharmaceuticals Corp. **Contact:** Mr. Robert Mandetta

Address: East Hanover, NJ **Phone:** (201) 503-8035 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 30-Sep-93 **Marketing Approval Date:**

Generic Name: Intraoral fluoride releasing system **Trade Name:** IFRS

Orphan Indication: Prevention of dental caries due to radiation-induced xerostomia in patients with head and neck cancer

Sponsor: Digestive Care, Inc. **Contact:** Dr. Jules Mitchel, MBA,

Address: Bethlehem, PA **Phone:** 2126812100 **Fax:** 2126812105

Status: Designated **Designation Date:** 31-Jul-01 **Marketing Approval Date:**

Generic Name: Iobenguane Sulfate I 131

Trade Name:

Orphan Indication: For use as a diagnostic adjunct in patients with pheochromocytoma.

Sponsor: University of Michigan **Contact:** Mr. David Hubers

Address: Ann Arbor, MI **Phone:** 7349365304 **Fax:** 7349368182

Status: Designated/Approved/With **Designation Date:** 14-Nov-84 **Marketing Approval Date:** 21-Mar-90
drawn

Generic Name: Iodine 131 6B-iodomethyl-19-norcholesterol

Trade Name:

Orphan Indication: For use in adrenal cortical imaging.

Sponsor: David E. Kuhl, M.D. **Contact:** Mr. David Hubers

Address: Ann Arbor, MI **Phone:** 7349365304 **Fax:** 7349368182

Status: Designated **Designation Date:** 01-Aug-84 **Marketing Approval Date:**

Generic Name: Iodine I 123 murine monoclonal antibody to alpha-fetoprotein

Trade Name:

Orphan Indication: Detection of hepatocellular carcinoma and hepatoblastoma.

Sponsor: Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz

Address: Morris Plains, NJ **Phone:** (201) 605-8200 **Fax:** (201) 605-8282

Status: Designated **Designation Date:** 30-Sep-88 **Marketing Approval Date:**

Generic Name: Iodine I 123 murine monoclonal antibody to alpha-fetoprotein

Trade Name:

Orphan Indication: Detection of alpha-fetoprotein producing germ cell tumors.

Sponsor: Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz

Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282

Status: Designated **Designation Date:** 30-Sep-88 **Marketing Approval Date:**

Generic Name: Iodine I 123 murine monoclonal antibody to hCG

Trade Name:

Orphan Indication: Detection of hCG producing tumors such as germ cell and trophoblastic cell tumors.

Sponsor: Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz

Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282

Status: Designated **Designation Date:** 07-Nov-88 **Marketing Approval Date:**

Generic Name: Iodine I 131 bis(indium-diethylenetriaminepentaacetic acid)tyrosyllysine/hMN-14 x m734 F(ab')₂ bispecific monoclonal antibody

Trade Name: Pentacea

Orphan Indication: Treatment of small-cell lung cancer.

Sponsor: IBC Pharmaceuticals, L.L.C. **Contact:** Dr. John Reno

Address: Morris Plains, NJ **Phone:** (973) 540-9595 **Fax:**

Status: Designated **Designation Date:** 22-Feb-00 **Marketing Approval Date:**

Generic Name: Iodine I 131 Lym-1 Monoclonal Antibody

Trade Name:

Orphan Indication: Treatment of B-cell lymphoma.

Sponsor: Lederle Laboratories Division **Contact:** Allan Hitchcock

Address: Pearl River, NY **Phone:** (914) 732-5000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 02-Nov-87 **Marketing Approval Date:**

Generic Name: Iodine I 131 murine monoclonal antibody IgG2a to B cell **Trade Name:** Immurait, LI-2-I-131

Orphan Indication: Treatment of B-cell leukemia and B-cell lymphoma.

Sponsor: Immunomedics, Inc. **Contact:** Dr. Irene Wei

Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282

Status: Designated **Designation Date:** 18-Sep-89 **Marketing Approval Date:**

Generic Name: Iodine I 131 murine monoclonal antibody to alpha-fetoprotein
Trade Name:

Orphan Indication: Treatment of hepatocellular carcinoma and hepatoblastoma.
Sponsor: Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz
Address: Morris Plains, NJ **Phone:** (201) 605-8200 **Fax:** (201) 605-8282
Status: Designated **Designation Date:** 30-Sep-88 Marketing Approval Date:

Generic Name: Iodine I 131 murine monoclonal antibody to alpha-fetoprotein
Trade Name:

Orphan Indication: Treatment of alpha-fetoprotein producing germ cell tumors.
Sponsor: Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz
Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282
Status: Designated **Designation Date:** 30-Sep-88 Marketing Approval Date:

Generic Name: Iodine I 131 murine monoclonal antibody to hCG
Trade Name:

Orphan Indication: Treatment of hCG producing tumors such as germ cell and trophoblastic cell tumors.
Sponsor: Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz
Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282
Status: Designated **Designation Date:** 07-Nov-88 Marketing Approval Date:

Generic Name: Iodine I-131 radiolabeled chimeric MAb tumor necrosis treatment (TNT-1B) **Trade Name:** 131IchTNT-1

Orphan Indication: Treatment of glioblastoma multiforme and anaplastic astrocytoma.
Sponsor: Peregrine Pharmaceuticals, Inc. **Contact:** Dr. Terrence Chew
Address: Tustin, CA **Phone:** 7145086070 **Fax:** (714) 734-1692
Status: Designated **Designation Date:** 12-Feb-99 Marketing Approval Date:

Generic Name: Isobutyramide
Trade Name:

Orphan Indication: Treatment of sickle cell disease and beta thalassemia.
Sponsor: Alpha Therapeutic Corporation **Contact:** Ms. M. Sue Preston
Address: Los Angeles, CA **Phone:** (213) 225-2221 **Fax:** () -
Status: Designated **Designation Date:** 25-May-94 Marketing Approval Date:

Generic Name: Isobutyramide **Trade Name:** Isobutyramide oral solution

Orphan Indication: Treatment of beta-hemoglobinopathies and beta-thalassemia syndromes.
Sponsor: Perrine, Susan P., M.D. **Contact:** Dr. Susan Perrine
Address: Boston, MA **Phone:** (617) 638-4173 Fax:
Status: Designated **Designation Date:** 18-Dec-92 Marketing Approval Date:

Generic Name: Japanese encephalitis vaccine (live, attenuated)
Trade Name:

Orphan Indication: Prevention of Japanese encephalitis.
Sponsor: Boran Pharmaceuticals **Contact:** Dr. John Petricciani
Address: South Korea, KR **Phone:** (760) 416-0097 **Fax:** (760) 320-8976
Status: Designated **Designation Date:** 19-May-99 Marketing Approval Date:

Generic Name: Ketoconazole **Trade Name:** Nizoral

Orphan Indication: For use with cyclosporine A to diminish the nephrotoxicity induced by cyclosporine in organ transplantation.
Sponsor: Pharmedic Company **Contact:** Joan Carter
Address: Lake Forest, IL **Phone:** (708) 549-8600 Fax:
Status: Designated/Withdrawn **Designation Date:** 27-Mar-91 Marketing Approval Date:

Generic Name: L-2-oxothiazolidine-4-carboxylic acid **Trade Name:** Procysteine

Orphan Indication: Treatment of amyotrophic lateral sclerosis.
Sponsor: Transcend Therapeutics, Inc. **Contact:** Mr. John Guley
Address: Cambridge, MA **Phone:** (617) 374-1200 **Fax:** (617) 374-1201
Status: Designated **Designation Date:** 30-Jul-96 Marketing Approval Date:

Generic Name: L-2-oxothiazolidine-4-carboxylic acid **Trade Name:** Procysteine

Orphan Indication: Treatment of adult respiratory distress syndrome.

Sponsor: Transcend Therapeutics, Inc. **Contact:** Mr. John Guley

Address: Cambridge, MA **Phone:** (617) 374-1200 **Fax:** (617) 374-1201

Status: Designated **Designation Date:** 14-Jun-94 Marketing Approval Date:

Generic Name: L-5-hydroxytryptophan

Trade Name:

Orphan Indication: Treatment of tetrahydrobiopterin deficiency.

Sponsor: Watson Laboratories, Inc. **Contact:** Dr. Ron Browne

Address: Corona, CA **Phone:** (909) 270-1400 **Fax:** (909) 270-1428

Status: Designated **Designation Date:** 20-Jan-99 Marketing Approval Date:

Generic Name: L-baclofen

Trade Name:

Orphan Indication: Treatment of trigeminal neuralgia.

Sponsor: Pharmascience Inc. **Contact:** Ms. Debbie Goodman Davis

Address: Canada H4P 2T4, CA **Phone:** (201) 569-4662 **Fax:** (201) 569-6678

Status: Designated **Designation Date:** 06-Jan-98 Marketing Approval Date:

Generic Name: L-baclofen

Trade Name:

Orphan Indication: Treatment of trigeminal neuralgia.

Sponsor: Fromm, Gerhard M.D. **Contact:** Dr. Gerhard Fromm

Address: Pittsburgh, PA **Phone:** (412) 648-9200 **Fax:**

Status: Designated **Designation Date:** 13-Jul-90 Marketing Approval Date:

Generic Name: L-baclofen

Trade Name: Neuralgon

Orphan Indication: Treatment of intractable spasticity associated with spinal cord injury or multiple sclerosis.

Sponsor: Pharmascience Inc. **Contact:** Ms. Debbie Goodman-Davis

Address: Canada, CA **Phone:** (201) 569-4662 **Fax:** (201) 569-6678

Status: Designated **Designation Date:** 17-Dec-91 Marketing Approval Date:

Generic Name: L-baclofen

Trade Name: Neuralgon

Orphan Indication: Treatment of intractable spasticity in children with cerebral palsy.

Sponsor: Pharmascience Inc. **Contact:** Ms. Debbie Goodman-Davis

Address: Canada, CA **Phone:** (201) 569-4662 **Fax:** (201) 569-6678

Status: Designated **Designation Date:** 30-Jan-92 Marketing Approval Date:

Generic Name: L-cycloserine

Trade Name:

Orphan Indication: Treatment of Gaucher's disease.

Sponsor: Lev, Meir M.D. **Contact:** Dr. Meir Lev

Address: New York, NY **Phone:** (212) 650-7788 **Fax:** (212) 650-6696

Status: Designated **Designation Date:** 01-Aug-89 Marketing Approval Date:

Generic Name: L-cysteine

Trade Name:

Orphan Indication: For the prevention and lessening of photosensitivity in erythropoietic protoporphyria.

Sponsor: Orphan Pharmaceuticals, U.S.A., Inc. **Contact:** Dr. Milton Ellis

Address: Nashville, TN **Phone:** (615) 399-0700 **Fax:** (615) 399-1217

Status: Designated **Designation Date:** 16-May-94 Marketing Approval Date:

Generic Name: L-glutamine

Trade Name:

Orphan Indication: Treatment of sickle cell disease

Sponsor: Orphan Drugs International, LLC (d.b.a. Hope Therapeutics) **Contact:** Dr. Yutaka Niihara

Address: Montrose, CA **Phone:** 3102223695 **Fax:** 3103281308

Status: Designated **Designation Date:** 01-Aug-01 Marketing Approval Date:

Generic Name: L-glutamyl-L-tryptophan

Trade Name:

Orphan Indication: Treatment of AIDS-related Kaposi's sarcoma.
Sponsor: Cytran Incorporated **Contact:** Mr. Paul Ketteridge
Address: Kirkland, WA **Phone:** (425) 889-5812 **Fax:** 4258223644
Status: Designated **Designation Date:** 20-Oct-99 **Marketing Approval Date:**

Generic Name: L-leucovorin **Trade Name:** Isovorin

Orphan Indication: For use in conjunction with high-dose methotrexate in the treatment of osteosarcoma.
Sponsor: Lederle Laboratories **Contact:** Dr. Vern DeVries
Address: Pearl River, NY **Phone:** (914) 732-5000 **Fax:**
Status: Designated **Designation Date:** 01-Aug-91 **Marketing Approval Date:**

Generic Name: L-leucovorin **Trade Name:** Isovorin

Orphan Indication: For use in combination chemotherapy with the approved agent 5-fluorouracil in the palliative treatment of metastatic adenocarcinoma of the colon and rectum.
Sponsor: Lederle Laboratories **Contact:** Dr. Vern DeVries
Address: Pearl River, NY **Phone:** (914) 732-5000 **Fax:**
Status: Designated **Designation Date:** 18-Dec-90 **Marketing Approval Date:**

Generic Name: L-threonine **Trade Name:** Threostat

Orphan Indication: Treatment of amyotrophic lateral sclerosis.
Sponsor: Tyson And Associates **Contact:** Ms. Yvonne Yeh
Address: Hawthorne, CA **Phone:** (213) 675-1080 **Fax:**
Status: Designated **Designation Date:** 06-Feb-89 **Marketing Approval Date:**

Generic Name: L-threonine

Trade Name:

Orphan Indication: Treatment of spasticity associated with familial spastic paraparesis.
Sponsor: Interneuron Pharmaceuticals, Inc. **Contact:** Dr. Bobby Sandage, Jr.
Address: Lexington, MA **Phone:** (781) 861-8444 **Fax:** (781) 861-3830
Status: Designated/Withdrawn **Designation Date:** 24-Jul-92 **Marketing Approval Date:**

Generic Name: Lactic acid **Trade Name:** Aphthaid

Orphan Indication: Treatment of severe aphthous stomatitis in severely, terminally immunocompromised patients.
Sponsor: Frontier Pharmaceutical, Inc. **Contact:** Ms. Valerie Alliger Bograd
Address: Farmingdale, NY **Phone:** (516) 777-1420 **Fax:** (516) 777-1422
Status: Designated **Designation Date:** 29-Jun-99 **Marketing Approval Date:**

Generic Name: Lactobin **Trade Name:** Lactobin

Orphan Indication: Treatment of AIDS-associated diarrhea unresponsive to initial antidiarrheal therapy.
Sponsor: Roxane Laboratories, Inc. **Contact:** Mr. Sean Alan F.X. Reade
Address: Columbus, OH **Phone:** (614) 241-4131 **Fax:** (614) 276-0321
Status: Designated/Withdrawn **Designation Date:** 12-Sep-90 **Marketing Approval Date:**

Generic Name: Lamotrigine **Trade Name:** Lamictal

Orphan Indication: Treatment of Lennox-Gastaut syndrome.
Sponsor: Glaxo Wellcome Research and Development **Contact:** Dr. Elizabeth McConnell
Address: Research Triangle Park, NC **Phone:** (919) 483-6466 **Fax:** (919) 483-5118
Status: Designated/Approved **Designation Date:** 23-Aug-95 **Marketing Approval Date:** 24-Aug-98

Generic Name: Lanreotide, Somatostatin **Trade Name:** Ipstyl

Orphan Indication: Treatment for acromegly
Sponsor: IPSEN, Inc. **Contact:** Mr. Steven Scott
Address: Milford, MA **Phone:** 5084780144 **Fax:** 5084733531
Status: Designated **Designation Date:** 11-Sep-00 **Marketing Approval Date:**

Generic Name: Latrodectus immune F(ab)2 **Trade Name:** Aracmyn

Orphan Indication: Treatment of black widow spider envenomations
Sponsor: Rare Disease Therapeutics, Inc. **Contact:** Mr. Milton Ellis
Address: Nashville, TN **Phone:** 6153990700 **Fax:**
Status: Designated **Designation Date:** 18-Jun-01 **Marketing Approval Date:**

Generic Name: Leflunomide
Trade Name:

Orphan Indication: Prevention of acute and chronic rejection in patients who have received solid organ transplants.

Sponsor: Williams, MD, James W. **Contact:** Dr. James Williams

Address: Chicago, IL **Phone:** (312) 942-4252 **Fax:** (312) 942-2867

Status: Designated **Designation Date:** 18-Oct-96 **Marketing Approval Date:**

Generic Name: Lepirudin **Trade Name:** Refluden

Orphan Indication: Treatment of heparin-associated thrombocytopenia type II.

Sponsor: Hoechst Marion Roussel **Contact:** Mr. B. Randall Vestal

Address: Germany, DE **Phone:** (919) 462-2342 **Fax:** (919) 380-1840

Status: Designated/Approved **Designation Date:** 13-Feb-97 **Marketing Approval Date:** 06-Mar-98

Generic Name: Leucovorin **Trade Name:** Leucovorin calcium

Orphan Indication: For rescue use after high dose methotrexate therapy in the treatment of osteosarcoma.

Sponsor: Immunex Corporation **Contact:** Ms. Sally Gould

Address: Seattle, WA **Phone:** (206) 389-4092 **Fax:**

Status: Designated/Approved **Designation Date:** 17-Aug-88 **Marketing Approval Date:** 31-Aug-88

Generic Name: Leucovorin **Trade Name:** Leucovorin calcium

Orphan Indication: For use in combination with 5-fluorouracil for the treatment of metastatic colorectal cancer.

Sponsor: Immunex Corporation **Contact:** Ms. Sally Gould

Address: Seattle, WA **Phone:** (206) 389-4092 **Fax:**

Status: Designated/Approved **Designation Date:** 08-Dec-86 **Marketing Approval Date:** 12-Dec-91

Generic Name: Leucovorin calcium **Trade Name:** Wellcovorin

Orphan Indication: For use in combination with 5-fluorouracil for the treatment of metastatic colorectal cancer.

Sponsor: Glaxo Wellcome Research and Development **Contact:** Mr. Douglas Jones

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 23-Jun-88 **Marketing Approval Date:**

Generic Name: Leupeptin

Trade Name:

Orphan Indication: For use as an adjunct to microsurgical peripheral nerve repair.

Sponsor: Neuromuscular Adjuncts, Inc. **Contact:** Dr. Lawrence Hurst

Address: Stony Brook, NY **Phone:** (516) 444-7830 **Fax:** () -

Status: Designated **Designation Date:** 18-Sep-90 **Marketing Approval Date:**

Generic Name: Leuprolide acetate **Trade Name:** Lupron Injection

Orphan Indication: Treatment of central precocious puberty.

Sponsor: Tap Pharmaceuticals, Inc. **Contact:** Dr. S. Albert Edwards

Address: Deerfield, IL **Phone:** (708) 317-5780 **Fax:**

Status: Designated/Approved **Designation Date:** 25-Jul-88 **Marketing Approval Date:** 16-Apr-93

Generic Name: Levocabastine HCl ophthalmic suspension 0.05%

Trade Name:

Orphan Indication: Treatment of vernal keratoconjunctivitis.

Sponsor: Iolab Pharmaceuticals **Contact:** Susan Caballa

Address: Claremont, CA **Phone:** (714) 399-1278 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 29-Feb-88 **Marketing Approval Date:**

Generic Name: Levocarnitine **Trade Name:** Carnitor

Orphan Indication: For the treatment of secondary carnitine deficiency in valproic acid toxicity.

Sponsor: Sigma-Tau Pharmaceuticals, Inc. **Contact:** Mr. A Hanzas

Address: Gaithersburg, MD **Phone:** (301) 670-2192 **Fax:** (301) 948-8627

Status: Designated **Designation Date:** 15-Nov-89 **Marketing Approval Date:**

Generic Name: Levocarnitine **Trade Name:** Carnitor**Orphan Indication:** For the prevention of secondary carnitine deficiency in valproic acid toxicity.**Sponsor:** Sigma-Tau Pharmaceuticals, Inc. **Contact:** Mr. A Hanzas**Address:** Gaithersburg, MD **Phone:** (301) 670-2192 **Fax:** (301) 948-8627**Status:** Designated **Designation Date:** 15-Nov-89 **Marketing Approval Date:****Generic Name:** Levocarnitine **Trade Name:** Carnitor**Orphan Indication:** Treatment of primary and secondary carnitine deficiency of genetic origin.**Sponsor:** Sigma-Tau Pharmaceuticals, Inc. **Contact:** Dr. Edward Helton**Address:** Gaithersburg, MD **Phone:** (301) 948-1041 **Fax:** (301) 948-3194**Status:** Designated/Approved **Designation Date:** 26-Jul-84 **Marketing Approval Date:** 22-Dec-88**Generic Name:** Levocarnitine **Trade Name:** Carnitor**Orphan Indication:** Treatment of pediatric cardiomyopathy.**Sponsor:** Sigma-Tau Pharmaceuticals, Inc. **Contact:** Mr. A Hanzas**Address:** Gaithersburg, MD **Phone:** (301) 670-2192 **Fax:** (301) 948-3194**Status:** Designated **Designation Date:** 22-Nov-93 **Marketing Approval Date:****Generic Name:** Levocarnitine **Trade Name:** Carnitor**Orphan Indication:** Treatment of zidovudine-induced mitochondrial myopathy.**Sponsor:** Sigma-Tau Pharmaceuticals, Inc. **Contact:** Mr. A. Hanzas**Address:** Gaithersburg, MD **Phone:** (301) 670-2192 **Fax:** (301) 948-3194**Status:** Designated **Designation Date:** 07-Apr-97 **Marketing Approval Date:****Generic Name:** Levocarnitine **Trade Name:** Carnitor**Orphan Indication:** Treatment of manifestations of carnitine deficiency in patients with end stage renal disease who require dialysis.**Sponsor:** Sigma-Tau Pharmaceuticals, Inc. **Contact:** Dr. Edward Helton**Address:** Gaithersburg, MD **Phone:** (301) 948-1041 **Fax:** (301) 948-3194**Status:** Designated/Withdrawn **Designation Date:** 24-Nov-86 **Marketing Approval Date:****Generic Name:** Levocarnitine **Trade Name:** Carnitor**Orphan Indication:** Treatment of manifestations of carnitine deficiency in patients with end stage renal disease who require dialysis.**Sponsor:** Sigma-Tau Pharmaceuticals, Inc. **Contact:** Mr. A Hanzas**Address:** Gaithersburg, MD **Phone:** (301) 670-2192 **Fax:** (301) 948-3194**Status:** Designated/Approved **Designation Date:** 06-Sep-88 **Marketing Approval Date:** 15-Dec-99**Generic Name:** Levocarnitine **Trade Name:** Carnitor**Orphan Indication:** Treatment of genetic carnitine deficiency.**Sponsor:** Sigma-Tau Pharmaceuticals, Inc. **Contact:** Dr. Edward Helton**Address:** Gaithersburg, MD **Phone:** (301) 948-1041 **Fax:** (301) 948-3194**Status:** Designated/Approved **Designation Date:** 28-Feb-84 **Marketing Approval Date:** 10-Apr-86**Generic Name:** Levodopa and carbidopa **Trade Name:** Duodopa**Orphan Indication:** Treatment of late stage Parkinson's disease.**Sponsor:** Nouvel Pharma, Inc. **Contact:** Dr. Daniel Walker**Address:** Lenexa, KS **Phone:** (913) 530-1780 **Fax:** (913) 327-7920**Status:** Designated **Designation Date:** 18-Jan-00 **Marketing Approval Date:****Generic Name:** Levomethadyl acetate hydrochloride **Trade Name:** Orlaam**Orphan Indication:** Treatment of heroin addicts suitable for maintenance on opiate agonists.**Sponsor:** Biodevelopment Corporation **Contact:** Mr. John Thomas**Address:** McLean, VA **Phone:** (703) 506-1904 **Fax:****Status:** Designated/Approved **Designation Date:** 24-Jan-85 **Marketing Approval Date:** 09-Jul-93**Generic Name:** Lidocaine patch 5% **Trade Name:** Lidoderm Patch**Orphan Indication:** For relief of allodynia (painful hypersensitivity), and chronic pain in post-herpetic neuralgia.**Sponsor:** Teikoku Pharma USA, Inc. **Contact:** Ms. Gale Sheirbon

Address: Campbell, CA **Phone:** (408) 341-0130 **Fax:** (408) 615-4147

Status: Designated/Approved **Designation Date:** 24-Oct-95 **Marketing Approval Date:** 19-Mar-99

Generic Name: Liothyronine sodium injection **Trade Name:** Triostat

Orphan Indication: Treatment of myxedema coma/precoma.

Sponsor: SmithKline Beecham Pharmaceuticals **Contact:** Dr. Paula Goldberg

Address: Philadelphia, PA **Phone:** (215) 751-4000 **Fax:** (215) 751-3400

Status: Designated/Approved **Designation Date:** 30-Jul-90 **Marketing Approval Date:** 31-Dec-91

Generic Name: Lipid/DNA human cystic fibrosis gene

Trade Name:

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: Genzyme Corporation **Contact:** Ms. Ruth Turner

Address: Framingham, MA **Phone:** (508) 270-2285 **Fax:** (508) 872-9080

Status: Designated **Designation Date:** 08-Apr-96 **Marketing Approval Date:**

Generic Name: Liposomal amphotericin B **Trade Name:** AmBisome

Orphan Indication: Treatment of histoplasmosis.

Sponsor: Fujisawa USA, Inc. **Contact:** Dr. Jerry Johnson

Address: Deerfield, IL **Phone:** (847) 317-8800 **Fax:** (847) 317-7286

Status: Designated **Designation Date:** 10-Dec-96 **Marketing Approval Date:**

Generic Name: Liposomal amphotericin B **Trade Name:** AmBisome

Orphan Indication: Treatment of visceral leishmaniasis.

Sponsor: Fujisawa USA, Inc. **Contact:** Dr. Jerry Johnson

Address: Deerfield, IL **Phone:** (847) 317-8800 **Fax:** (847) 317-7286

Status: Designated/Approved **Designation Date:** 06-Dec-96 **Marketing Approval Date:** 11-Aug-97

Generic Name: Liposomal amphotericin B **Trade Name:** AmBisome

Orphan Indication: Treatment of cryptococcal meningitis.

Sponsor: Fujisawa USA, Inc. **Contact:** Dr. Jerry Johnson

Address: Deerfield, IL **Phone:** (847) 317-8800 **Fax:** (847) 317-7286

Status: Designated/Approved **Designation Date:** 10-Dec-96 **Marketing Approval Date:** 11-Aug-97

Generic Name: Liposomal cyclosporin A **Trade Name:** Cyclospire

Orphan Indication: For aerosolized administration in the prevention and treatment of lung allograft rejection

and pulmonary rejection events associated with bone marrow transplantation.

Sponsor: Vernon Knight, M.D. **Contact:** Dr. Vernon Knight

Address: Houston, TX **Phone:** (713) 798-5155 **Fax:** (713) 798-3125

Status: Designated **Designation Date:** 30-Apr-98 **Marketing Approval Date:**

Generic Name: Liposomal N-Acetylglucosminyl-N-Acetylmuramyl-L-Ala-D-isoGln-L-Ala-glycerolipalmitoyl **Trade Name:** ImmTher

Orphan Indication: Treatment of Ewing's sarcoma.

Sponsor: Endorex Corp. **Contact:** Dr. Rickey Wilson

Address: Lake Bluff, IL **Phone:** (847) 573-8990 **Fax:** (847) 573-9285

Status: Designated **Designation Date:** 10-Jun-98 **Marketing Approval Date:**

Generic Name: Liposomal N-Acetylglucosminyl-N-Acetylmuramyl-L-Ala-D-isoGln-L-Ala-glycerolipalmitoyl **Trade Name:** ImmTher

Orphan Indication: Treatment of osteosarcoma.

Sponsor: Endorex Corp. **Contact:** Dr. Rickey Wilson

Address: Lake Bluff, IL **Phone:** (847) 573-8990 **Fax:** (847) 573-9285

Status: Designated **Designation Date:** 10-Jun-98 **Marketing Approval Date:**

Generic Name: Liposomal nystatin **Trade Name:** Nyotran

Orphan Indication: Treatment of invasive fungal infections.

Sponsor: Aronex Pharmaceuticals, Inc. **Contact:** Dr. William Schary

Address: The Woodlands, TX **Phone:** (281) 367-1666 **Fax:** (281) 367-1676

Status: Designated **Designation Date:** 13-Jun-00 **Marketing Approval Date:**

Generic Name: Liposomal prostaglandin E1 injection
Trade Name:

Orphan Indication: Treatment of acute respiratory distress syndrome.
Sponsor: Liposome Company, Inc. **Contact:** Dr. James Boyle
Address: Princeton, NJ **Phone:** (609) 520-6557 **Fax:** (609) 452-1890
Status: Designated/Withdrawn **Designation Date:** 25-Apr-96 Marketing Approval Date:

Generic Name: Liposomal-cis-bis-neodecanoato-trans-R,R-1,2-diaminocyclohexane-Pt (II)
Trade Name:

Orphan Indication: Treatment of malignant mesothelioma.
Sponsor: Aronex Pharmaceuticals, Inc. **Contact:** Dr. William Schary
Address: The Woodlands, TX **Phone:** (281) 367-1666 **Fax:** (281) 367-1666
Status: Designated **Designation Date:** 01-Sep-99 Marketing Approval Date:

Generic Name: Liposome encapsulated recombinant interleukin-2
Trade Name:

Orphan Indication: Treatment of brain and CNS tumors.
Sponsor: Biomira USA, Inc. **Contact:** Ms. Jillian Castrucci
Address: Cranbury, NJ **Phone:** (609) 655-5300 **Fax:** (609) 655-1755
Status: Designated **Designation Date:** 25-Nov-91 Marketing Approval Date:

Generic Name: Liposome encapsulated recombinant interleukin-2
Trade Name:

Orphan Indication: Treatment of cancers of the kidney and renal pelvis.
Sponsor: Biomira USA, Inc. **Contact:** Ms. Jillian Castrucci
Address: Cranbury, NJ **Phone:** (609) 655-5300 **Fax:** (609) 655-1755
Status: Designated **Designation Date:** 20-Jun-94 Marketing Approval Date:

Generic Name: Lisofylline
Trade Name:

Orphan Indication: Treatment of patients undergoing induction therapy for acute myeloid leukemia.
Sponsor: Cell Therapeutics, Inc. **Contact:** Ms. Jennie Allewell
Address: Seattle, WA **Phone:** (206) 282-7100 **Fax:** 2062846206
Status: Designated **Designation Date:** 10-Jun-99 Marketing Approval Date:

Generic Name: Lodoxamide tromethamine **Trade Name:** Alomide Ophthalmic Solution

Orphan Indication: Treatment of vernal keratoconjunctivitis.
Sponsor: Alcon Laboratories, Inc. **Contact:** Dr. Robert Roehrs
Address: Fort Worth, TX **Phone:** (817) 551-8512 **Fax:** (817) 551-8512
Status: Designated/Approved **Designation Date:** 16-Oct-91 **Marketing Approval Date:** 23-Sep-93

Generic Name: Loxoribine
Trade Name:

Orphan Indication: Treatment of common variable immunodeficiency.
Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Jean O'connor
Address: Raritan, NJ **Phone:** (908) 704-5121 **Fax:** (908) 704-5121
Status: Designated/Withdrawn **Designation Date:** 24-Feb-92 Marketing Approval Date:

Generic Name: Lucinactant **Trade Name:** Surfaxin

Orphan Indication: Treatment of meconium aspiration syndrome in newborn infants.
Sponsor: Discovery Laboratories, Inc. **Contact:** Mr. Christopher Schaber
Address: Doylestown, PA **Phone:** (215) 340-4699 **Fax:** (215) 340-3940
Status: Designated **Designation Date:** 30-Jul-96 Marketing Approval Date:

Generic Name: Lucinactant **Trade Name:** Surfaxin

Orphan Indication: Treatment of acute respiratory distress syndrome in adults.
Sponsor: Discovery Laboratories, Inc. **Contact:** Mr. Christopher Schaber
Address: Doylestown, PA **Phone:** (215) 340-4699 **Fax:** (215) 340-3940
Status: Designated **Designation Date:** 17-Jul-95 Marketing Approval Date:

Generic Name: Lucinactant **Trade Name:** Surfaxin**Orphan Indication:** Treatment of respiratory distress syndrome in premature infants.**Sponsor:** Discovery Laboratories, Inc. **Contact:** Mr. Christopher Schaber**Address:** Doylestown, PA **Phone:** (215) 340-4699 **Fax:** (215) 340-3940**Status:** Designated **Designation Date:** 18-Oct-95 **Marketing Approval Date:****Generic Name:** Lysine acetylsalicylate injectable

Trade Name:

Orphan Indication: Treatment of pain and fever secondary to sickle cell disease crisis.**Sponsor:** G.D. Searle & Company **Contact:****Address:** , **Phone:** Fax:**Status:** Designated/Withdrawn **Designation Date:** 01-Aug-89 **Marketing Approval Date:****Generic Name:** Mafenide acetate solution **Trade Name:** Sulfamylon solution**Orphan Indication:** For use as an adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds.**Sponsor:** Mylan Laboratories, Inc. **Contact:** Mr. Frank Sisto**Address:** Morgantown, WV **Phone:** (304) 599-2595 **Fax:****Status:** Designated/Approved **Designation Date:** 18-Jul-90 **Marketing Approval Date:** 05-Jun-98**Generic Name:** Marijuana

Trade Name:

Orphan Indication: Treatment of HIV-associated wasting syndrome.**Sponsor:** Multidisciplinary Association for Psychedelic Studies, **Contact:** Mr. Rick Doblin Inc.**Address:** Belmont, MA **Phone:** (617) 484-8711 **Fax:** (617) 484-8427**Status:** Designated **Designation Date:** 25-May-99 **Marketing Approval Date:****Generic Name:** MART-1 adenoviral gene therapy for malignant melanoma

Trade Name:

Orphan Indication: Treatment of metastatic melanoma.**Sponsor:** Genzyme Corporation **Contact:** Mr. Robert Martin**Address:** Framingham, MA **Phone:** 5082713961 **Fax:** 5082712692**Status:** Designated **Designation Date:** 28-Mar-97 **Marketing Approval Date:****Generic Name:** Matrix metalloproteinase inhibitor **Trade Name:** Galardin**Orphan Indication:** Treatment of corneal ulcers.**Sponsor:** Glycomed, Inc **Contact:** Dr. Mary Treuhaft**Address:** Alameda, CA **Phone:** (510) 523-5555 **Fax:****Status:** Designated **Designation Date:** 05-Dec-91 **Marketing Approval Date:****Generic Name:** Mazindol **Trade Name:** Sanorex**Orphan Indication:** Treatment of Duchenne muscular dystrophy.**Sponsor:** Collipp, Platon J. M.D. **Contact:** Dr. Platon Collipp**Address:** Jesup, GA **Phone:** (912) 427-9378 **Fax:****Status:** Designated **Designation Date:** 08-Dec-86 **Marketing Approval Date:****Generic Name:** Mecamylamine **Trade Name:** Inversine**Orphan Indication:** Treatment of Tourette's syndrome.**Sponsor:** Layton Bioscience, Inc. **Contact:** Ms. Caire Lockey**Address:** Sunnyvale, CA **Phone:** 4086161034 **Fax:** 4086161005**Status:** Designated **Designation Date:** 14-Oct-98 **Marketing Approval Date:****Generic Name:** Mecasermin **Trade Name:** Myotrophin**Orphan Indication:** Treatment of amyotrophic lateral sclerosis.**Sponsor:** Cephalon, Inc. **Contact:** Mr. Paul Kirsch**Address:** West Chester, PA **Phone:** (610) 738-6122 **Fax:** (610) 344-0065**Status:** Designated **Designation Date:** 05-Aug-91 **Marketing Approval Date:****Generic Name:** Mecasermin

Trade Name:

Orphan Indication: Treatment of growth hormone insufficiency syndrome.
Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane
Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000
Status: Designated **Designation Date:** 12-Dec-95 **Marketing Approval Date:**

Generic Name: Medroxyprogesterone acetate **Trade Name:** Hematrol

Orphan Indication: Treatment of immune thrombocytopenic purpura.
Sponsor: InKine Pharmaceutical Company, Inc. **Contact:** Dr. Monroe Klein
Address: Blue Bell, PA **Phone:** 2152836866 **Fax:**
Status: Designated **Designation Date:** 22-Feb-01 **Marketing Approval Date:**

Generic Name: Mefloquine HCl **Trade Name:** Lariam

Orphan Indication: Prophylaxis of Plasmodium falciparum malaria which is resistant to other available drugs.
Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Jeannie-Marie Skinner
Address: Nutley, NJ **Phone:** (201) 235-5405 **Fax:**
Status: Designated/Approved **Designation Date:** 13-Apr-88 **Marketing Approval Date:** 02-May-89

Generic Name: Mefloquine HCl **Trade Name:** Mephaquin

Orphan Indication: Treatment of chloroquine-resistant Falciparummalaria.
Sponsor: Mepha AG **Contact:** Mr. Lorne Campbell
Address: Aesch Basel, Switzerland, CH **Phone:** (816) 221-4442 **Fax:**
Status: Designated **Designation Date:** 22-Jul-87 **Marketing Approval Date:**

Generic Name: Mefloquine HCl **Trade Name:** Mephaquin

Orphan Indication: Prevention of chloroquine-resistant Falciparum malaria.
Sponsor: Mepha AG **Contact:** Mr. Lorne Campbell
Address: Aesch Basel, Switzerland, CH **Phone:** (816) 221-4442 **Fax:**
Status: Designated **Designation Date:** 22-Jul-87 **Marketing Approval Date:**

Generic Name: Mefloquine HCl **Trade Name:** Lariam

Orphan Indication: Treatment of acute malaria due to Plasmodium falciparum and Plasmodium vivax.
Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Jeannie-Marie Skinner
Address: Nutley, NJ **Phone:** (201) 235-5405 **Fax:**
Status: Designated/Approved **Designation Date:** 13-Apr-88 **Marketing Approval Date:** 02-May-89

Generic Name: Megestrol acetate **Trade Name:** Megace

Orphan Indication: Treatment of patients with anorexia, cachexia, or significant weight loss ($\geq 10\%$ of baseline body weight) and confirmed diagnosis of AIDS.
Sponsor: Bristol-Myers Squibb Pharmaceutical Research **Contact:** Ms. Marygayle Ritzert
 Institute
Address: Evansville, IN **Phone:** (812) 429-5584 **Fax:**
Status: Designated/Approved **Designation Date:** 13-Apr-88 **Marketing Approval Date:** 10-Sep-93

Generic Name: Melanoma cell vaccine
 Trade Name:

Orphan Indication: Treatment of invasive melanoma.
Sponsor: Morton, Donald L. M.D. **Contact:** Monica Batra
Address: Santa Monica, CA **Phone:** 3105827426 **Fax:** 3105827022
Status: Designated **Designation Date:** 13-Oct-94 **Marketing Approval Date:**

Generic Name: Melanoma vaccine **Trade Name:** Melacine

Orphan Indication: Treatment of stage III - IV melanoma.
Sponsor: Ribi ImmunoChem Research, Inc. **Contact:** Ms. Kathleen Tomsu
Address: Hamilton, MT **Phone:** (406) 363-6214 **Fax:** (406) 363-6129
Status: Designated **Designation Date:** 20-Dec-89 **Marketing Approval Date:**

Generic Name: Melatonin
 Trade Name:

Orphan Indication: Treatment of circadian rhythm sleep disorders in blind people with no light perception.
Sponsor: Sack, Robert, M.D. **Contact:** Dr. Robert Sack
Address: Portland, OR **Phone:** (503) 494-6577 **Fax:**

Status: Designated **Designation Date:** 15-Nov-93 **Marketing Approval Date:**

Generic Name: Melphalan **Trade Name:** Alkeran for Injection

Orphan Indication: For use in hyperthermic regional limb perfusion to treat metastatic melanoma of the extremity.

Sponsor: Glaxo Wellcome Research and Development **Contact:** Mr. Douglas Jones

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 03-Mar-92 **Marketing Approval Date:**

Generic Name: Melphalan **Trade Name:** Alkeran For Injection

Orphan Indication: Treatment of patients with multiple myeloma for whom oral therapy is inappropriate.

Sponsor: Glaxo Wellcome Inc. **Contact:** Dr. Michael Dalton

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Withdrawn by OPD **Designation Date:** 24-Feb-92 **Marketing Approval Date:** 18-Nov-92

Generic Name: Meropenem **Trade Name:** Merrem IV

Orphan Indication: Management of acute pulmonary exacerbations, in cystic fibrosis patients, due to respiratory tract infection with susceptible organisms.

Sponsor: Zeneca Pharmaceuticals **Contact:** Mr. Gerald Limp

Address: Wilmington, DE **Phone:** (302) 886-8017 **Fax:** (302) 886-2822

Status: Designated **Designation Date:** 27-Apr-00 **Marketing Approval Date:**

Generic Name: Mesna **Trade Name:** Mesnex

Orphan Indication: For use as a prophylactic agent in reducing the incidence of ifosfamide-induced hemorrhagic cystitis.

Sponsor: Degussa Corporation **Contact:** Mr. Ralph Venhaus

Address: Ridgefield Park, NJ **Phone:** (201) 641-6100 **Fax:**

Status: Designated/Approved **Designation Date:** 14-Nov-85 **Marketing Approval Date:** 30-Dec-88

Generic Name: Mesna

Trade Name:

Orphan Indication: Inhibition of the urotoxic effects induced by oxazaphosphorine compounds such as cyclophosphamide.

Sponsor: Asta Medica, Inc. **Contact:** Ms. Roberta Tucker

Address: Tewksbury, MA **Phone:** (978) 851-5981 **Fax:** (978) 851-7346

Status: Designated **Designation Date:** 16-Dec-87 **Marketing Approval Date:**

Generic Name: Methionine/L-methionine

Trade Name:

Orphan Indication: Treatment of AIDS myelopathy.

Sponsor: Di Rocco, Alessandro M.D. **Contact:** Dr. Alessandro Di Rocco

Address: New York, NY **Phone:** (212) 844-8362 **Fax:** (212) 844-8710

Status: Designated **Designation Date:** 21-Aug-96 **Marketing Approval Date:**

Generic Name: Methotrexate **Trade Name:** Rheumatrex

Orphan Indication: Treatment of juvenile rheumatoid arthritis.

Sponsor: Wyeth-Ayerst Laboratories **Contact:** Mr. James O'Shaughnessy

Address: Philadelphia, PA **Phone:** (610) 902-3761 **Fax:** (610) 964-5973

Status: Designated/Withdrawn **Designation Date:** 23-Aug-93 **Marketing Approval Date:**

Generic Name: Methotrexate sodium **Trade Name:** Methotrexate

Orphan Indication: Treatment of osteogenic sarcoma.

Sponsor: Lederle Laboratories **Contact:** Dr. Vern De Vries

Address: Pearl River, NY **Phone:** (914) 732-5000 **Fax:**

Status: Designated/Approved **Designation Date:** 21-Oct-85 **Marketing Approval Date:** 07-Apr-88

Generic Name: Methotrexate with laurocapram **Trade Name:** Methotrexate/azone

Orphan Indication: Topical treatment of mycosis fungoides.

Sponsor: Durham Pharmaceuticals LLC **Contact:** Ms. Lynda Sutton

Address: Durham, NC **Phone:** (919) 361-2286 **Fax:** (919) 361-2290

Status: Designated **Designation Date:** 15-Oct-90 **Marketing Approval Date:**

Generic Name: Methoxsalen **Trade Name:** Uvadex**Orphan Indication:** For use in conjunction with the UVAR photopheresis system to treat graft versus host disease.**Sponsor:** Therakos, Inc. **Contact:** Ms. Peggy Schwartz**Address:** Exton, PA **Phone:** (610) 280-1021 **Fax:****Status:** Designated **Designation Date:** 14-Oct-98 **Marketing Approval Date:****Generic Name:** Methylalntrexone**Trade Name:****Orphan Indication:** Treatment of chronic opioid-induced constipation unresponsive to conventional therapy.**Sponsor:** University of Chicago **Contact:** Dr. Michael Roizen**Address:** Chicago, IL **Phone:** (312) 702-2545 **Fax:****Status:** Designated/Withdrawn by **Designation Date:** 17-Jun-96 **Marketing Approval Date:**

OPD

Generic Name: metreleptin**Trade Name:****Orphan Indication:** Treatment of leptin deficiency secondary to generalized lipodystrophy and partial familial lipodystrophy**Sponsor:** Amgen, Inc. **Contact:** Mr. Dean Waters**Address:** Thousand Oaks, CA **Phone:** 8054472638 **Fax:** 8053762014**Status:** Designated **Designation Date:** 22-Aug-01 **Marketing Approval Date:****Generic Name:** metreleptin**Trade Name:****Orphan Indication:** Treatment of metabolic disorders secondary to lipodystrophy**Sponsor:** Amgen, Inc., **Contact:** Mr. Dean Waters**Address:** Thousand Oaks, CA **Phone:** 8054472638 **Fax:** 8053762014**Status:** Designated **Designation Date:** 22-Aug-01 **Marketing Approval Date:****Generic Name:** Metronidazole **Trade Name:** Metrogel**Orphan Indication:** Treatment of perioral dermatitis.**Sponsor:** Galderma Laboratories, Inc. **Contact:** Ms. Christine Shank**Address:** Fort Worth, TX **Phone:** (817) 263-2600 **Fax:** (817) 263-2667**Status:** Designated **Designation Date:** 24-Oct-91 **Marketing Approval Date:****Generic Name:** Metronidazole (topical) **Trade Name:** Metrogel**Orphan Indication:** Treatment of acne rosacea.**Sponsor:** Galderma Laboratories, Inc. **Contact:** Ms. Christine Shank**Address:** Fort Worth, TX **Phone:** (817) 263-2600 **Fax:** (817) 263-2667**Status:** Designated/Approved **Designation Date:** 22-Oct-87 **Marketing Approval Date:** 22-Nov-88**Generic Name:** Metronidazole (topical) **Trade Name:** Flagyl**Orphan Indication:** Treatment of grade III and IV, anaerobically infected, decubitus ulcers.**Sponsor:** Searle **Contact:** Dr. Lynne Weissberger**Address:** Skokie, IL **Phone:** (847) 982-7469 **Fax:** (847) 982-8090**Status:** Designated/Withdrawn **Designation Date:** 24-Nov-87 **Marketing Approval Date:****Generic Name:** Microbubble contrast agent **Trade Name:** Filmix Neurosonographic Contrast Agent**Orphan Indication:** Intraoperative aid in the identification and localization of intracranial tumors.**Sponsor:** Cav-Con, Inc. **Contact:** Dr. Joseph D'Arrigo**Address:** Farmington, CT **Phone:** (860) 673-0507 **Fax:****Status:** Designated **Designation Date:** 16-Nov-90 **Marketing Approval Date:****Generic Name:** Midodrine HCl **Trade Name:** Amatine**Orphan Indication:** Treatment of patients with symptomatic orthostatic hypotension.**Sponsor:** Schier Ridgewood F.K.A. (Roberts **Contact:** Mr. Drew Karlan
Pharmaceutical Corp.)**Address:** Eatontown, NJ **Phone:** 8008282088 **Fax:****Status:** Designated/Approved **Designation Date:** 05-Dec-96 **Marketing Approval Date:** 06-Sep-96

Generic Name: Minocycline HCl	Trade Name: Minocin Intravenous
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Orphan Indication: Treatment of chronic malignant pleural effusion.

Sponsor: Lederle Laboratories Division **Contact:** Dr. Vern Devries

Address: Pearl River, NY **Phone:** (914) 732-5000 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 19-Jun-92 **Marketing Approval Date:**

Generic Name: Mitoguazone	Trade Name: apep
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Orphan Indication: Treatment of diffuse non-Hodgkin's lymphoma, including AIDS-related diffuse non-Hodgkin's lymphoma.

Sponsor: ILEX Oncology, Inc. **Contact:** Mr. Edward Martinez

Address: San Antonio, TX **Phone:** (210) 949-8270 **Fax:** (210) 949-8282

Status: Designated **Designation Date:** 18-Mar-94 **Marketing Approval Date:**

Generic Name: Mitolactol

Trade Name:

Orphan Indication: Treatment of recurrent invasive or metastatic squamous carcinoma of the cervix.

Sponsor: Biopharmaceutics, Inc. **Contact:** Dr. Stewart Ehrreich

Address: Bellport, NY **Phone:** (941) 561-2110 **Fax:** (941) 561-2009

Status: Designated **Designation Date:** 23-Jan-89 **Marketing Approval Date:**

Generic Name: Mitolactol

Trade Name:

Orphan Indication: As adjuvant therapy in the treatment of primary brain tumors.

Sponsor: Biopharmaceutics, Inc. **Contact:** Dr. Stewart Ehrreich

Address: Bellport, NY **Phone:** (941) 561-2110 **Fax:** (941) 561-2009

Status: Designated **Designation Date:** 12-Jul-95 **Marketing Approval Date:**

Generic Name: Mitomycin-C

Trade Name:

Orphan Indication: Treatment of refractory glaucoma as an adjunct to ab externo glaucoma surgery.

Sponsor: IOP Inc. **Contact:** Mr. Jason Malecka

Address: Costa Mesa, CA **Phone:** (714) 549-1185 **Fax:** (714) 549-0557

Status: Designated **Designation Date:** 20-Aug-93 **Marketing Approval Date:**

Generic Name: Mitoxantrone	Trade Name: Novantrone
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Orphan Indication: Treatment of secondary-progressive multiple sclerosis.

Sponsor: Immunex Corporation **Contact:** Mr. Mark Gauthier

Address: Seattle, WA **Phone:** 2063816266 **Fax:**

Status: Designated/Approved **Designation Date:** 13-Aug-99 **Marketing Approval Date:** 13-Oct-00

Generic Name: Mitoxantrone	Trade Name: Novantrone
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Orphan Indication: Treatment of hormone refractory prostate cancer.

Sponsor: Immunex Corporation **Contact:** Mr. Mark Gauthier

Address: Seattle, WA **Phone:** (206) 389-4066 **Fax:** (206) 587-0606

Status: Designated/Approved **Designation Date:** 21-Aug-96 **Marketing Approval Date:** 13-Nov-96

Generic Name: Mitoxantrone	Trade Name: Novantrone
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Orphan Indication: Treatment of progressive-relapsing multiple sclerosis.

Sponsor: Immunex Corporation **Contact:** Mr. Mark Gauthier

Address: Seattle, WA **Phone:** (206) 389-4066 **Fax:**

Status: Designated/Approved **Designation Date:** 13-Aug-99 **Marketing Approval Date:** 13-Oct-00

Generic Name: Mitoxantrone HCl	Trade Name: Novantrone
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Orphan Indication: Treatment of acute myelogenous leukemia, also referred to as acute nonlymphocytic leukemia.

Sponsor: Lederle Laboratories **Contact:** Dr. Vern DeVries

Address: Pearl River, NY **Phone:** (914) 732-5000 **Fax:**

Status: Designated/Approved **Designation Date:** 13-Jul-87 **Marketing Approval Date:** 23-Dec-87

Generic Name: MN14 monoclonal antibody to carcinoembryonic antigen	Trade Name: Cea-Cide
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Orphan Indication: For the treatment of small cell lung cancer.
Sponsor: Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz
Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-1103
Status: Designated **Designation Date:** 18-Sep-98 **Marketing Approval Date:**

Generic Name: MN14 monoclonal antibody to carcinoembryonic antigen **Trade Name:** Cea-Cide

Orphan Indication: Treatment of pancreatic cancer.
Sponsor: Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz
Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282
Status: Designated **Designation Date:** 24-Nov-98 **Marketing Approval Date:**

Generic Name: Modafinil **Trade Name:** Provigil

Orphan Indication: Treatment of excessive daytime sleepiness in narcolepsy.
Sponsor: Cephalon, Inc. **Contact:** Mr. Paul Kirsch
Address: West Chester, PA **Phone:** (610) 738-6122 **Fax:** (610) 344-0065
Status: Designated/Approved **Designation Date:** 15-Mar-93 **Marketing Approval Date:** 24-Dec-98

Generic Name: Molgramostim **Trade Name:** Leucomax

Orphan Indication: Treatment of AIDS patients with neutropenia due to the disease, AZTor ganciclovir.
Sponsor: Schering Corporation **Contact:** Dr. Alexander Giaquinto
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 24-Jan-89 **Marketing Approval Date:**

Generic Name: Molgramostim **Trade Name:** Leucomax

Orphan Indication: Treatment of aplastic anemia.
Sponsor: Schering Corporation **Contact:** Dr. Alexander Giaquinto
Address: Kenilworth, NJ **Phone:** (201) 298-4000 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 25-Sep-89 **Marketing Approval Date:**

Generic Name: Monoclonal Ab(murine) anti-idiotypic melanoma-associated antigen **Trade Name:** Melimmune

Orphan Indication: Treatment of invasive cutaneous melanoma.
Sponsor: IDEC Pharmaceuticals Corporation **Contact:** Ms. Alice Wei
Address: San Diego, CA **Phone:** (619) 458-8920 **Fax:** (619) 458-8450
Status: Designated/Withdrawn **Designation Date:** 19-Sep-94 **Marketing Approval Date:**

Generic Name: Monoclonal antibodies (murine or human) to B-cell lymphoma
Trade Name:

Orphan Indication: Treatment of B-cell lymphoma.
Sponsor: IDEC Pharmaceuticals Corporation **Contact:** Ms. Alice Wei
Address: San Diego, CA **Phone:** (619) 550-8500 **Fax:** (619) 550-8750
Status: Designated/Withdrawn **Designation Date:** 06-May-86 **Marketing Approval Date:**

Generic Name: Monoclonal antibodies PM-81 and AML-2-23
Trade Name:

Orphan Indication: For the exogenous depletion of CD14 and CD15 positive acute myeloid leukemic bone marrow cells from patients undergoing bone marrow transplantation.
Sponsor: Medarex, Inc. **Contact:** Dr. Randall Curnow
Address: Annandale, NJ **Phone:** (908) 713-1903 **Fax:** (908) 713-6002
Status: Designated **Designation Date:** 12-Mar-90 **Marketing Approval Date:**

Generic Name: Monoclonal antibody 17-1a **Trade Name:** Panorex

Orphan Indication: Treatment of pancreatic cancer.
Sponsor: Centocor, Inc. **Contact:** Mr. Martin Page
Address: Malvern, PA **Phone:** (215) 889-4786 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 04-Apr-88 **Marketing Approval Date:**

Generic Name: Monoclonal antibody for immunization against lupus nephritis
Trade Name:

Orphan Indication: Treatment of lupus nephritis.
Sponsor: VivoRx Autoimmune, Inc. **Contact:** Mr. Mitchall Clark

Address: Santa Monica, CA **Phone:** (310) 264-7768 **Fax:**
Status: Designated **Designation Date:** 07-Jan-93 **Marketing Approval Date:**

Generic Name: Monoclonal antibody PM-81
Trade Name:

Orphan Indication: Adjunctive treatment of acute myelogenous leukemia.
Sponsor: Medarex, Inc. **Contact:** Dr. Randall Curnow
Address: Bloomsbury, NJ **Phone:** 9084792400 **Fax:** 9084792401
Status: Designated **Designation Date:** 27-Jun-91 **Marketing Approval Date:**

Generic Name: Monoclonal antibody to cytomegalovirus (human)
Trade Name:

Orphan Indication: Treatment of cytomegalovirus retinitis in patients with AIDS.
Sponsor: Protein Design Labs, Inc. **Contact:** Dr. Daniel Levitt
Address: Mountain View, CA **Phone:** (650) 903-3700 **Fax:** (650) 903-3730
Status: Designated/Withdrawn **Designation Date:** 15-Nov-91 **Marketing Approval Date:**

Generic Name: Monoclonal antibody to cytomegalovirus (human)
Trade Name:

Orphan Indication: Prophylaxis of cytomegalovirus disease in patients undergoing solid organ transplantation.
Sponsor: Protein Design Labs, Inc. **Contact:** Dr. Ellen Wallace
Address: Mountain View, CA **Phone:** (415) 903-3950 **Fax:** (415) 903-3730
Status: Designated/Withdrawn **Designation Date:** 13-Sep-91 **Marketing Approval Date:**

Generic Name: Monoclonal antibody to hepatitis B virus (human)
Trade Name:

Orphan Indication: Prophylaxis of hepatitis B reinfection in patients undergoing liver transplantation secondary to end-stage chronic hepatitis B infection.
Sponsor: Protein Design Labs, Inc. **Contact:** Dr. Gene Mason
Address: Fremont, CA **Phone:** (510) 574-1553 **Fax:** (510) 574-1500
Status: Designated/Withdrawn **Designation Date:** 17-Jun-91 **Marketing Approval Date:**

Generic Name: Monoclonal antibody-B43.13 **Trade Name:** Ovarex MAb-B43.13

Orphan Indication: Treatment of epithelial ovarian cancer.
Sponsor: AltaRex US Corp. **Contact:** Ms. Marlene Booth
Address: Waltham, MA **Phone:** (781) 622-3790 **Fax:** (781) 672-0142
Status: Designated **Designation Date:** 25-Nov-96 **Marketing Approval Date:**

Generic Name: Monoclonal antiendotoxin antibody XMMEn-0e5
Trade Name:

Orphan Indication: Treatment of patients with gram-negative sepsis which has progressed to shock.
Sponsor: Pfizer, Inc. **Contact:** Dr. John Wolleben
Address: New York, NY **Phone:** (212) 573-3414 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 04-Nov-85 **Marketing Approval Date:**

Generic Name: Monolaurin **Trade Name:** Glylorin

Orphan Indication: Treatment of congenital primary ichthyosis.
Sponsor: Glaxo Wellcome Inc. **Contact:** Ms. Janice McKellar
Address: Research Triangle Park, NC **Phone:** (919) 483-3030 **Fax:** (919) 483-3012
Status: Designated **Designation Date:** 29-Apr-93 **Marketing Approval Date:**

Generic Name: Monoctanoic **Trade Name:** Moctanin

Orphan Indication: For dissolution of cholesterol gallstones retained in the common bile duct.
Sponsor: Ethitek Pharmaceuticals, Inc. **Contact:** Dr. Alan Raff
Address: Skokie, IL **Phone:** (708) 966-2200 **Fax:**
Status: Designated/Approved **Designation Date:** 30-May-84 **Marketing Approval Date:** 31-Oct-85

Generic Name: Morphine sulfate concentrate (preservative free) **Trade Name:** Infumorph

Orphan Indication: For use in microinfusion devices for intraspinal administration in the treatment of intractable chronic pain.

Sponsor: Elkins-Sinn, Inc. **Contact:** Ms. Thelma Hilibrand
Address: Cherry Hill, NJ **Phone:** (609) 424-3700 **Fax:**
Status: Designated/Approved **Designation Date:** 12-Jul-90 **Marketing Approval Date:** 19-Jul-91

Generic Name: MTC-DOX for Injection
Trade Name:

Orphan Indication: Treatment of hepatocellular carcinoma
Sponsor: FeRx Incorporated **Contact:** Ms. Caryn Peterson
Address: San Diego, CA **Phone:** 8586777788 **Fax:** 8586779898
Status: Designated **Designation Date:** 03-Jan-01 **Marketing Approval Date:**

Generic Name: Mucoid exopolysaccharide Pseudomonas hyperimmune globulin **Trade Name:** MEP IGIV

Orphan Indication: Treatment of pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis.
Sponsor: North American Biologicals, Inc. **Contact:** Dr. Lewis Pollack
Address: Rockville, MD **Phone:** (301) 770-3099 **Fax:** () -
Status: Designated/Withdrawn **Designation Date:** 09-Jan-91 **Marketing Approval Date:**

Generic Name: Mucoid exopolysaccharide Pseudomonas hyperimmune globulin **Trade Name:** MEP IGIV

Orphan Indication: Prevention of pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis.
Sponsor: North American Biologicals, Inc. **Contact:** Dr. Lewis Pollack
Address: Rockville, MD **Phone:** (301) 770-3099 **Fax:** () -
Status: Designated/Withdrawn **Designation Date:** 07-Nov-90 **Marketing Approval Date:**

Generic Name: Multi-vitamin infusion (neonatal formula)
Trade Name:

Orphan Indication: For establishment and maintenance of total parenteral nutrition in very low birth weight infants.
Sponsor: Astra Pharmaceuticals, L.P. **Contact:** Mr. Paul Alessandro
Address: Wayne, PA **Phone:** (508) 836-8404 **Fax:** (508) 366-7406
Status: Designated **Designation Date:** 12-Dec-89 **Marketing Approval Date:**

Generic Name: muramyltripeptide, phosphatidyl-ethanolamine encased in multi-lamellar liposomes
Trade Name:

Orphan Indication: Treatment of children and adolescent osteosarcoma
Sponsor: Jenner Biotherapies, Inc. **Contact:** Dr. Bruce Merchant
Address: Walworth, WI **Phone:** 7606343100 **Fax:** 7606343168
Status: Designated **Designation Date:** 05-Jun-01 **Marketing Approval Date:**

Generic Name: Murine MAb (Lym-1) and Iodine 131-I radiolabeled murine MAb (Lym-1) to human B-cell lymphoma **Trade Name:** Oncolym

Orphan Indication: Treatment of B-cell non-Hodgkin's lymphoma.
Sponsor: Berlex Laboratories **Contact:** Mr. Anthony Bourdakis
Address: Richmond, CA **Phone:** (510) 669-4469 **Fax:** (510) 262-7878
Status: Designated **Designation Date:** 27-Nov-98 **Marketing Approval Date:**

Generic Name: Murine MAb to polymorphic epithelial mucin, human milk fat globule I **Trade Name:** Theragyn

Orphan Indication: Adjuvant treatment of ovarian cancer.
Sponsor: Antisoma plc **Contact:** Ms. Nancy Smerkanich
Address: London W5 3QR, UK **Phone:** 6109138450 **Fax:** 6109138457
Status: Designated **Designation Date:** 22-Mar-99 **Marketing Approval Date:**

Generic Name: Mycobacterium avium sensitin RS-10
Trade Name:

Orphan Indication: For use in the diagnosis of invasive Mycobacterium avium disease in immunocompetent individuals.
Sponsor: Statens Seruminstitut **Contact:** Dr. C. Fordham Von Reyn
Address: Denmark, **Phone:** (603) 650-8840 **Fax:**
Status: Designated **Designation Date:** 11-Oct-95 **Marketing Approval Date:**

Generic Name: Myelin

Trade Name:

Orphan Indication: Treatment of multiple sclerosis.**Sponsor:** AutoImmune, Inc. **Contact:** Dr. Malcolm Fletcher**Address:** Lexington, MA **Phone:** (617) 860-0710 **Fax:** (617) 860-0705**Status:** Designated/Withdrawn **Designation Date:** 27-Jun-91 **Marketing Approval Date:****Generic Name:** N-acetyl-procainamide

Trade Name:

Orphan Indication: Prevention of life-threatening ventricular arrhythmias in patients with documented procainamide-induced lupus.**Sponsor:** NAPA of the Bahamas **Contact:** Dr. Barry Scherr**Address:** Dubuque, IA **Phone:** (319) 557-9684 **Fax:****Status:** Designated **Designation Date:** 10-Dec-96 **Marketing Approval Date:****Generic Name:** N-acetylcysteinate **Trade Name:** Nacystelyn Dry Powder Inhaler**Orphan Indication:** For the management of cystic fibrosis**Sponsor:** Galephar Pharmaceutical Research, Inc. **Contact:** Ms. Mimi Brennan**Address:** Juncos, PR **Phone:** 7877130340 **Fax:** 7877130344**Status:** Designated **Designation Date:** 27-Dec-00 **Marketing Approval Date:****Generic Name:** N-acetylgalactosamine-4-sulfatase, recombinant human

Trade Name:

Orphan Indication: Treatment of mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome).**Sponsor:** BioMarin Pharmaceutical, Inc. **Contact:** Mr. Matthew Patterson**Address:** Novato, CA **Phone:** (415) 884-6720 **Fax:** (415) 382-7889**Status:** Designated **Designation Date:** 17-Feb-99 **Marketing Approval Date:****Generic Name:** N-acetylprocainamide **Trade Name:** Napa**Orphan Indication:** To lower the defibrillation energy requirement sufficiently to allow automatic implantable cardioverter defibrillator therapy in those patients who could otherwise not use the device.**Sponsor:** Medco Research, Inc. **Contact:** Dr. Sam Teichman**Address:** Los Angeles, CA **Phone:** (213) 966-4155 **Fax:****Status:** Designated/Withdrawn **Designation Date:** 23-Mar-90 **Marketing Approval Date:****Generic Name:** Nafarelin acetate **Trade Name:** Synarel Nasal Solution**Orphan Indication:** Treatment of central precocious puberty.**Sponsor:** Syntex (USA), Inc. **Contact:** Dr. Michael Perry**Address:** Palo Alto, CA **Phone:** (415) 354-7453 **Fax:****Status:** Designated/Approved **Designation Date:** 20-Jul-88 **Marketing Approval Date:** 26-Feb-92**Generic Name:** Naltrexone HCl **Trade Name:** Trexan**Orphan Indication:** 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.**Sponsor:** DuPont Pharmaceuticals **Contact:** Mr. Edward Adams**Address:** Wilmington, DE **Phone:** (302) 992-5094 **Fax:****Status:** Designated/Approved **Designation Date:** 11-Mar-85 **Marketing Approval Date:** 30-Nov-84**Generic Name:** Natural human lymphoblastoid interferon-alpha

Trade Name:

Orphan Indication: Treatment of papillomavirus warts in the oral cavity of HIV positive patients.**Sponsor:** Amarillo Biosciences, Inc. **Contact:** Mr. Martin Cummins**Address:** Amarillo, TX **Phone:** 8063761741 **Fax:** 8063769301**Status:** Designated **Designation Date:** 10-Aug-00 **Marketing Approval Date:****Generic Name:** Natural human lymphoblastoid interferon-alpha

Trade Name:

Orphan Indication: Treatment of Behcet's disease.**Sponsor:** Amarillo Biosciences, Inc. **Contact:** Dr. Philip Fox**Address:** Amarillo, TX **Phone:** (301) 320-8200 **Fax:** (301) 320-3884**Status:** Designated **Designation Date:** 18-Jan-00 **Marketing Approval Date:**

Generic Name: NDROGE

Trade Name:

Orphan Indication: Treatment of postanoxic intention myoclonus.**Sponsor:** WATSON Laboratories, Inc. **Contact:** Ms. Joyce Anne Del Gaudio**Address:** Copiaque, NY **Phone:** (516) 842-8383 **Fax:** (516) 842-8630**Status:** Designated **Designation Date:** 01-Nov-84 Marketing Approval Date:**Generic Name:** Nebacumab**Trade Name:** Centoxin**Orphan Indication:** Treatment of patients with gram-negative bacteremia which has progressed to endotoxin shock.**Sponsor:** Centocor, Inc. **Contact:** Mr. Martin Page**Address:** Malvern, PA **Phone:** (610) 651-6000 **Fax:****Status:** Designated **Designation Date:** 01-Oct-86 Marketing Approval Date:**Generic Name:** Neurotrophin-1

Trade Name:

Orphan Indication: Treatment of motor neuron disease/amyotrophic lateral sclerosis.**Sponsor:** Ericsson, Arthur Dale, M.D. **Contact:** Dr. Arthur Ericsson**Address:** Houston, TX **Phone:** (713) 790-9590 **Fax:****Status:** Designated **Designation Date:** 13-Sep-94 Marketing Approval Date:**Generic Name:** NG-29**Trade Name:** Somatrel**Orphan Indication:** Diagnostic measure of the capacity of the pituitary gland to release growth hormone.**Sponsor:** Ferring Laboratories, Inc. **Contact:** Mr. Isidoro Nudelman**Address:** Suffern, NY **Phone:** (888) 793-6367 **Fax:****Status:** Designated **Designation Date:** 08-Aug-89 Marketing Approval Date:**Generic Name:** Nifedipine

Trade Name:

Orphan Indication: Treatment of interstitial cystitis.**Sponsor:** Fleischmann, Jonathan M.D. **Contact:** Dr. John Fleischmann**Address:** Cleveland, OH **Phone:** (216) 459-4257 **Fax:****Status:** Designated **Designation Date:** 13-Jun-91 Marketing Approval Date:**Generic Name:** Nitazoxanide**Trade Name:** Cryptaz**Orphan Indication:** Treatment of cryptosporidiosis.**Sponsor:** Romark Laboratories, L.C. **Contact:** Mr. Marc Ayers**Address:** Tampa, FL **Phone:** (813) 282-8544 **Fax:** (813) 282-4910**Status:** Designated **Designation Date:** 12-Dec-96 Marketing Approval Date:**Generic Name:** nitazoxanide**Trade Name:** Cryptaz**Orphan Indication:** Treatment for intestinal amebiasis**Sponsor:** Romark Laboratories, L.C. **Contact:** Mr. Marc Ayers**Address:** Tampa, FL **Phone:** **Fax:****Status:** Designated **Designation Date:** 23-Oct-01 Marketing Approval Date:**Generic Name:** Nitisinone**Trade Name:** Orfadin**Orphan Indication:** Treatment of tyrosinemia type 1.**Sponsor:** Swedish Orphan AB **Contact:** Dr. Ronald Leonardi**Address:** Sweden, SE **Phone:** (858) 586-0751 **Fax:** (858) 586-1108**Status:** Designated **Designation Date:** 16-May-95 Marketing Approval Date:**Generic Name:** Nitisinone**Trade Name:** Orfadin**Orphan Indication:** Treatment of alkaptonuria**Sponsor:** Swedish Orphan AB **Contact:** Dr. Ronald Leonardi**Address:** Stockholm, Sweden, **Phone:** 8585860751 **Fax:** 8585861108**Status:** Designated **Designation Date:** 19-Oct-01 Marketing Approval Date:**Generic Name:** Nitric oxide**Trade Name:** INOmax

Orphan Indication: Treatment of persistent pulmonary hypertension in the newborn.

Sponsor: INO Therapeutics, Inc. **Contact:** Mr. Richard Williams

Address: Clinton, NJ **Phone:** (908) 238-6622 **Fax:** (908) 238-0779

Status: Designated/Approved **Designation Date:** 22-Jun-93 **Marketing Approval Date:** 23-Dec-99

Generic Name: Nitric oxide

Trade Name:

Orphan Indication: Treatment of acute respiratory distress syndrome in adults.

Sponsor: INO Therapeutics, Inc. **Contact:** Mrs. Priya Jambhekar

Address: Clinton, NJ **Phone:** (908) 604-7722 **Fax:**

Status: Designated **Designation Date:** 10-Jul-95 **Marketing Approval Date:**

Generic Name: Nitroprusside

Trade Name:

Orphan Indication: Treatment and prevention of cerebral vasospasm following subarachnoid hemorrhage.

Sponsor: Thomas, MD, Jeffrey Evan **Contact:** Dr. Jeffrey Thomas

Address: Philadelphia, PA **Phone:** (215) 928-7000 **Fax:** (215) 928-7007

Status: Designated **Designation Date:** 21-Feb-01 **Marketing Approval Date:**

Generic Name: nolatrexed **Trade Name:** THYMITAQ

Orphan Indication: Treatment of hepatocellular carcinoma

Sponsor: Zarix, Inc. **Contact:** Mr. Keith Ryan

Address: Berwyn, PA **Phone:** 6102407710 **Fax:** 6102407999

Status: Designated **Designation Date:** 18-Oct-01 **Marketing Approval Date:**

Generic Name: Novel Acting Thrombolytic (NAT)

Trade Name:

Orphan Indication: Treatment of peripheral arterial occlusion (PAO)

Sponsor: Amgen, Inc. **Contact:** Ms. Paula Adams

Address: Thousand Oaks, CA **Phone:** 8054476658 **Fax:** 8054997232

Status: Designated **Designation Date:** 26-Jan-01 **Marketing Approval Date:**

Generic Name: NZ-1002

Trade Name:

Orphan Indication: Enzyme replacement therapy in patients with all subtypes of Mucopolysaccharidosis I.

Sponsor: Novazyme Pharmaceuticals, Inc. **Contact:** Mr. Anthony McKinney

Address: Oklahoma City, OK **Phone:** 4052718144 **Fax:** 4052718154

Status: Designated **Designation Date:** 11-Apr-01 **Marketing Approval Date:**

Generic Name: Octreotide **Trade Name:** Sandostatin LAR

Orphan Indication: Treatment of severe diarrhea and flushing associated with malignant carcinoid tumors.

Sponsor: Novartis Pharmaceuticals Corporation **Contact:** Ms. Eileen Ryan

Address: East Hanover, NJ **Phone:** (973) 781-7661 **Fax:** (973) 781-6325

Status: Designated/Approved **Designation Date:** 24-Aug-98 **Marketing Approval Date:** 25-Nov-98

Generic Name: Octreotide **Trade Name:** Sandostatin LAR

Orphan Indication: Treatment of diarrhea associated with vasoactive intestinal peptide tumors (VIPoma).

Sponsor: Novartis Pharmaceuticals Corporation **Contact:** Ms. Eileen Ryan

Address: East Hanover, NJ **Phone:** (973) 781-7661 **Fax:** (973) 781-6325

Status: Designated/Approved **Designation Date:** 24-Aug-98 **Marketing Approval Date:** 25-Nov-98

Generic Name: Octreotide **Trade Name:** Sandostatin LAR

Orphan Indication: Treatment of acromegaly.

Sponsor: Novartis Pharmaceuticals Corporation **Contact:** Ms. Eileen Ryan

Address: East Hanover, NJ **Phone:** (973) 781-7661 **Fax:** (973) 781-6325

Status: Designated/Approved **Designation Date:** 24-Aug-98 **Marketing Approval Date:** 25-Nov-98

Generic Name: Ofloxacin **Trade Name:** Ocuflax Ophthalmic Solution

Orphan Indication: Treatment of bacterial corneal ulcers.

Sponsor: Allergan, Inc. **Contact:** Ms. Elizabeth Bancroft

Address: Irvine, CA **Phone:** (714) 752-4500 **Fax:**

Status: Designated/Approved **Designation Date:** 18-Apr-91 **Marketing Approval Date:** 22-May-96

Generic Name: oglufanide disodium

Trade Name:

Orphan Indication: Treatment of ovarian cancer

Sponsor: Cytran, Inc. **Contact:** Mr. Paul Ketteridge

Address: Kirkland, WA **Phone:** 4258895812 **Fax:** 4258223644

Status: Designated **Designation Date:** 24-Sep-01 **Marketing Approval Date:**

Generic Name: OM 401 **Trade Name:** Drepanol

Orphan Indication: Prophylactic treatment of sickle cell disease.

Sponsor: Omex International, Inc. **Contact:** Mr. S. Murphy Murthy

Address: Houston, TX **Phone:** (713) 438-6057 **Fax:**

Status: Designated **Designation Date:** 24-Oct-91 **Marketing Approval Date:**

Generic Name: Omega-3 (n-3) polyunsaturated fatty acid with all double bonds in the cis configuration

Trade Name:

Orphan Indication: Prevention of organ graft rejection.

Sponsor: Research Triangle Pharmaceuticals **Contact:** Mr. Peter Vaccari

Address: Durham, NC **Phone:** (301) 309-1260 **Fax:** () -

Status: Designated **Designation Date:** 22-Nov-95 **Marketing Approval Date:**

Generic Name: Omega-3 (n-3) polyunsaturated fatty acids **Trade Name:** Omacor

Orphan Indication: Treatment of IgA nephropathy.

Sponsor: Pronova Biocare, AS **Contact:** Dr. Ron Leonardi

Address: Norway, **Phone:** 8585860751 **Fax:** 8585861108

Status: Designated **Designation Date:** 04-May-00 **Marketing Approval Date:**

Generic Name: Oncorad Ov103

Trade Name:

Orphan Indication: Treatment of ovarian cancer.

Sponsor: Cytogen Corporation **Contact:** Mr. Michael Tripani

Address: Princeton, NJ **Phone:** (609) 987-6450 **Fax:**

Status: Designated **Designation Date:** 24-Apr-90 **Marketing Approval Date:**

Generic Name: Oprelvekin **Trade Name:** Neumega

Orphan Indication: Prevention of severe chemotherapy-induced thrombocytopenia.

Sponsor: Genetics Institute, Inc. **Contact:** Ms. Ingrid Bartinique

Address: Cambridge, MA **Phone:** (617) 498-8652 **Fax:** (617) 498-8876

Status: Designated/Approved **Designation Date:** 17-Dec-96 **Marketing Approval Date:** 25-Nov-97

Generic Name: Orgotein for injection

Trade Name:

Orphan Indication: Treatment of familial amyotrophic lateral sclerosis associated with a mutation of the gene (on chromosome 21q) for copper, zinc superoxide dismutase.

Sponsor: Oxis International, Inc. **Contact:** Dr. Timothy Rodell

Address: Portland, OR **Phone:** (503) 283-3911 **Fax:** (503) 283-4058

Status: Designated/Withdrawn **Designation Date:** 22-Dec-94 **Marketing Approval Date:**

Generic Name: Oxaliplatin

Trade Name:

Orphan Indication: Treatment of ovarian cancer.

Sponsor: Debio Pharm S.A. **Contact:** Mr. N. Peter Kostopulos

Address: Lausanne 9 Switzerland, CH **Phone:** (703) 751-7777 **Fax:**

Status: Designated **Designation Date:** 06-Oct-92 **Marketing Approval Date:**

Generic Name: Oxandrolone **Trade Name:** Hepandrin

Orphan Indication: Treatment of moderate/severe acute alcoholic hepatitis in the presence of moderate protein calorie malnutrition.

Sponsor: Bio-Technology General Corp. **Contact:** Ms. Briti Kundo
Address: Iselin, NJ **Phone:** (908) 603-7911 **Fax:** (908) 632-8844
Status: Designated/Withdrawn **Designation Date:** 18-Mar-94 **Marketing Approval Date:**

Generic Name: Oxandrolone **Trade Name:** Oxandrin

Orphan Indication: Treatment of patients with Duchenne's muscular dystrophy and Becker's muscular dystrophy.

Sponsor: Bio-Technology General Corp. **Contact:** Ms. Annmarie Petraglia
Address: Iselin, NJ **Phone:** (908) 603-7911 **Fax:** (908) 632-8844
Status: Designated **Designation Date:** 22-Apr-97 **Marketing Approval Date:**

Generic Name: Oxandrolone **Trade Name:** Oxandrin

Orphan Indication: Treatment of short stature associated with Turner's syndrome.

Sponsor: Bio-Technology General Corp. **Contact:** Ms. Annmarie Petraglia
Address: Iselin, NJ **Phone:** (703) 603-7911 **Fax:** (908) 632-8844
Status: Designated/Withdrawn **Designation Date:** 05-Jul-90 **Marketing Approval Date:**

Generic Name: Oxandrolone

Trade Name:

Orphan Indication: Treatment of constitutional delay of growth and puberty.

Sponsor: Bio-Technology General Corp. **Contact:** Ms. Annmarie Petraglia
Address: Iselin, NJ **Phone:** (908) 632-8800 **Fax:** (908) 632-8844
Status: Designated/Withdrawn **Designation Date:** 05-Oct-90 **Marketing Approval Date:**

Generic Name: Oxandrolone **Trade Name:** Oxandrin

Orphan Indication: Adjunctive therapy for AIDS patients suffering from HIV-wasting syndrome.

Sponsor: Bio-Technology General Corp. **Contact:** Ms. Briti Kundo
Address: Iselin, NJ **Phone:** 7326328800 **Fax:** (732) 632-8844
Status: Designated **Designation Date:** 06-Sep-91 **Marketing Approval Date:**

Generic Name: Oxybate **Trade Name:** Xyrem

Orphan Indication: Treatment of narcolepsy.

Sponsor: Orphan Medical, Inc. **Contact:** Dr. Dayton Reardan
Address: Minnetonka, MN **Phone:** (612) 513-6969 **Fax:** (612) 541-9209
Status: Designated **Designation Date:** 07-Nov-94 **Marketing Approval Date:**

Generic Name: Oxymorphone **Trade Name:** Numorphan H.P.

Orphan Indication: For relief of severe intractable pain in narcotic-tolerant patients.

Sponsor: DuPont Merck Pharmaceutical Company **Contact:** Mr. Edward Adams
Address: Wilmington, DE **Phone:** (302) 992-5094 **Fax:**
Status: Designated **Designation Date:** 19-Mar-85 **Marketing Approval Date:**

Generic Name: Oxypurinol

Trade Name:

Orphan Indication: Treatment of hyperuricemia in patients intolerant to allopurinol.

Sponsor: ILEX Oncology, Inc. **Contact:** Mr. Edward Martinez
Address: San Antonio, TX **Phone:** (210) 949-8270 **Fax:** (210) 949-8282
Status: Designated **Designation Date:** 09-Nov-98 **Marketing Approval Date:**

Generic Name: P1, P4-Di(uridine 5'-tetrphosphate), tetrasodium salt

Trade Name:

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: Inspire Pharmaceuticals, Inc. **Contact:** Dr. Donald Kellerman
Address: Durham, NC **Phone:** (919) 941-9777 **Fax:** (919) 941-9797
Status: Designated/Withdrawn **Designation Date:** 27-Oct-98 **Marketing Approval Date:**

Generic Name: p1-(uridine 5'-)-p4-(2'-deoxycytidine 5'-) tetrphosphate, tetrasodium salt

Trade Name:

Orphan Indication: For the treatment of cystic fibrosis

Sponsor: Inspire Pharmaceuticals, Inc. **Contact:** Dr. Donald Kellerman
Address: Durham, NC **Phone:** 9199419777 **Fax:** 9194748507

Status: Designated **Designation Date:** 07-Mar-01 **Marketing Approval Date:**

Generic Name: Paclitaxel **Trade Name:** Taxol

Orphan Indication: Treatment of AIDS-related Kaposi's sarcoma.

Sponsor: Bristol-Myers Squibb Pharmaceutical Research **Contact:** Ms. Cheryl Anderson
Institute

Address: Wallingford, CT **Phone:** (203) 284-6083 **Fax:** (203) 284-7630

Status: Designated/Approved **Designation Date:** 25-Mar-97 **Marketing Approval Date:** 04-Aug-97

Generic Name: Paclitaxel **Trade Name:** Paxene

Orphan Indication: Treatment of AIDS-related Kaposi's sarcoma.

Sponsor: Baker Norton Pharmaceuticals, Inc. **Contact:** Dr. John Howes

Address: Miami, FL **Phone:** (305) 575-6326 **Fax:**

Status: Designated **Designation Date:** 15-Apr-97 **Marketing Approval Date:**

Generic Name: Papain, trypsin, and chymotrypsin **Trade Name:** Wobe-Mugos

Orphan Indication: Treatment of multiple myeloma.

Sponsor: Marlyn Nutraceuticals, Inc. **Contact:** Mr. Edward Allera

Address: Scottsdale, AZ **Phone:** (202) 887-4080 **Fax:**

Status: Designated **Designation Date:** 21-Dec-98 **Marketing Approval Date:**

Generic Name: Papaverine topical gel

Trade Name:

Orphan Indication: Treatment of sexual dysfunction in spinal cord injury patients.

Sponsor: Pharmedic Company **Contact:** Dr. Ragab El-Rashidy

Address: Wheeling, IL **Phone:** (708) 215-6603 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 06-Feb-92 **Marketing Approval Date:**

Generic Name: Parovirus B19 (recombinant VP1 and VP2; S.frugiperda cells) vaccine **Trade Name:** MEDI-491

Orphan Indication: Prevention of transient aplastic crisis in patients with sickle cell anemia.

Sponsor: MedImmune, Inc. **Contact:** Dr. Peter Patriarca

Address: Gaithersburg, MD **Phone:** 2406324229 **Fax:** 3015274200

Status: Designated **Designation Date:** 07-May-99 **Marketing Approval Date:**

Generic Name: Patul-end

Trade Name:

Orphan Indication: Treatment of patulous eustachian tube.

Sponsor: Ear Foundation **Contact:** Dr. Joseph DiBartolomeo

Address: Santa Barbara, CA **Phone:** (805) 563-1111 **Fax:** (805) 563-2277

Status: Designated **Designation Date:** 18-Feb-97 **Marketing Approval Date:**

Generic Name: PEG-glucocerebrosidase **Trade Name:** Lysodase

Orphan Indication: For use as chronic enzyme replacement therapy in patients with Gaucher's disease who are deficient in glucocerebrosidase.

Sponsor: National Institute of Mental Health, NIH **Contact:** Dr. Edward Ginns

Address: Bethesda, MD **Phone:** (908) 980-4500 **Fax:** (908) 980-5911

Status: Designated **Designation Date:** 09-Dec-92 **Marketing Approval Date:**

Generic Name: PEG-interleukin-2

Trade Name:

Orphan Indication: Treatment of primary immunodeficiencies associated with T-cell defects.

Sponsor: Chiron Corporation **Contact:** Dr. Gwen Fyfe

Address: Emeryville, CA **Phone:** (510) 655-8730 **Fax:**

Status: Designated **Designation Date:** 01-Feb-90 **Marketing Approval Date:**

Generic Name: Pegademase bovine **Trade Name:** Adagen

Orphan Indication: For enzyme replacement therapy for ADA deficiency in patients with severe combined immunodeficiency.

Sponsor: Enzon, Inc. **Contact:** Mr. Brian Bollwage

Address: Piscataway, NJ **Phone:** (908) 980-4500 **Fax:** (908) 980-5911

Status: Designated/Approved **Designation Date:** 29-May-84 **Marketing Approval Date:** 21-Mar-90

Generic Name: Pegaspargase **Trade Name:** Oncaspar

Orphan Indication: Treatment of acute lymphocytic leukemia.

Sponsor: Enzon, Inc. **Contact:** Mr. Brian Bollwage

Address: Piscataway, NJ **Phone:** (908) 980-4500 **Fax:** (908) 980-5911

Status: Designated/Approved **Designation Date:** 20-Oct-89 **Marketing Approval Date:** 01-Feb-94

Generic Name: Peginterferon alfa-2a **Trade Name:** PEGASYS

Orphan Indication: Treatment of chronic myelogenous leukemia.

Sponsor: Hoffman-La Roche Inc. **Contact:** Mr. Mark Hope

Address: Nutley, NJ **Phone:** (973) 562-2926 **Fax:** (973) 562-3700

Status: Designated **Designation Date:** 30-Sep-99 **Marketing Approval Date:**

Generic Name: Peginterferon alfa-2a **Trade Name:** PEGASYS

Orphan Indication: Treatment of renal cell carcinoma.

Sponsor: Hoffman-La Roche Inc. **Contact:** Ms. Loni da Silva

Address: Nutley, NJ **Phone:** (973) 562-3674 **Fax:** (973) 562-3700

Status: Designated **Designation Date:** 13-Jul-98 **Marketing Approval Date:**

Generic Name: Pegvisomant **Trade Name:** Somavert

Orphan Indication: Treatment of acromegaly.

Sponsor: Sensus Corporation **Contact:** Dr. Robert Davis

Address: Austin, TX **Phone:** (512) 476-0270 **Fax:** (512) 476-3327

Status: Designated **Designation Date:** 24-Jun-97 **Marketing Approval Date:**

Generic Name: Pegylated arginine deiminase **Trade Name:** Melanoid

Orphan Indication: Treatment of invasive malignant melanoma.

Sponsor: Phoenix Pharmacologics, Inc. **Contact:** Dr. John Bomalaski

Address: Exton, PA **Phone:** (610) 688-6056 **Fax:** (610) 524-6384

Status: Designated **Designation Date:** 12-Apr-99 **Marketing Approval Date:**

Generic Name: Pegylated arginine deiminase **Trade Name:** Hepacid

Orphan Indication: Treatment of hepatocellular carcinoma.

Sponsor: Phoenix Pharmacologics, Inc. **Contact:** Dr. John Bomalaski

Address: Exton, PA **Phone:** (610) 524-7710 **Fax:** (610) 524-6384

Status: Designated **Designation Date:** 26-Mar-99 **Marketing Approval Date:**

Generic Name: Pegylated recombinant human megakaryocyte growth and development factor **Trade Name:** MEGAGEN

Orphan Indication: For reducing the period of thrombocytopenia in patients undergoing hematopoietic stem cell transplantation.

Sponsor: Amgen, Inc. **Contact:** Mr. Ralph Smalling

Address: Thousand Oaks, CA **Phone:** (805) 447-3058 **Fax:** (805) 447-3058

Status: Designated **Designation Date:** 20-Oct-97 **Marketing Approval Date:**

Generic Name: Peldesine

Trade Name:

Orphan Indication: Treatment of cutaneous T-cell lymphoma.

Sponsor: BioCryst Pharmaceuticals, Inc. **Contact:** Mr. Lance Lang

Address: Birmingham, AL **Phone:** (205) 444-4635 **Fax:** (205) 444-4640

Status: Designated **Designation Date:** 05-Oct-93 **Marketing Approval Date:**

Generic Name: pemetrexed disodium **Trade Name:** Alimta

Orphan Indication: Treatment of malignant pleural mesothelioma

Sponsor: Eli Lilly and Company **Contact:** Mr. John Worzalla

Address: Indianapolis, IN **Phone:** 3172765052 **Fax:** 3172761652

Status: Designated **Designation Date:** 28-Aug-01 **Marketing Approval Date:**

Generic Name: Pentamidine isethionate
Trade Name:

Orphan Indication: Treatment of Pneumocystis carinii pneumonia.
Sponsor: Aventis Behring L.L.C. **Contact:** Ms. Carol Marchione
Address: King of Prussia, PA **Phone:** 6108784026 **Fax:**
Status: Designated **Designation Date:** 29-Oct-84 **Marketing Approval Date:**

Generic Name: Pentamidine isethionate **Trade Name:** Nebupent

Orphan Indication: Prevention of Pneumocystis carinii pneumonia in patients at high risk of developing this disease.
Sponsor: Fujisawa USA, Inc. **Contact:** Dr. Jerry Johnson
Address: Deerfield, IL **Phone:** (847) 317-8800 **Fax:** (847) 317-7286
Status: Designated/Approved **Designation Date:** 12-Jan-88 **Marketing Approval Date:** 15-Jun-89

Generic Name: Pentamidine isethionate **Trade Name:** Pentam 300

Orphan Indication: Treatment of Pneumocystis carinii pneumonia.
Sponsor: Fujisawa USA, Inc. **Contact:** Dr. Jerry Johnson
Address: Deerfield, IL **Phone:** (847) 317-8800 **Fax:** (847) 317-7286
Status: Designated/Approved **Designation Date:** 28-Feb-84 **Marketing Approval Date:** 16-Oct-84

Generic Name: Pentamidine isethionate (inhalation) **Trade Name:** Pneumopent

Orphan Indication: Prevention of Pneumocystis carinii pneumonia in patients at high risk of developing this disease.
Sponsor: Fisons Corporation **Contact:** Ms. Susan Raymond
Address: Rochester, NY **Phone:** (716) 475-9000 **Fax:**
Status: Designated **Designation Date:** 05-Oct-87 **Marketing Approval Date:**

Generic Name: Pentastarch **Trade Name:** Pentaspan

Orphan Indication: As an adjunct in leukapheresis to improve the harvesting and increase the yield of leukocytes by centrifugal means.
Sponsor: Du Pont Pharmaceuticals **Contact:** Mr. Edward Adams
Address: Wilmington, DE **Phone:** (302) 992-5094 **Fax:**
Status: Designated/Approved **Designation Date:** 28-Aug-85 **Marketing Approval Date:** 19-May-87

Generic Name: Pentosan polysulfate sodium **Trade Name:** Elmiron

Orphan Indication: Treatment of interstitial cystitis.
Sponsor: Alza Corporation **Contact:** Ms. Mirka Dunn
Address: Palo Alto, CA **Phone:** (650) 564-2524 **Fax:** (650) 564-2581
Status: Designated/Approved **Designation Date:** 07-Aug-85 **Marketing Approval Date:** 26-Sep-96

Generic Name: Pentostatin **Trade Name:** Nipent

Orphan Indication: Treatment of patients with chronic lymphocytic leukemia.
Sponsor: SuperGen, Inc. **Contact:** Dr. Sam Boddapati
Address: Dublin, CA **Phone:** 9255600100 **Fax:** 9255516472
Status: Designated **Designation Date:** 29-Jan-91 **Marketing Approval Date:**

Generic Name: Pentostatin **Trade Name:** Nipent

Orphan Indication: Treatment of peripheral T-cell lymphomas.
Sponsor: SuperGen, Inc. **Contact:** Dr. Audrey Jakubowski
Address: Dublin, CA **Phone:** 9255600100 **Fax:** 9255516472
Status: Designated **Designation Date:** 24-Nov-99 **Marketing Approval Date:**

Generic Name: Pentostatin **Trade Name:** Nipent

Orphan Indication: Treatment of cutaneous T-cell lymphoma.
Sponsor: SuperGen, Inc. **Contact:** Dr. Sam Boddapati
Address: Dublin, CA **Phone:** 9255600100 **Fax:** 9255516472
Status: Designated **Designation Date:** 27-Mar-98 **Marketing Approval Date:**

Generic Name: Pentostatin for injection **Trade Name:** Nipent

Orphan Indication: Treatment of hairy cell leukemia.

Sponsor: SuperGen, Inc. **Contact:** Dr. Sam Boddapati

Address: Dublin, CA **Phone:** 9255600100 **Fax:** 9255516472

Status: Designated/Approved **Designation Date:** 10-Sep-87 **Marketing Approval Date:** 11-Oct-91

Generic Name: Perflubron **Trade Name:** LiquiVent

Orphan Indication: Treatment of acute respiratory distress disease (ARDS) in adults

Sponsor: Alliance Pharmaceutical Corp. **Contact:** Dr. Mark Wedel

Address: San Diego, CA **Phone:** 8584105112 **Fax:**

Status: Designated **Designation Date:** 26-Apr-01 **Marketing Approval Date:**

Generic Name: Perfosfamide **Trade Name:** Pergamid

Orphan Indication: For use in the ex-vivo treatment of autologous bone marrow and subsequent reinfusion in patients with acute myelogenous leukemia, also referred to as acute nonlymphocytic leukemia.

Sponsor: Scios Nova, Inc. **Contact:** Ellen Martin

Address: Mountain View, CA **Phone:** (415) 966-1550 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 04-Dec-89 **Marketing Approval Date:**

Generic Name: Pergolide **Trade Name:** Permax

Orphan Indication: Treatment of Tourette's syndrome.

Sponsor: Sallee, Floyd R. M.D., Ph.D. **Contact:** Dr. Floyd Sallee

Address: Charleston, SC **Phone:** (803) 792-5443 **Fax:** (803) 792-7352

Status: Designated **Designation Date:** 20-Nov-97 **Marketing Approval Date:**

Generic Name: Phenylacetate

Trade Name:

Orphan Indication: For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma.

Sponsor: Elan Pharmaceutical Research Corp. **Contact:** Mr. Roger Wiley

Address: Gainesville, GA **Phone:** (770) 534-8239 **Fax:** (770) 534-8247

Status: Designated **Designation Date:** 06-Mar-98 **Marketing Approval Date:**

Generic Name: Phenylalanine ammonia-lyase **Trade Name:** Phenylase

Orphan Indication: Treatment of hyperphenylalaninemia.

Sponsor: Ibex Technologies, Inc. **Contact:** Dr. Jan Charles Horrow

Address: Canada H4P 1P7, CA **Phone:** 6104074200 **Fax:** 6104474270

Status: Designated **Designation Date:** 08-Mar-95 **Marketing Approval Date:**

Generic Name: Phenylbutyrate

Trade Name:

Orphan Indication: Treatment of acute promyelocytic leukemia.

Sponsor: Elan Corporation **Contact:** Mr. Roger Wiley

Address: Gainesville, GA **Phone:** (770) 538-6360 **Fax:** (770) 531-0835

Status: Designated **Designation Date:** 19-Jan-00 **Marketing Approval Date:**

Generic Name: Phosphocysteamine

Trade Name:

Orphan Indication: Treatment of cystinosis.

Sponsor: Medea Research Laboratories **Contact:** Ms. Olga Lockhart

Address: Port Jefferson, NY **Phone:** (516) 331-7718 **Fax:**

Status: Designated **Designation Date:** 12-Sep-88 **Marketing Approval Date:**

Generic Name: physostigmine salicylate **Trade Name:** Antilirium

Orphan Indication: Treatment of Friedreich's and other inherited ataxias.

Sponsor: Forest Pharmaceuticals, Inc. **Contact:** Dr. Michael Rosen

Address: New York, NY **Phone:** (212) 421-7850 **Fax:**

Status: Designated **Designation Date:** 16-Jan-85 **Marketing Approval Date:**

Generic Name: Pilocarpine **Trade Name:** Salagen

Orphan Indication: Treatment of xerostomia induced by radiation therapy for head and neck cancer.

Sponsor: MGI Pharma, Inc. **Contact:** Dr. Jo Gustafson

Address: Bloomington, MN **Phone:** (612) 346-4722 **Fax:** (612) 346-4800

Status: Designated/Approved **Designation Date:** 24-Sep-90 **Marketing Approval Date:** 22-Mar-94

Generic Name: Pilocarpine HCl **Trade Name:** Salagen

Orphan Indication: Treatment of xerostomia and keratoconjunctivitis sicca in Sjogren's syndrome patients.

Sponsor: MGI Pharma, Inc. **Contact:** Dr. Jo Gustafson

Address: Bloomington, MN **Phone:** (612) 346-4722 **Fax:** (612) 346-4800

Status: Designated/Approved **Designation Date:** 28-Feb-92 **Marketing Approval Date:** 11-Feb-98

Generic Name: Piracetam **Trade Name:** Nootropil

Orphan Indication: Treatment of myoclonus.

Sponsor: UCB Pharma, Inc. **Contact:** Ms. Kim Christopher

Address: Smyrna, GA **Phone:** (770) 437-5645 **Fax:** (770) 437-5507

Status: Designated **Designation Date:** 02-Oct-87 **Marketing Approval Date:**

Generic Name: Piritrexim isethionate

Trade Name:

Orphan Indication: Treatment of infections caused by *Pneumocystis carinii*, *Toxoplasma gondii*, and *Mycobacterium avium-intracellulare*.

Sponsor: Burroughs Wellcome Company **Contact:** Dr. Michael Dalton

Address: Research Triangle Park, NC **Phone:** (919) 315-4453 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 13-Jun-88 **Marketing Approval Date:**

Generic Name: Polifeprosan 20 with carmustine **Trade Name:** Gliadel

Orphan Indication: Treatment of malignant glioma.

Sponsor: Guilford Pharmaceuticals, Inc. **Contact:** Mr. Ross Laderman

Address: Baltimore, MD **Phone:** (410) 631-6306 **Fax:** (410) 631-6338

Status: Designated/Approved **Designation Date:** 13-Dec-89 **Marketing Approval Date:** 23-Sep-96

Generic Name: Poloxamer 188

Trade Name:

Orphan Indication: Treatment of vasospasm in subarachnoid hemorrhage patients following surgical repair of a ruptured cerebral aneurysm.

Sponsor: CytRx Corporation **Contact:** Dr. R. Martin Emanuele

Address: Norcross, GA **Phone:** (770) 368-9500 **Fax:**

Status: Designated **Designation Date:** 05-Aug-97 **Marketing Approval Date:**

Generic Name: Poloxamer 188 **Trade Name:** Flocor

Orphan Indication: Treatment of sickle cell crisis.

Sponsor: CytRx Corporation **Contact:** Ms. Margaret Valnoski

Address: Norcross, GA **Phone:** (609) 799-7580 **Fax:** (609) 799-4148

Status: Designated **Designation Date:** 27-Jun-89 **Marketing Approval Date:**

Generic Name: Poloxamer 188 **Trade Name:** Florcor

Orphan Indication: Treatment of severe burns requiring hospitalization.

Sponsor: CytRx Corporation **Contact:** Ms. Margaret Valnoski

Address: Norcross, GA **Phone:** (609) 799-7580 **Fax:** (609) 799-4148

Status: Designated **Designation Date:** 22-Feb-90 **Marketing Approval Date:**

Generic Name: Poloxamer 331 **Trade Name:** Protox

Orphan Indication: Initial therapy of toxoplasmosis in patients with AIDS.

Sponsor: CytRx Corporation **Contact:** Dr. R. Martin Emanuele

Address: Norcross, GA **Phone:** (770) 453-0107 **Fax:** (770) 448-3357

Status: Designated **Designation Date:** 21-Mar-91 **Marketing Approval Date:**

Generic Name: Poly I: poly C12U **Trade Name:** Ampligen

Orphan Indication: Treatment of renal cell carcinoma.

Sponsor: Hemispherx Biopharma, Inc. **Contact:** Dr. David Strayer

Address: Philadelphia, PA **Phone:** (215) 988-0080 **Fax:** (215) 988-1739
Status: Designated **Designation Date:** 20-May-91 **Marketing Approval Date:**

Generic Name: Poly I: poly C12U **Trade Name:** Ampligen

Orphan Indication: Treatment of chronic fatigue syndrome.
Sponsor: Hemispherx Biopharma, Inc. **Contact:** Dr. David Strayer
Address: Philadelphia, PA **Phone:** (215) 988-0080 **Fax:** (215) 988-1739
Status: Designated **Designation Date:** 09-Dec-93 **Marketing Approval Date:**

Generic Name: Poly I: poly C12U **Trade Name:** Ampligen

Orphan Indication: Treatment of invasive metastatic melanoma (stage IIb, III, IV).
Sponsor: Hemispherx Biopharma, Inc. **Contact:** Dr. David Strayer
Address: Philadelphia, PA **Phone:** (215) 988-0080 **Fax:** (215) 988-1739
Status: Designated **Designation Date:** 09-Dec-93 **Marketing Approval Date:**

Generic Name: Poly I: poly C12U **Trade Name:** Ampligen

Orphan Indication: Treatment of AIDS.
Sponsor: Hemispherx Biopharma, Inc. **Contact:** Dr. David Strayer
Address: Philadelphia, PA **Phone:** (215) 988-0080 **Fax:** (215) 988-1739
Status: Designated **Designation Date:** 19-Jul-88 **Marketing Approval Date:**

Generic Name: Poly-ICLC
Trade Name:

Orphan Indication: Treatment of primary brain tumors.
Sponsor: Salazar, Andres M. M.D. and Levy, Hilton B. Ph.D. **Contact:** Dr. Andres Salazar
Address: Washington, DC **Phone:** (202) 782-6345 **Fax:**
Status: Designated **Designation Date:** 17-Mar-97 **Marketing Approval Date:**

Generic Name: Polyethylene glycol (PEG)-uricase
Trade Name:

Orphan Indication: To control the clinical consequences of hyperuricemia in patients with severe gout in whom conventional therapy is contraindicated or has been ineffective.
Sponsor: Bio-Technology General Corporation **Contact:** Briti Kundu
Address: Iselin, NJ **Phone:** (732) 632-8800 **Fax:** (732) 321-1705
Status: Designated **Designation Date:** 21-Feb-01 **Marketing Approval Date:**

Generic Name: Polyethylene glycol-modified uricase **Trade Name:** Zurase

Orphan Indication: Prophylaxis of hyperuricemia in cancer patients prone to develop tumor lysis syndrome during chemotherapy.
Sponsor: Phoenix Pharmacologics, Inc. **Contact:** Dr. John Bomalaski
Address: Exton, PA **Phone:** (610) 524-7710 **Fax:** (610) 524-6384
Status: Designated **Designation Date:** 14-Sep-99 **Marketing Approval Date:**

Generic Name: Polyethylene glycol-modified uricase **Trade Name:** Zurase

Orphan Indication: Treatment of tumor lysis syndrome in cancer patients undergoing chemotherapy.
Sponsor: Phoenix Pharmacologics, Inc. **Contact:** Dr. John Bomalaski
Address: Exton, PA **Phone:** (610) 524-7710 **Fax:** (610) 524-6384
Status: Designated **Designation Date:** 21-Dec-98 **Marketing Approval Date:**

Generic Name: Polymeric oxygen
Trade Name:

Orphan Indication: Treatment of sickle cell anemia.
Sponsor: Capmed USA **Contact:** Mr. James Caplan
Address: Bryn Mawr, PA **Phone:** (610) 394-1172 **Fax:** (610) 394-1175
Status: Designated **Designation Date:** 25-Mar-92 **Marketing Approval Date:**

Generic Name: Porcine fetal neural dopaminergic cells and/or precursors aseptically prepared and coated with anti-MHC-I Ab for intracerebral implantation **Trade Name:** NeuroCell-PD

Orphan Indication: Treatment of Hoehn and Yahr stage 4 and 5 Parkinson's disease.
Sponsor: Diacrin, Inc. **Contact:** Mr. E. Michael Egan
Address: Cambridge, MA **Phone:** (617) 242-9100 **Fax:** (617) 242-0070

Status: Designated **Designation Date:** 17-Dec-96 **Marketing Approval Date:**

Generic Name: Porcine fetal neural dopaminergic cells and/or precursors aseptically prepared for intracerebral implantation.	Trade Name: NeuroCell-PD
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Orphan Indication: Treatment of Hoehn and Yahr stage 4 and 5 Parkinson's disease.

Sponsor: Diacrin, Inc. **Contact:** Mr. E. Michael Egan

Address: Cambridge, MA **Phone:** (617) 242-9100 **Fax:** (617) 242-0070

Status: Designated **Designation Date:** 17-Dec-96 **Marketing Approval Date:**

Generic Name: Porcine fetal neural gabaergic cells and/or precursors aseptically prepared and coated with anti-MHC-1 Ab for intracerebral implantation	Trade Name: NeuroCell-HD
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Orphan Indication: Treatment of Huntington's disease.

Sponsor: Diacrin, Inc. **Contact:** Mr. E. Michael Egan

Address: Cambridge, MA **Phone:** (617) 242-9100 **Fax:** (617) 242-0070

Status: Designated **Designation Date:** 10-Dec-96 **Marketing Approval Date:**

Generic Name: Porcine fetal neural gabaergic cells and/or precursors aseptically prepared for intracerebral implantation for Huntington's disease.	Trade Name: NeuroCell-HD
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Orphan Indication: Treatment of Huntington's disease.

Sponsor: Diacrin, Inc. **Contact:** Mr. E. Michael Egan

Address: Cambridge, MA **Phone:** (617) 242-9100 **Fax:** (617) 242-0070

Status: Designated **Designation Date:** 10-Dec-96 **Marketing Approval Date:**

Generic Name: Porcine Sertoli cells aseptically prepared for intracerebral co-implantation with fetal neural tissue	Trade Name: N-Graft
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Orphan Indication: Treatment of Hoehn and Yahr stage four and five Parkinson's disease.

Sponsor: Titan Pharmaceuticals, Inc. **Contact:** Dr. Richard Allen

Address: Somerville, NJ **Phone:** (908) 429-9880 **Fax:** (908) 429-9096

Status: Designated **Designation Date:** 24-Jun-97 **Marketing Approval Date:**

Generic Name: porfimer	Trade Name: Photofrin
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Orphan Indication: For the ablation of High-Grade Dysplasia in Barrett's Esophagus in patients who are not considered to be candidates for esophagectomy

Sponsor: Axcan Scandipharm Inc. **Contact:** Dr. Becky Prokipcak

Address: Birmingham, AL **Phone:** 8478378824 **Fax:** 8478278825

Status: Designated **Designation Date:** 19-Oct-01 **Marketing Approval Date:**

Generic Name: Porfimer sodium	Trade Name: Photofrin
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Orphan Indication: For the photodynamic therapy of patients with primary or recurrent obstructing (either partially or completely) esophageal carcinoma.

Sponsor: QLT Phototherapeutics, Inc. **Contact:** Mr. Louis Gura

Address: Pearl River, NY **Phone:** (914) 732-5000 **Fax:**

Status: Designated/Approved **Designation Date:** 06-Jun-89 **Marketing Approval Date:** 27-Dec-95

Generic Name: Porfimer sodium	Trade Name: Photofrin
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Orphan Indication: For the photodynamic therapy of patients with transitional cell carcinoma in situ of the urinary bladder.

Sponsor: QLT Phototherapeutics, Inc. **Contact:** Mr. Louis Gura

Address: Pearl River, NY **Phone:** (914) 732-5000 **Fax:**

Status: Designated **Designation Date:** 15-Nov-89 **Marketing Approval Date:**

Generic Name: Porfiromycin	Trade Name: Promycin
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Orphan Indication: Treatment of head and neck cancer.

Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc. **Contact:** Dr. David Brill

Address: Ridgefield, CT **Phone:** 2037984340 **Fax:** 2037916262

Status: Designated **Designation Date:** 19-Sep-95 **Marketing Approval Date:**

Generic Name: Porfiromycin	Trade Name: Promycin
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Orphan Indication: Treatment of cervical cancer.

Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc. **Contact:** Dr. David Brill

Address: Ridgefield, CT **Phone:** 2037984310 **Fax:** 2037916262

Status: Designated **Designation Date:** 13-Mar-97 **Marketing Approval Date:**

Generic Name: Potassium citrate **Trade Name:** Urocit-K

Orphan Indication: Prevention of uric acid nephrolithiasis.

Sponsor: University of Texas Health Science Center at Dallas **Contact:** Dr. Charles Y.C. Pak

Address: Dallas, TX **Phone:** (214) 688-2100 **Fax:**

Status: Designated/Approved **Designation Date:** 01-Nov-84 **Marketing Approval Date:** 30-Aug-85

Generic Name: Potassium citrate **Trade Name:** Urocit-K

Orphan Indication: Prevention of calcium renal stones in patients with hypocitraturia.

Sponsor: University of Texas Health Science Center at Dallas **Contact:** Dr. Charles Y.C. Pak

Address: Dallas, TX **Phone:** (214) 688-2100 **Fax:**

Status: Designated/Approved **Designation Date:** 16-Sep-85 **Marketing Approval Date:** 30-Aug-85

Generic Name: Potassium citrate **Trade Name:** Urocit-K

Orphan Indication: For avoidance of the complication of calcium stone formation in patients with uric lithiasis.

Sponsor: University of Texas Health Science Center at Dallas **Contact:** Dr. Charles Y.C. Pak

Address: Dallas, TX **Phone:** (214) 688-2100 **Fax:**

Status: Designated/Approved **Designation Date:** 12-Sep-85 **Marketing Approval Date:** 30-Aug-85

Generic Name: Potassium citrate and citric acid

Trade Name:

Orphan Indication: For the dissolution and control of uric acid and cysteine calculi in the urinary tract.

Sponsor: Willen Drug Company **Contact:**

Address: , **Phone:** **Fax:**

Status: Designated/Withdrawn **Designation Date:** 14-Feb-86 **Marketing Approval Date:**

Generic Name: Pr-122 (redox-phenytoin)

Trade Name:

Orphan Indication: For the emergency rescue treatment of status epilepticus, grand mal type.

Sponsor: Pharmos **Contact:** John Howes

Address: Alachua, FL **Phone:** (904) 462-1210 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 05-Jul-90 **Marketing Approval Date:**

Generic Name: PR-225 (redox-acyclovir)

Trade Name:

Orphan Indication: Treatment of herpes simplex encephalitis in individuals afflicted with AIDS.

Sponsor: Pharmos **Contact:** John Howes

Address: Alachua, FL **Phone:** (904) 462-1210 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 29-May-90 **Marketing Approval Date:**

Generic Name: PR-239 (redox penicillin G)

Trade Name:

Orphan Indication: Treatment of AIDS associated neurosyphilis.

Sponsor: Pharmos **Contact:** John Howes

Address: Alachua, FL **Phone:** (904) 462-1210 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 23-May-90 **Marketing Approval Date:**

Generic Name: Pr-320 (moleculsol-carbamazepine)

Trade Name:

Orphan Indication: For the emergency rescue treatment of status epilepticus, grand mal type.

Sponsor: Pharmos **Contact:** John Howes

Address: Alachua, FL **Phone:** (904) 462-1210 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 20-Jul-90 **Marketing Approval Date:**

Generic Name: Pramiracetam Sulfate

Trade Name:

Orphan Indication: For the management of cognitive dysfunction and enhancement of antidepressant activity associated with electroconvulsive therapy.

Sponsor: Cambridge Neuroscience, Inc. **Contact:** Lisa Burns
Address: Cambridge, MA **Phone:** (919) 361-2286 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 04-Nov-91 **Marketing Approval Date:**

Generic Name: Praziquantel
Trade Name:

Orphan Indication: Treatment of neurocysticercosis.
Sponsor: EM Pharmaceuticals, Inc. **Contact:**
Address: , **Phone:** **Fax:**
Status: Designated/Withdrawn **Designation Date:** 18-Apr-88 **Marketing Approval Date:**

Generic Name: Prednimustine **Trade Name:** Sterecyt

Orphan Indication: Treatment of malignant non-Hodgkin's lymphomas.
Sponsor: Pharmacia Inc. **Contact:** Dr. Daniel Mannix
Address: Columbus, OH **Phone:** (614) 764-8100 **Fax:** (614) 761-8102
Status: Designated/Withdrawn **Designation Date:** 17-Jun-85 **Marketing Approval Date:**

Generic Name: Primaquine phosphate
Trade Name:

Orphan Indication: For use in combination with clindamycin hydrochloride in the treatment of Pneumocystis carinii pneumonia associated with AIDS.
Sponsor: Sanofi Winthrop, Inc. **Contact:** Dr. Gregory Torre
Address: New York, NY **Phone:** (212) 551-4000 **Fax:**
Status: Designated **Designation Date:** 23-Jul-93 **Marketing Approval Date:**

Generic Name: Progesterone
Trade Name:

Orphan Indication: Establishment and maintenance of pregnancy in women undergoing in vitro fertilization or embryo transfer procedures.
Sponsor: Watson Laboratories, Inc. **Contact:** Mr. Ron Lapre
Address: Corona, CA **Phone:** (909) 270-1400 **Fax:** (909) 270-1096
Status: Designated **Designation Date:** 22-Dec-94 **Marketing Approval Date:**

Generic Name: Propamidine isethionate 0.1% ophthalmic solution **Trade Name:** Brolene

Orphan Indication: Treatment of acanthamoeba keratitis.
Sponsor: Bausch & Lomb **Contact:** Ms. Carol Rose
Address: Tampa, FL **Phone:** (813) 975-7775 **Fax:** (813) 975-7770
Status: Designated/Withdrawn **Designation Date:** 10-Mar-88 **Marketing Approval Date:**

Generic Name: Prostaglandin E1 enol ester (AS-013)
Trade Name:

Orphan Indication: Treatment of Fontaine Stage IV chronic critical limb ischemia.
Sponsor: Welfide International Corporation **Contact:** Ms. Karen Cha
Address: Los Angeles, CA **Phone:** 6265688645 **Fax:** 6265688667
Status: Designated **Designation Date:** 12-Jun-98 **Marketing Approval Date:**

Generic Name: Prostaglandin E1 in lipid emulsion **Trade Name:** Lipo-PGE1

Orphan Indication: Treatment of ischemic ulceration of the lower limbs due to peripheral arterial disease.
Sponsor: Alpha Therapeutic Corporation **Contact:** Ms. M. Sue Preston
Address: Los Angeles, CA **Phone:** (213) 227-7580 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 10-Sep-96 **Marketing Approval Date:**

Generic Name: Protein C concentrate **Trade Name:** Protein C Concentrate (human) Vapor Heated, Immuno

Orphan Indication: For use in the prevention and treatment of purpura fulminans in meningococcemia.
Sponsor: Immuno Clinical Research Corp. **Contact:** Ms. Marianne Kunschak
Address: New York, NY **Phone:** (212) 759-3875 **Fax:** (212) 751-4971
Status: Designated/Withdrawn **Designation Date:** 22-Apr-93 **Marketing Approval Date:**

Generic Name: Protein C concentrate **Trade Name:** Protein C Concentrate (human) Vapor Heated, Immuno

Orphan Indication: For replacement therapy in congenital protein C deficiency for the prevention and treatment of thrombosis, pulmonary emboli, and purpura fulminans.

Sponsor: Baxter Healthcare Corporation **Contact:** Ms. Arlene Vidor
Address: Glendale, CA **Phone:** (818) 507-5523 **Fax:** (818) 507-5596
Status: Designated **Designation Date:** 23-Jun-92 **Marketing Approval Date:**

Generic Name: Protein C concentrate **Trade Name:** Protein C Concentrate (human) Vapor Heated, Immuno

Orphan Indication: 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.

Sponsor: Immuno Clinical Research Corp. **Contact:** Ms. Marianne Kunschak
Address: New York, NY **Phone:** (212) 759-3875 **Fax:** (212) 751-4971
Status: Designated **Designation Date:** 19-Jun-92 **Marketing Approval Date:**

Generic Name: Protirelin

Trade Name:

Orphan Indication: Prevention of infant respiratory distress syndrome associated with prematurity.

Sponsor: UCB Pharma, Inc. **Contact:** Dr. Diane Vandeputte
Address: Smyrna, GA **Phone:** (770) 437-5559 **Fax:** (770) 437-5507
Status: Designated/Withdrawn **Designation Date:** 24-Aug-93 **Marketing Approval Date:**

Generic Name: Protirelin injection

Trade Name:

Orphan Indication: Treatment of amyotrophic lateral sclerosis.

Sponsor: Abbott Laboratories **Contact:**
Address: , **Phone:** Fax:
Status: Designated/Withdrawn **Designation Date:** 10-Jan-85 **Marketing Approval Date:**

Generic Name: Pulmonary surfactant replacement

Trade Name:

Orphan Indication: Prevention and treatment of infant respiratory distress syndrome.

Sponsor: Scios Nova, Inc. **Contact:** Ms. Karen Harder
Address: Mountain View, CA **Phone:** (415) 966-1550 **Fax:** (415) 968-2438
Status: Designated/Withdrawn **Designation Date:** 05-Dec-88 **Marketing Approval Date:**

Generic Name: Pulmonary surfactant replacement, porcine **Trade Name:** Curosurf

Orphan Indication: For the treatment and prevention of respiratory distress syndrome in premature infants.

Sponsor: Dey Laboratories **Contact:** Ms. Kim Carneal
Address: Napa, CA **Phone:** (707) 224-3200 **Fax:** 7072241364
Status: Designated/Approved **Designation Date:** 02-Aug-93 **Marketing Approval Date:** 18-Nov-99

Generic Name: Purified extract of Pseudomonas aeruginosa **Trade Name:** ImmuDyn

Orphan Indication: Treatment of immune thrombocytopenia purpura where it is required to increase platelet counts.

Sponsor: DynaGen, Inc. **Contact:** Mr. Peter Mione
Address: Cambridge, MA **Phone:** (617) 491-2527 **Fax:** (617) 354-3902
Status: Designated **Designation Date:** 22-Sep-97 **Marketing Approval Date:**

Generic Name: Purified type II collagen **Trade Name:** Colloral

Orphan Indication: Treatment of juvenile rheumatoid arthritis.

Sponsor: AutoImmune, Inc. **Contact:** Mr. J Bernardy
Address: Lexington, MA **Phone:** (781) 860-0710 **Fax:** (781) 860-0705
Status: Designated **Designation Date:** 09-Feb-95 **Marketing Approval Date:**

Generic Name: pVGI.1(VEGF2)

Trade Name:

Orphan Indication: Treatment of thromboangiitis obliterans.

Sponsor: Vascular Genetics, Inc. **Contact:** Mr. Peter Vaccari
Address: Durham, NC **Phone:** (301) 309-1260 **Fax:** (301) 309-8470
Status: Designated **Designation Date:** 09-Nov-99 **Marketing Approval Date:**

Generic Name: Pyruvate

Trade Name:

Orphan Indication: Treatment of interstitial lung disease.
Sponsor: Cellular Sciences, Inc **Contact:** Dr. Ronald Amen
Address: Flemington, NJ **Phone:** 7146399839 **Fax:** 7146396250
Status: Designated **Designation Date:** 21-Feb-01 Marketing Approval Date:

Generic Name: Quinacrine hydrochloride
Trade Name:

Orphan Indication: For prevention of recurrence of pneumothorax in patients at high risk of recurrence.
Sponsor: Lyphomed, Inc. **Contact:**
Address: , **Phone:** Fax:
Status: Designated/Withdrawn **Designation Date:** 17-Oct-84 Marketing Approval Date:

Generic Name: Radiolabeled monoclonal antibody to CD22 antigen on B-cells **Trade Name:** LymphoCIDE

Orphan Indication: Treatment of non-Hodgkin's lymphoma.
Sponsor: Immunomedics, Inc. **Contact:** Dr. Irene Wei
Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282
Status: Designated **Designation Date:** 13-Jul-98 Marketing Approval Date:

Generic Name: Recombinant bactericidal/permeability-increasing protein **Trade Name:** Neuprex

Orphan Indication: Treatment of severe meningococcal disease.
Sponsor: Xoma Corporation **Contact:** Mr. Dan Cafaro
Address: Berkeley, CA **Phone:** (510) 644-1170 **Fax:** (510) 644-0539
Status: Designated **Designation Date:** 22-Jun-98 Marketing Approval Date:

Generic Name: Recombinant glycine2-human glucagon-like peptide-2
Trade Name:

Orphan Indication: Treatment of short bowel syndrome.
Sponsor: NPS Allelix Corp. **Contact:** Dr. Susan Peers
Address: L4V 1V7 Canada, CA **Phone:** 9056770831 **Fax:** 9056779595
Status: Designated **Designation Date:** 29-Jun-00 Marketing Approval Date:

Generic Name: Recombinant human acid alpha-glucosidase
Trade Name:

Orphan Indication: Treatment of glycogen storage disease type II.
Sponsor: Genzyme Corporation **Contact:** Dr. Alexander Kuta
Address: Framingham, MA **Phone:** 5082702138 **Fax:** 5082712692
Status: Designated **Designation Date:** 19-Aug-97 Marketing Approval Date:

Generic Name: recombinant human alpha-1 antitrypsin
Trade Name:

Orphan Indication: Treatment of cystic fibrosis.
Sponsor: PPL Therapeutics (Scotland) Limited **Contact:** Dr. Julian Cooper
Address: EH25 9PP Scotland, GB **Phone:** (540) 961-5559 **Fax:** (540) 961-7958
Status: Designated **Designation Date:** 06-Mar-98 Marketing Approval Date:

Generic Name: recombinant human alpha-1 antitrypsin (rAAT)
Trade Name:

Orphan Indication: To delay progression of chronic obstructive pulmonary disease resulting from AAT deficiency-mediated emphysema and bronchiectasis
Sponsor: Baxter Healthcare Corporation **Contact:** Dr. James L'Italien
Address: Glendale, CA **Phone:** 8185504469 **Fax:** 8185504714
Status: Designated **Designation Date:** 28-Aug-01 Marketing Approval Date:

Generic Name: Recombinant Human Alpha-Fetoprotein (rhAFP)
Trade Name:

Orphan Indication: Treatment of myasthenia gravis
Sponsor: Atlantic Biopharmaceuticals, Inc. **Contact:** Dr. Ann Rose
Address: Cambridge, MA **Phone:** 7037576947 Fax:
Status: Designated **Designation Date:** 22-Feb-01 Marketing Approval Date:

Generic Name: Recombinant human antithrombin III
Trade Name:

Orphan Indication: Treatment of antithrombin III dependent heparin resistance requiring anticoagulation.

Sponsor: AT III LLC **Contact:** Dr. Alex Kuta

Address: Framingham, MA **Phone:** (508) 270-2138 **Fax:**

Status: Designated **Designation Date:** 06-Apr-00 Marketing Approval Date:

Generic Name: Recombinant human C1-esterase inhibitor

Trade Name:

Orphan Indication: Prophylactic treatment of angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.

Sponsor: Pharming N.V. **Contact:** Mr. Charles Morin

Address: Belgium, BE **Phone:** (415) 957-0101 **Fax:** (415) 957-5905

Status: Designated **Designation Date:** 23-Feb-99 Marketing Approval Date:

Generic Name: Recombinant human C1-esterase inhibitor

Trade Name:

Orphan Indication: Treatment of (acute attacks of) angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.

Sponsor: Pharming N.V. **Contact:** Mr. Charles Morin

Address: Belgium, BE **Phone:** (415) 957-0101 **Fax:** (415) 957-5905

Status: Designated **Designation Date:** 23-Feb-99 Marketing Approval Date:

Generic Name: Recombinant human CD4 immunoglobulin G

Trade Name:

Orphan Indication: Treatment of AIDS resulting from infection with HIV-1.

Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane

Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000

Status: Designated **Designation Date:** 30-Aug-90 Marketing Approval Date:

Generic Name: Recombinant human Clara Cell 10kDa protein

Trade Name:

Orphan Indication: Prevention of neonatal bronchopulmonary dysplasia in premature neonates with respiratory distress syndrome.

Sponsor: Claragen, Inc. **Contact:** Mr. Mark Zimmer

Address: College Park, MD **Phone:** (301) 405-8593 **Fax:** (301) 405-4989

Status: Designated **Designation Date:** 13-Jul-98 Marketing Approval Date:

Generic Name: recombinant human endostatin protein

Trade Name:

Orphan Indication: Treatment of neuroendocrine tumors.

Sponsor: EntreMed, Inc. **Contact:** Dr. Edward Gubish, Jr.

Address: Rockville, MD **Phone:** 3012179858 **Fax:** 3012179594

Status: Designated **Designation Date:** 13-Aug-01 Marketing Approval Date:

Generic Name: Recombinant human gelsolin

Trade Name:

Orphan Indication: Treatment of the respiratory symptoms of cystic fibrosis.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvie Gregoire

Address: Cambridge, MA **Phone:** (617) 679-2631 **Fax:** (617) 679-3170

Status: Designated **Designation Date:** 12-Jan-94 Marketing Approval Date:

Generic Name: Recombinant human gelsolin

Trade Name:

Orphan Indication: Treatment of acute and chronic respiratory symptoms of bronchiectasis.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvie Gregoire

Address: Cambridge, MA **Phone:** 6176792631 **Fax:** 6176793170

Status: Designated **Designation Date:** 06-Mar-95 Marketing Approval Date:

Generic Name: Recombinant human highly phosphorylated acid alpha-glucosidase **Trade Name:** TBD

Orphan Indication: For enzyme replacement therapy in patients with all subtypes of glycogen storage disease type II (GSDII, Pompe Disease)

Sponsor: Novazyme Pharmaceuticals, Inc. **Contact:** Mr. Anthony McKinney

Address: Oklahoma City, OK **Phone:** 4052718144 **Fax:** 4052718154

Status: Designated **Designation Date:** 20-Sep-00 Marketing Approval Date:

Generic Name: Recombinant human insulin-like growth factor 1 **Trade Name:** IGF-1

Orphan Indication: Treatment of growth hormone receptor deficiency.

Sponsor: Pharmacia & Upjohn **Contact:** Mr. Robert Paarlberg

Address: Kalamazoo, MI **Phone:** (616) 833-0646 **Fax:** (616) 833-8237

Status: Designated/Withdrawn **Designation Date:** 07-Jun-95 **Marketing Approval Date:**

Generic Name: Recombinant human insulin-like growth factor 1 **Trade Name:** IGF-1

Orphan Indication: Treatment of antibody-mediated growth hormone resistance in patients with isolated growth hormone deficiency Ia.

Sponsor: Pharmacia & Upjohn **Contact:** Mr. Robert Paarlberg

Address: Kalamazoo, MI **Phone:** (616) 833-0646 **Fax:** (616) 833-8237

Status: Designated/Withdrawn **Designation Date:** 07-Jun-95 **Marketing Approval Date:**

Generic Name: Recombinant human insulin-like growth factor-I
Trade Name:

Orphan Indication: Treatment of post-poliomyelitis syndrome.

Sponsor: Cephalon, Inc. **Contact:** Mr. Paul Kirsch

Address: West Chester, PA **Phone:** (610) 738-6122 **Fax:** (610) 344-0065

Status: Designated **Designation Date:** 13-Oct-95 **Marketing Approval Date:**

Generic Name: Recombinant human insulin-like growth factor-I **Trade Name:** PV802

Orphan Indication: Treatment of short-bowel syndrome as a result of resection of the small bowel or as a result of congenital dysfunction of the intestines.

Sponsor: GroPep Pty Ltd. **Contact:** Dr. J. Dane Rigden

Address: Australia, AU **Phone:** (603) 429-0688 **Fax:** (617)687-0384

Status: Designated **Designation Date:** 16-Feb-00 **Marketing Approval Date:**

Generic Name: Recombinant human insulin-like growth factor-I/insulin-like growth factor binding protein-3
Trade Name:

Orphan Indication: Treatment of major burns that require hospitalization.

Sponsor: Celtrix Pharmaceuticals, Inc. **Contact:** Dr. Malcolm McKay

Address: Santa Clara, CA **Phone:** (408) 573-6237 **Fax:** (408) 573-6228

Status: Designated **Designation Date:** 15-Jun-99 **Marketing Approval Date:**

Generic Name: Recombinant human interleukin-12
Trade Name:

Orphan Indication: Treatment of renal cell carcinoma.

Sponsor: Genetics Institute, Inc. **Contact:** Dr. Frederick Gates

Address: Cambridge, MA **Phone:** (617) 498-8618 **Fax:** (617) 498-8618

Status: Designated **Designation Date:** 20-Oct-97 **Marketing Approval Date:**

Generic Name: Recombinant human keratinocyte growth factor
Trade Name:

Orphan Indication: Reducing the incidence and severity of radiation-induced xerostomia.

Sponsor: Amgen Inc. **Contact:** Ms. Zubeda Kara

Address: Thousand Oaks, CA **Phone:** (805) 447-6157 **Fax:** (805) 498-1425

Status: Designated **Designation Date:** 20-Dec-99 **Marketing Approval Date:**

Generic Name: Recombinant human luteinizing hormone **Trade Name:** LHadi

Orphan Indication: For use in association with recombinant human follicle stimulating hormone for the treatment of women with chronic anovulation due to hypogonadotropic hypogonadism.

Sponsor: Serono Laboratories, Inc. **Contact:** Ms. Lisa Mills

Address: Norwell, MA **Phone:** 7816812273 **Fax:** (781) 871-6754

Status: Designated **Designation Date:** 07-Oct-94 **Marketing Approval Date:**

Generic Name: Recombinant human nerve growth factor
Trade Name:

Orphan Indication: Treatment of HIV-associated sensory neuropathy.

Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane

Address: South San Francisco, CA **Phone:** (650) 225-1557 **Fax:** (415) 225-1397

Status: Designated **Designation Date:** 16-Apr-99 Marketing Approval Date:

Generic Name: Recombinant human relaxin

Trade Name:

Orphan Indication: Treatment of progressive systemic sclerosis.

Sponsor: Connetics Corporation **Contact:** Ms. M. Sue Preston

Address: Palo Alto, CA **Phone:** 6508432800 **Fax:** (650) 843-2899

Status: Designated **Designation Date:** 03-Nov-95 Marketing Approval Date:

Generic Name: Recombinant human superoxide dismutase **Trade Name:** Oxsodrol

Orphan Indication: Prevention of bronchopulmonary dysplasia in premature neonates weighing less than 1500 grams.

Sponsor: Bio-Technology General Corp. **Contact:** Ms. Briti Kundu

Address: Iselin, NJ **Phone:** 7326328800 **Fax:** 7326328844

Status: Designated **Designation Date:** 18-Apr-91 Marketing Approval Date:

Generic Name: Recombinant human thrombopoietin

Trade Name:

Orphan Indication: For use in accelerating platelet recovery in patients undergoing hematopoietic stem cell transplantation.

Sponsor: Genentech, Inc. **Contact:** Dr. Robert Garnick

Address: South San Francisco, CA **Phone:** (650) 225-1520 **Fax:** (650) 225-6000

Status: Designated **Designation Date:** 29-Sep-97 Marketing Approval Date:

Generic Name: Recombinant humanized MAb 5c8

Trade Name:

Orphan Indication: Prevention of rejection of pancreatic islet cell transplants.

Sponsor: Biogen, Inc. **Contact:** Dr. Burt Adelman

Address: Cambridge, MA **Phone:** (617) 679-2775 **Fax:**

Status: Designated **Designation Date:** 22-Mar-99 Marketing Approval Date:

Generic Name: Recombinant humanized MAb 5c8

Trade Name:

Orphan Indication: Prevention of rejection of solid organ transplants.

Sponsor: Biogen, Inc. **Contact:** Dr. Burt Adelman

Address: Cambridge, MA **Phone:** (617) 679-2775 **Fax:**

Status: Designated **Designation Date:** 22-Mar-99 Marketing Approval Date:

Generic Name: Recombinant humanized MAb 5c8

Trade Name:

Orphan Indication: Prevention and treatment of Factor VIII/Factor IX inhibitors in patients with hemophilia A or B.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvie Gregoire

Address: Cambridge, MA **Phone:** (617) 679-2631 **Fax:**

Status: Designated **Designation Date:** 14-Oct-98 Marketing Approval Date:

Generic Name: Recombinant humanized monoclonal antibody 5c8

Trade Name:

Orphan Indication: Treatment of immune thrombocytopenic purpura.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvie Gregoire

Address: Cambridge, MA **Phone:** (617) 679-2631 **Fax:** (617) 679-3170

Status: Designated **Designation Date:** 03-Feb-98 Marketing Approval Date:

Generic Name: Recombinant humanized monoclonal antibody 5c8

Trade Name:

Orphan Indication: Treatment of systemic lupus erythematosus.

Sponsor: Biogen, Inc. **Contact:** Dr. Sylvie Gregoire

Address: Cambridge, MA **Phone:** (617) 679-2631 **Fax:** (617) 679-3170

Status: Designated **Designation Date:** 18-Feb-98 Marketing Approval Date:

Generic Name: Recombinant methionyl brain-derived neurotrophic factor

Trade Name:

Orphan Indication: Treatment of amyotrophic lateral sclerosis.

Sponsor: Amgen, Inc. **Contact:** Armine Balian

Address: Thousand Oaks, CA **Phone:** (805) 447-4320 **Fax:** (805) 499-7232

Status: Designated **Designation Date:** 28-Nov-94 **Marketing Approval Date:**

Generic Name: Recombinant methionyl human stem cell factor

Trade Name:

Orphan Indication: Treatment of primary bone marrow failure.

Sponsor: Amgen, Inc. **Contact:** Mr. Neal Birkett

Address: Thousand Oaks, CA **Phone:** (805) 447-3416 **Fax:** 8054801330

Status: Designated **Designation Date:** 22-Nov-95 **Marketing Approval Date:**

Generic Name: Recombinant retroviral vector - glucocerebrosidase

Trade Name:

Orphan Indication: For use as enzyme replacement therapy for patients with types I, II, or III Gaucher disease.

Sponsor: Genetic Therapy, Inc. **Contact:** Mr. Jeffrey Carey

Address: Gaithersburg, MD **Phone:** (301) 208-2451 **Fax:** (301) 948-0097

Status: Designated **Designation Date:** 15-Nov-93 **Marketing Approval Date:**

Generic Name: Recombinant secretory leucocyte protease inhibitor

Trade Name:

Orphan Indication: Treatment of congenital alpha-1 antitrypsin deficiency.

Sponsor: Amgen Inc. **Contact:** Ms. Clara Li Yee

Address: Boulder, CO **Phone:** (303) 938-6200 **Fax:**

Status: Designated **Designation Date:** 29-Mar-91 **Marketing Approval Date:**

Generic Name: Recombinant secretory leucocyte protease inhibitor

Trade Name:

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: Amgen, Inc. **Contact:** Mr. Jeffery Fellows

Address: Boulder, CO **Phone:** (303) 938-6200 **Fax:**

Status: Designated **Designation Date:** 29-Mar-91 **Marketing Approval Date:**

Generic Name: Recombinant soluble human CD4 **Trade Name:** Receptin

Orphan Indication: Treatment of acquired immunodeficiency syndrome.

Sponsor: Biogen, Inc. **Contact:** Dr. Burt Adelman

Address: Cambridge, MA **Phone:** (617) 679-2000 **Fax:** (617) 679-2617

Status: Designated/Withdrawn **Designation Date:** 20-Nov-89 **Marketing Approval Date:**

Generic Name: Recombinant soluble human CD4 (rCD4)

Trade Name:

Orphan Indication: Treatment of AIDS in patients infected with HIV virus.

Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane

Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000

Status: Designated **Designation Date:** 23-Mar-89 **Marketing Approval Date:**

Generic Name: Recombinant urate oxidase

Trade Name:

Orphan Indication: Treatment of malignancy-associated or chemotherapy-induced hyperuricemia.

Sponsor: Sanofi-Synthelabo Research **Contact:** Ms. Danette Cathcart

Address: Malvern, PA **Phone:** (610) 889-6398 **Fax:** (610) 889-6910

Status: Designated **Designation Date:** 11-Oct-00 **Marketing Approval Date:**

Generic Name: Recombinant urate oxidase

Trade Name:

Orphan Indication: Prophylaxis of chemotherapy-induced hyperuricemia.

Sponsor: Sanofi-Synthelabo Research **Contact:** Ms. Danette Cathcart

Address: Malvern, PA **Phone:** (610) 889-6398 **Fax:** (610) 889-6993

Status: Designated **Designation Date:** 11-Oct-00 **Marketing Approval Date:**

Generic Name: Recombinant vaccinia (human papillomavirus) **Trade Name:** TA-HPV

Orphan Indication: Treatment of cervical cancer.

Sponsor: Cantab Pharmaceuticals Research Limited **Contact:** Dr. James Kenimer

Address: Great Britain, GB **Phone:** (703) 739-5695 **Fax:** (703) 548-7457

Status: Designated **Designation Date:** 24-Aug-94 **Marketing Approval Date:**

Generic Name: Reduced L-glutathione **Trade Name:** Cachexon

Orphan Indication: Treatment of AIDS-associated cachexia.

Sponsor: Telluride Pharmaceutical Corporation **Contact:** Dr. Thomas Kenyhercz

Address: Hillsborough, NJ **Phone:** (908) 359-1375 **Fax:** (908) 359-8236

Status: Designated **Designation Date:** 14-Feb-94 **Marketing Approval Date:**

Generic Name: Remacemide **Trade Name:** Ecovia

Orphan Indication: Treatment of Huntington's disease.

Sponsor: AstraZeneca LP **Contact:** Dr. Paul Nemeth

Address: Wayne, PA **Phone:** (610) 578-8355 **Fax:** (610) 695-1829

Status: Designated **Designation Date:** 06-Mar-00 **Marketing Approval Date:**

Generic Name: Respiratory Syncytial Virus Immune Globulin (human) **Trade Name:** Hypermune RSV

Orphan Indication: Treatment of respiratory syncytial virus lower respiratory tract infections in hospitalized infants and young children.

Sponsor: MedImmune, Inc. **Contact:** Mr. Bogdan Dziurzynski

Address: Gaithersburg, MD **Phone:** (301) 417-0770 **Fax:**

Status: Designated **Designation Date:** 27-Sep-90 **Marketing Approval Date:**

Generic Name: Respiratory syncytial virus immune globulin (Human) **Trade Name:** Respigam

Orphan Indication: Prophylaxis of respiratory syncytial virus lower respiratory tract infections in infants and young children at high risk of RSV disease.

Sponsor: MedImmune & Massachusetts Public Health Biologics **Contact:** Mr. Bogdan Dziurzynski Labs.

Address: Gaithersburg, MD **Phone:** (301) 417-0770 **Fax:** (301) 417-0770

Status: Designated/Approved **Designation Date:** 27-Sep-90 **Marketing Approval Date:** 18-Jan-96

Generic Name: Retroviral vector, R-GC and GC gene 1750

Trade Name:

Orphan Indication: Treatment of Gaucher disease.

Sponsor: Genzyme Corporation **Contact:** Mr. Robert Martin

Address: Framingham, MA **Phone:** 5082713772 **Fax:** 5082712692

Status: Designated **Designation Date:** 06-May-97 **Marketing Approval Date:**

Generic Name: Reviparin sodium **Trade Name:** Clivarine

Orphan Indication: Treatment of deep vein thrombosis which may lead to pulmonary embolism in pediatric patients

Sponsor: Knoll AG **Contact:** Dr. Susan Mondabaugh

Address: Ludwigshafen, Germany, **Phone:** 9736359898 **Fax:** 9736359881

Status: Designated **Designation Date:** 18-Jun-01 **Marketing Approval Date:**

Generic Name: Reviparin sodium **Trade Name:** Clivarine

Orphan Indication: Long-term treatment of acute deep vein thrombosis with or without pulmonary embolism in pregnant patients

Sponsor: Knoll AG **Contact:** Dr. Susan Mondabaugh

Address: Ludwigshafen, Germany, **Phone:** 9736359898 **Fax:** 9736359881

Status: Designated **Designation Date:** 18-Jun-01 **Marketing Approval Date:**

Generic Name: RGG0853, E1A lipid complex

Trade Name:

Orphan Indication: Treatment of ovarian cancer.

Sponsor: Targeted Genetics Corporation **Contact:** Ms. Johanne Gallagher

Address: Seattle, WA **Phone:** 2065217355 **Fax:** (206) 223-0288

Status: Designated **Designation Date:** 15-Sep-95 **Marketing Approval Date:**

Generic Name: Rho (D) immune globulin intravenous (human) **Trade Name:** WinRho SD

Orphan Indication: Treatment of immune thrombocytopenic purpura.

Sponsor: Rh Pharmaceuticals, Inc. **Contact:** Mr. Kelvin Li

Address: Canada R3T 2N2, CA **Phone:** (301) 770-3099 **Fax:**

Status: Designated/Approved **Designation Date:** 09-Nov-93 **Marketing Approval Date:** 24-Mar-95

Generic Name: Ribavirin **Trade Name:** Virazole

Orphan Indication: Treatment of hemorrhagic fever with renal syndrome.

Sponsor: ICN Pharmaceuticals, Inc. **Contact:** Ms. Anil Hiteshi

Address: Costa Mesa, CA **Phone:** (800) 548-5100 **Fax:** (714) 641-7287

Status: Designated **Designation Date:** 12-Apr-91 **Marketing Approval Date:**

Generic Name: Ricin (blocked) conjugated murine mca (anti-b4)

Trade Name:

Orphan Indication: 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.

Sponsor: ImmunoGen, Inc. **Contact:** Dr. John Lambert

Address: Cambridge, MA **Phone:** (617) 497-1113 **Fax:** (617) 497-5406

Status: Designated **Designation Date:** 24-Jan-91 **Marketing Approval Date:**

Generic Name: Ricin (blocked) conjugated murine MCA (anti-B4)

Trade Name:

Orphan Indication: Treatment of B-cell leukemia and B-cell lymphoma.

Sponsor: ImmunoGen, Inc. **Contact:** Dr. Carol Gloff

Address: Cambridge, MA **Phone:** (617) 661-9312 **Fax:** (617) 661-9334

Status: Designated **Designation Date:** 17-Nov-88 **Marketing Approval Date:**

Generic Name: Ricin (blocked) conjugated murine MCA (anti-my9)

Trade Name:

Orphan Indication: For use in the ex-vivo treatment of autologous bone marrow and subsequent reinfusion in patients with acute myelogenous leukemia.

Sponsor: ImmunoGen, Inc. **Contact:** Dr. Carol Gloff

Address: Cambridge, MA **Phone:** (617) 661-9312 **Fax:** (617) 661-9334

Status: Designated **Designation Date:** 01-Feb-90 **Marketing Approval Date:**

Generic Name: Ricin (blocked) conjugated murine MCA (anti-my9)

Trade Name:

Orphan Indication: Treatment of myeloid leukemia, including AML, and blast crisis of CML.

Sponsor: ImmunoGen, Inc. **Contact:** Dr. John Lambert

Address: Cambridge, MA **Phone:** (617) 497-1113 **Fax:** (617) 497-5406

Status: Designated **Designation Date:** 03-Aug-89 **Marketing Approval Date:**

Generic Name: Ricin (blocked) conjugated murine MCA (n901)

Trade Name:

Orphan Indication: Treatment of small cell lung cancer.

Sponsor: ImmunoGen, Inc. **Contact:** Dr. John Lambert

Address: Cambridge, MA **Phone:** (617) 497-1113 **Fax:** (617) 497-5406

Status: Designated **Designation Date:** 25-Jan-91 **Marketing Approval Date:**

Generic Name: Ricin (blocked) conjugated murine monoclonal antibody (CD6)

Trade Name:

Orphan Indication: Treatment of cutaneous T-cell lymphomas, acute T-cell leukemia-lymphoma, and related mature T-cell malignancies.

Sponsor: ImmunoGen, Inc. **Contact:** Dr. Carol Gloff

Address: Cambridge, MA **Phone:** (617) 661-9312 **Fax:** (617) 661-9334

Status: Designated **Designation Date:** 06-Sep-94 **Marketing Approval Date:**

Generic Name: Rifabutin

Trade Name:

Orphan Indication: Treatment of disseminated Mycobacterium avium complex disease.

Sponsor: Pharmacia & Upjohn **Contact:** Mr. Gregory Brier

Address: Kalamazoo, MI **Phone:** (616) 833-0286 **Fax:** (606) 833-0409

Status: Designated **Designation Date:** 18-Dec-89 **Marketing Approval Date:**

Generic Name: Rifabutin **Trade Name:** Mycobutin**Orphan Indication:** Prevention of disseminated Mycobacterium avium complex disease in patients with advanced HIV infection.**Sponsor:** Adria Laboratories, Inc. **Contact:** Mr. Douglas Jones**Address:** Columbus, OH **Phone:** (614) 764-8100 **Fax:** (614) 764-8102**Status:** Designated/Approved **Designation Date:** 18-Dec-89 **Marketing Approval Date:** 23-Dec-92**Generic Name:** Rifalazil

Trade Name:

Orphan Indication: Treatment of pulmonary tuberculosis.**Sponsor:** PathoGenesis Corporation **Contact:** Dr. William Pitlick**Address:** Seattle, WA **Phone:** (206) 270-3319 **Fax:** (206) 282-5065**Status:** Designated **Designation Date:** 13-Apr-99 **Marketing Approval Date:****Generic Name:** Rifampin **Trade Name:** Rifadin I.V.**Orphan Indication:** For antituberculosis treatment where use of the oral form of the drug is not feasible.**Sponsor:** Hoechst Marion Roussel **Contact:** Dr. Jack Dunn**Address:** Kansas City, MO **Phone:** (816) 966-5000 **Fax:****Status:** Designated/Approved **Designation Date:** 09-Dec-85 **Marketing Approval Date:** 25-May-89**Generic Name:** Rifampin, isoniazid, pyrazinamide **Trade Name:** Rifater**Orphan Indication:** For the short-course treatment of tuberculosis.**Sponsor:** Hoechst Marion Roussel **Contact:** Dr. Jack Dunn**Address:** Kansas City, MO **Phone:** (816) 966-5000 **Fax:****Status:** Designated/Approved **Designation Date:** 12-Sep-85 **Marketing Approval Date:** 31-May-94**Generic Name:** Rifapentine **Trade Name:** Priftin**Orphan Indication:** Treatment of pulmonary tuberculosis.**Sponsor:** Hoechst Marion Roussel **Contact:** Ms. Libby Hayes**Address:** Kansas City, MO **Phone:** (816) 966-7185 **Fax:****Status:** Designated/Approved **Designation Date:** 09-Jun-95 **Marketing Approval Date:** 22-Jun-98**Generic Name:** Rifapentine **Trade Name:** Priftin**Orphan Indication:** Treatment of Mycobacterium avium complex in patients with AIDS.**Sponsor:** Hoechst Marion Roussel, Inc. **Contact:** Ms. Libby Hayes**Address:** Kansas City, MO **Phone:** (816) 966-7185 **Fax:****Status:** Designated **Designation Date:** 09-Jun-95 **Marketing Approval Date:****Generic Name:** Rifapentine **Trade Name:** Priftin**Orphan Indication:** Prophylactic treatment of Mycobacterium avium complex in patients with AIDS and a CD4+ count less than or equal to 75/mm³.**Sponsor:** Hoechst Marion Roussel, Inc. **Contact:** Ms. Libby Hayes**Address:** Kansas City, MO **Phone:** (816) 966-7185 **Fax:** (816) 966-6790**Status:** Designated **Designation Date:** 12-Mar-96 **Marketing Approval Date:****Generic Name:** Rifaximin **Trade Name:** Normix**Orphan Indication:** Treatment of hepatic encephalopathy.**Sponsor:** Salix Pharmaceuticals, Inc. **Contact:** Dr. Lorin Johnson**Address:** Palo Alto, CA **Phone:** 6508495903 **Fax:** (650) 856-1555**Status:** Designated **Designation Date:** 10-Feb-98 **Marketing Approval Date:****Generic Name:** RII retinamide

Trade Name:

Orphan Indication: Treatment of myelodysplastic syndromes.**Sponsor:** Sparta Pharmaceuticals, Inc. **Contact:** Ms. Cris Triolo**Address:** Horsham, PA **Phone:** (215) 442-1700 **Fax:** (215) 442-1827**Status:** Designated **Designation Date:** 06-May-93 **Marketing Approval Date:****Generic Name:** Riluzole **Trade Name:** Rilutek

Orphan Indication: Treatment of amyotrophic lateral sclerosis.

Sponsor: Rhone-Poulenc Rorer Pharmaceuticals, Inc. **Contact:** Dr. Thomas Donnelly, Jr.

Address: Collegeville, PA **Phone:** (610) 454-3023 **Fax:** (610) 454-5299

Status: Designated/Approved **Designation Date:** 16-Mar-93 **Marketing Approval Date:** 12-Dec-95

Generic Name: Riluzole **Trade Name:** Rilutek

Orphan Indication: Treatment of Huntington's disease.

Sponsor: Rhone-Poulenc Rorer Pharmaceuticals, Inc. **Contact:** Dr. Ronald Dundore

Address: Collegeville, PA **Phone:** (610) 454-5305 **Fax:** (610) 454-5779

Status: Designated **Designation Date:** 15-Oct-96 **Marketing Approval Date:**

Generic Name: Rituximab **Trade Name:** Rituxan

Orphan Indication: Treatment of non-Hodgkin's B-cell lymphoma.

Sponsor: IDEC Pharmaceuticals Corporation **Contact:** Ms. Alice Wei

Address: San Diego, CA **Phone:** (858) 431-8920 **Fax:** (858) 431-8889

Status: Designated/Approved **Designation Date:** 13-Jun-94 **Marketing Approval Date:** 26-Nov-97

Generic Name: Roquinimex **Trade Name:** Linomide

Orphan Indication: To prolong time to relapse in leukemia patients who have undergone autologous bone marrow transplantation.

Sponsor: Pharmacia & Upjohn **Contact:** Mr. Robert Paarlberg

Address: Kalamazoo, MI **Phone:** (616) 833-0646 **Fax:** (616) 833-8237

Status: Designated/Withdrawn **Designation Date:** 01-Jul-93 **Marketing Approval Date:**

Generic Name: rSP-C lung surfactant **Trade Name:** Venticute

Orphan Indication: Treatment of adult respiratory distress syndrome.

Sponsor: Byk Gulden Pharmaceuticals **Contact:** Mr. Robert Anderson

Address: Germany, DE **Phone:** (631) 454-7677 **Fax:** (631) 756-5114

Status: Designated **Designation Date:** 03-Apr-00 **Marketing Approval Date:**

Generic Name: S-adenosylmethionine

Trade Name:

Orphan Indication: Treatment of AIDS-myelopathy.

Sponsor: Di Rocco, Alessandro M.D. **Contact:** Dr. Alessandro Di Rocco

Address: New York, NY **Phone:** (212) 844-8652 **Fax:** (212) 844-8461

Status: Designated **Designation Date:** 30-Apr-98 **Marketing Approval Date:**

Generic Name: Sacrosidase **Trade Name:** Sucraid

Orphan Indication: Treatment of congenital sucrase-isomaltase deficiency.

Sponsor: Orphan Medical, Inc. **Contact:** Dr. Dayton Reardon

Address: Minnetonka, MN **Phone:** (612) 513-6900 **Fax:** (612) 541-9209

Status: Designated/Approved **Designation Date:** 10-Dec-93 **Marketing Approval Date:** 09-Apr-98

Generic Name: Sargramostim **Trade Name:** Leukine

Orphan Indication: To reduce neutropenia and leukopenia and decrease the incidence of death due to infection in patients with acute myelogenous leukemia.

Sponsor: Immunex Corporation **Contact:** Ms. Sally Gould

Address: Seattle, WA **Phone:** (206) 587-0430 **Fax:**

Status: Designated/Approved **Designation Date:** 06-Mar-95 **Marketing Approval Date:** 15-Sep-95

Generic Name: Sargramostim **Trade Name:** Leukine

Orphan Indication: 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.

Sponsor: Immunex Corporation **Contact:** Ms. Sally Gould

Address: Seattle, WA **Phone:** (206) 587-0430 **Fax:**

Status: Designated/Approved **Designation Date:** 03-May-90 **Marketing Approval Date:** 05-Mar-91

Generic Name: Satumomab pendetide **Trade Name:** Oncoscint CR/OV

Orphan Indication: Detection of ovarian carcinoma.

Sponsor: Cytogen Corporation **Contact:** Dr. Melvin Fisher

Address: Princeton, NJ **Phone:** (609) 987-8200 **Fax:**

Status: Designated/Approved **Designation Date:** 25-Sep-89 **Marketing Approval Date:** 29-Dec-92

Generic Name: SB-408075

Trade Name:

Orphan Indication: For pancreatic cancer

Sponsor: SmithKline Beecham Pharmaceuticals **Contact:** Dr. Olivia Pinkett

Address: Collegeville, PA **Phone:** 6109175840 **Fax:** 6109177665

Status: Designated **Designation Date:** 07-Dec-00 **Marketing Approval Date:**

Generic Name: SCH 58500

Trade Name:

Orphan Indication: Treatment of primary ovarian cancer.

Sponsor: Schering Corporation **Contact:** Dr. Joseph Lamendola

Address: Kenilworth, NJ **Phone:** (908) 740-2628 **Fax:**

Status: Designated **Designation Date:** 12-Apr-99 **Marketing Approval Date:**

Generic Name: Secalciferol **Trade Name:** Osteo-D

Orphan Indication: Treatment of familial hypophosphatemic rickets.

Sponsor: Teva Pharmaceuticals USA **Contact:** Dr. Scott Grossman

Address: Sellersville, PA **Phone:** (215) 256-8400 **Fax:** (215) 256-7855

Status: Designated **Designation Date:** 26-Jul-93 **Marketing Approval Date:**

Generic Name: Secretory leukocyte protease inhibitor

Trade Name:

Orphan Indication: Treatment of bronchopulmonary dysplasia.

Sponsor: Synergen, Inc. **Contact:** Mr. Jeffrey Fellows

Address: Boulder, CO **Phone:** (303) 938-6200 **Fax:**

Status: Designated **Designation Date:** 30-Jun-92 **Marketing Approval Date:**

Generic Name: Selegiline HCl **Trade Name:** Eldepryl

Orphan Indication: As an adjuvant to levodopa and carbidopa treatment of idiopathic Parkinson's disease (paralysis agitans), postencephalitic Parkinsonism, and symptomatic Parkinsonism.

Sponsor: Somerset Pharmaceuticals, Inc. **Contact:** Mr. John Saenger

Address: Tampa, FL **Phone:** (813) 223-7677 **Fax:**

Status: Designated/Approved **Designation Date:** 07-Nov-84 **Marketing Approval Date:** 05-Jun-89

Generic Name: Sermorelin acetate **Trade Name:** Geref

Orphan Indication: Treatment of idiopathic or organic growth hormone deficiency in children with growth failure.

Sponsor: Serono Laboratories, Inc. **Contact:** Mr. Thomas Lang

Address: Norwell, MA **Phone:** (617) 982-9000 **Fax:** (617) 871-6754

Status: Designated/Approved **Designation Date:** 14-Sep-88 **Marketing Approval Date:** 26-Sep-97

Generic Name: Sermorelin acetate **Trade Name:** Geref

Orphan Indication: Treatment of AIDS-associated catabolism/weight loss.

Sponsor: Serono Laboratories, Inc. **Contact:** Ms. Pamela Williamson Joyce

Address: Norwell, MA **Phone:** (781) 681-2298 **Fax:** (781) 871-6754

Status: Designated **Designation Date:** 05-Dec-91 **Marketing Approval Date:**

Generic Name: Sermorelin acetate **Trade Name:** Geref

Orphan Indication: 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.

Sponsor: Serono Laboratories, Inc. **Contact:** Ms. Pamela Williamson

Joyce

Address: Norwell, MA **Phone:** (781) 982-9000 **Fax:** (617) 871-6754

Status: Designated **Designation Date:** 13-Feb-90 **Marketing Approval Date:**

Generic Name: Serratia marcescens extract (polyribosomes) **Trade Name:** Imuvert

Orphan Indication: Treatment of primary brain malignancies.

Sponsor: Cell Technology, Inc. **Contact:** Mr. Michael Andrews

Address: Boulder, CO **Phone:** (303) 443-8155 Fax:

Status: Designated **Designation Date:** 07-Sep-88 Marketing Approval Date:

Generic Name: Short chain fatty acid enema **Trade Name:** Colomed

Orphan Indication: Treatment of chronic radiation proctitis.

Sponsor: Richard I. Breuer, M.D. **Contact:** Dr. Richard Breuer

Address: Evanston, IL **Phone:** 8475701530 Fax:

Status: Designated **Designation Date:** 19-Aug-97 Marketing Approval Date:

Generic Name: Short chain fatty acid solution **Trade Name:** Colomed

Orphan Indication: Treatment of the active phase of ulcerative colitis with involvement restricted to the left side of the colon.

Sponsor: Richard I. Breuer **Contact:** Dr. Richard Breuer

Address: Evanston, IL **Phone:** 8475701530 Fax:

Status: Designated **Designation Date:** 29-May-90 Marketing Approval Date:

Generic Name: Silver sulfadiazine and cerium nitrate **Trade Name:** Flammacerium

Orphan Indication: Prevention of mortality in severely burned patients.

Sponsor: Synthes (USA) **Contact:** Mr. Jim McCracken

Address: Paoli, PA **Phone:** (610) 647-9700 **Fax:** (610) 251-2848

Status: Designated **Designation Date:** 17-Nov-99 Marketing Approval Date:

Generic Name: SK&F; 110679

Trade Name:

Orphan Indication: For the long term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.

Sponsor: SmithKline Beecham Pharmaceuticals **Contact:** Dr. Stella Jones

Address: Philadelphia, PA **Phone:** (215) 751-4000 **Fax:** (215) 751-3400

Status: Designated/Withdrawn **Designation Date:** 23-May-90 Marketing Approval Date:

Generic Name: Sodium 1,3-propanedisulfonate

Trade Name:

Orphan Indication: Treatment of secondary amyloidosis.

Sponsor: Neurochem, Inc. **Contact:** Mr. Douglas Hunt

Address: Canada H4S 2A1, CA **Phone:** (301) 272-3106 **Fax:** (301) 272-2150

Status: Designated **Designation Date:** 06-Apr-99 Marketing Approval Date:

Generic Name: Sodium dichloroacetate

Trade Name:

Orphan Indication: Treatment of homozygous familial hypercholesterolemia.

Sponsor: Stacpoole, Peter W. M.D., Ph.D. **Contact:** Dr. Peter Stacpoole

Address: Gainesville, FL **Phone:** (352) 392-2321 **Fax:** (352) 846-0990

Status: Designated **Designation Date:** 11-Jun-90 Marketing Approval Date:

Generic Name: Sodium dichloroacetate

Trade Name:

Orphan Indication: Treatment of congenital lactic acidosis.

Sponsor: Stacpoole, Peter W. M.D., Ph.D. **Contact:** Dr. Peter Stacpoole

Address: Gainesville, FL **Phone:** (352) 392-2321 **Fax:** (352) 846-0990

Status: Designated **Designation Date:** 11-Jun-90 Marketing Approval Date:

Generic Name: Sodium dichloroacetate

Trade Name:

Orphan Indication: Treatment of lactic acidosis in patients with severe malaria.

Sponsor: Stacpoole, Peter W. M.D., Ph.D. **Contact:** Dr. Peter Stacpoole

Address: Gainesville, FL **Phone:** (904) 392-2321 Fax:

Status: Designated **Designation Date:** 10-Nov-94 Marketing Approval Date:

Generic Name: Sodium dichloroacetate **Trade Name:** Ceresine

Orphan Indication: Treatment of severe head injury.

Sponsor: Questcor Pharmaceuticals, Inc. **Contact:** Dr. Jonathan Goldsmith

Address: Hayward, CA **Phone:** 5107325551 **Fax:**
Status: Designated **Designation Date:** 14-Jun-99 **Marketing Approval Date:**

Generic Name: Sodium dichloroacetate
Trade Name:

Orphan Indication: Treatment of congenital lactic acidosis.
Sponsor: Questcor Pharmaceuticals, Inc. **Contact:** Dr. Jonathan Goldsmith
Address: Hayward, CA **Phone:** 5107325551 **Fax:** 5107327741
Status: Designated **Designation Date:** 31-Dec-97 **Marketing Approval Date:**

Generic Name: Sodium Monomercaptoundecahydro-closo-dodecaborate **Trade Name:** Borocell

Orphan Indication: For use in boron neutron capture therapy (BNCT) in the treatment of glioblastoma multiforme.
Sponsor: Neutron Technology Corp.& Neutron R&D; Partner **Contact:** Mr. Ron Twilegar
Address: Boise, ID **Phone:** (208) 345-3460 **Fax:** (208) 367-9156
Status: Designated **Designation Date:** 15-Apr-92 **Marketing Approval Date:**

Generic Name: Sodium monomercaptoundecahydro-closo-dodecaborate
Trade Name:

Orphan Indication: For use in conjunction with a thermal or epithermal neutron beam in boron nuclear capture therapy of glioblastoma multiforme.
Sponsor: Theragenics Corporation **Contact:**
Address: , **Phone:** **Fax:**
Status: Designated/Withdrawn **Designation Date:** 18-Dec-84 **Marketing Approval Date:**

Generic Name: sodium phenylbutyrate
Trade Name:

Orphan Indication: Treatment for sickling disorders, which include S-S hemoglobinopathy, S-C hemoglobinopathy, and S-thalassemia hemoglobinopathy.
Sponsor: Medicis Pharmaceutical Corp. **Contact:** Ms. Lynn Hansen
Address: Scottsdale, AZ **Phone:** 6028083813 **Fax:** 6028080822
Status: Designated **Designation Date:** 02-Jul-92 **Marketing Approval Date:**

Generic Name: sodium phenylbutyrate **Trade Name:** Buphenyl

Orphan Indication: Treatment of urea cycle disorders: carbamylphosphate synthetase deficiency, ornithine transcarbamylase deficiency, and argininosuccinic acid synthetase deficiency.
Sponsor: Medicis Pharmaceutical Corp. **Contact:** Ms. Lynn Hansen
Address: Scottsdale, AZ **Phone:** 6028083813 **Fax:** 6028080822
Status: Designated/Approved **Designation Date:** 22-Nov-93 **Marketing Approval Date:** 29-Jul-94

Generic Name: Sodium phenylbutyrate
Trade Name:

Orphan Indication: For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma.
Sponsor: Elan Pharmaceutical Research Corporation **Contact:** Mr. Roger Wiley
Address: Gainesville, GA **Phone:** (770) 534-8239 **Fax:** (770) 534-8247
Status: Designated **Designation Date:** 24-Apr-98 **Marketing Approval Date:**

Generic Name: Sodium tetradecyl sulfate **Trade Name:** Sotradecol

Orphan Indication: Treatment of bleeding esophageal varices.
Sponsor: Elkins-Sinn, Inc. **Contact:** Ms. Thelma Hilibrand
Address: Cherry Hill, NJ **Phone:** (609) 424-3700 **Fax:**
Status: Designated **Designation Date:** 10-Jun-86 **Marketing Approval Date:**

Generic Name: Soluble complement receptor type 1
Trade Name:

Orphan Indication: Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass.
Sponsor: Avant Immunotherapeutics, Inc. **Contact:** Ms. Joan Shankle
Address: Needham, MA **Phone:** (781) 433-3129 **Fax:**
Status: Designated **Designation Date:** 06-Mar-00 **Marketing Approval Date:**

Generic Name: Soluble recombinant human complement receptor type 1
Trade Name:

Orphan Indication: Prevention or reduction of adult respiratory distress syndrome.
Sponsor: T Cell Sciences, Inc. **Contact:** Dr. Ellen Essigmann
Address: Needham Heights, MA **Phone:** (617) 621-1400 **Fax:**
Status: Designated **Designation Date:** 21-Nov-94 **Marketing Approval Date:**

Generic Name: Somatostatin
Trade Name:

Orphan Indication: Treatment of bleeding esophageal varices.
Sponsor: UCB Pharmaceuticals, Inc. **Contact:** Ms. Sandy Bonsall
Address: Smyrna, GA **Phone:** (770) 437-5654 **Fax:** (770) 437-5507
Status: Designated **Designation Date:** 22-Dec-94 **Marketing Approval Date:**

Generic Name: Somatostatin **Trade Name:** Zecnil

Orphan Indication: Adjunct to the non-operative management of secreting cutaneous fistulas of the stomach, duodenum, small intestine (jejunum and ileum), or pancreas.
Sponsor: Ferring Laboratories, Inc. **Contact:** Mr. Isidoro Nudelman
Address: Suffern, NY **Phone:** (888) 793-6367 **Fax:**
Status: Designated **Designation Date:** 20-Jun-88 **Marketing Approval Date:**

Generic Name: Somatrem for injection **Trade Name:** Protropin

Orphan Indication: Treatment of short stature associated with Turner's syndrome.
Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane
Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000
Status: Designated **Designation Date:** 09-Dec-85 **Marketing Approval Date:**

Generic Name: Somatrem for injection **Trade Name:** Protropin

Orphan Indication: For long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.
Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane
Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000
Status: Designated/Approved **Designation Date:** 09-Dec-85 **Marketing Approval Date:** 17-Oct-85

Generic Name: Somatropin **Trade Name:** Nutropin

Orphan Indication: For use in the long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.
Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane
Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000
Status: Designated/Approved **Designation Date:** 06-Mar-87 **Marketing Approval Date:** 17-Oct-85

Generic Name: Somatropin **Trade Name:** Norditropin

Orphan Indication: Treatment of short stature associated with Turner's syndrome.
Sponsor: Novo Nordisk Pharmaceuticals **Contact:** Mr. Lawrence Rosania
Address: Princeton, NJ **Phone:** (609) 987-5847 **Fax:** (609) 921-8082
Status: Designated/Withdrawn **Designation Date:** 05-Nov-87 **Marketing Approval Date:**

Generic Name: Somatropin **Trade Name:** Norditropin

Orphan Indication: Adjunct for the induction of ovulation in women with infertility due to hypogonadotropic hypogonadism or bilateral tubal occlusion or unexplained infertility, who are undergoing in vivo or in vitro fertilization procedures.
Sponsor: Novo Nordisk Pharmaceuticals **Contact:** Lawrence Rosania
Address: Princeton, NJ **Phone:** (609) 987-5847 **Fax:** (609) 921-8082
Status: Designated/Withdrawn **Designation Date:** 01-Sep-87 **Marketing Approval Date:**

Generic Name: Somatropin **Trade Name:** Genotropin

Orphan Indication: Treatment of adults with growth hormone deficiency.
Sponsor: Pharmacia & Upjohn **Contact:** Mr. Gregory Shawaryn
Address: Kalamazoo, MI **Phone:** (616) 833-8239 **Fax:** (616) 833-8237
Status: Designated/Approved **Designation Date:** 06-Sep-94 **Marketing Approval Date:** 31-Oct-97

Generic Name: Somatropin **Trade Name:** Biotropin

Orphan Indication: Treatment of cachexia associated with AIDS.

Sponsor: Bio-Technology General Corp. **Contact:** Ms. Annmarie Petraglia

Address: Iselin, NJ **Phone:** (908) 632-8800 **Fax:** (908) 632-8844

Status: Designated/Withdrawn **Designation Date:** 12-Feb-93 **Marketing Approval Date:**

Generic Name: Somatropin **Trade Name:** Humatrope

Orphan Indication: Treatment of short stature associated with Turner syndrome.

Sponsor: Eli Lilly and Company **Contact:** Dr. Timothy Franson

Address: Indianapolis, IN **Phone:** (317) 276-2000 **Fax:**

Status: Designated/Approved **Designation Date:** 08-May-90 **Marketing Approval Date:** 11-Mar-97

Generic Name: Somatropin (rDNA) **Trade Name:** Saizen

Orphan Indication: For the enhancement of nitrogen retention in hospitalized patients suffering from severe burns.

Sponsor: Serono Laboratories, Inc. **Contact:** Ms. Pamela Williamson Joyce

Address: Norwell, MA **Phone:** (781) 982-9000 **Fax:** (617) 871-6754

Status: Designated **Designation Date:** 03-May-89 **Marketing Approval Date:**

Generic Name: Somatropin (r-DNA) **Trade Name:** Serostim

Orphan Indication: For use alone or in combination with glutamine in the treatment of short bowel syndrome.

Sponsor: Serono Laboratories, Inc. **Contact:** Ms. Pamela Williamson Joyce

Address: Norwell, MA **Phone:** (781) 982-9000 **Fax:** (781) 871-6754

Status: Designated **Designation Date:** 06-Mar-95 **Marketing Approval Date:**

Generic Name: Somatropin (r-DNA) for injection **Trade Name:** Serostim

Orphan Indication: Treatment of children with AIDS-associated failure-to-thrive including AIDS-associated wasting.

Sponsor: Serono Laboratories, Inc. **Contact:** Ms. Pamela Williamson Joyce

Address: Norwell, MA **Phone:** (781) 982-9000 **Fax:** (781) 871-6754

Status: Designated **Designation Date:** 26-Mar-96 **Marketing Approval Date:**

Generic Name: Somatropin (rDNA origin) **Trade Name:** Saizen

Orphan Indication: Treatment of idiopathic or organic growth hormone deficiency in children with growth failure.

Sponsor: Serono Laboratories, Inc. **Contact:** Ms. Pamela Williamson Joyce

Address: Norwell, MA **Phone:** (800) 283-8088 **Fax:** (617) 871-6754

Status: Designated/Approved **Designation Date:** 06-Mar-87 **Marketing Approval Date:** 08-Oct-96

Generic Name: Somatropin (rDNA origin) **Trade Name:** Nutropin Depot

Orphan Indication: Long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion.

Sponsor: Genentech, Inc. **Contact:** Dr. Robert Garnick

Address: South San Francisco, CA **Phone:** (650) 225-1202 **Fax:** (650) 225-5927

Status: Designated/Approved **Designation Date:** 28-Oct-99 **Marketing Approval Date:** 22-Dec-99

Generic Name: Somatropin (rDNA origin) injection **Trade Name:** Norditropin

Orphan Indication: Treatment of growth failure in children due to inadequate growth hormone secretion.

Sponsor: Novo Nordisk Pharmaceuticals **Contact:** Mr. Lawrence Rosania

Address: Princeton, NJ **Phone:** (609) 987-5847 **Fax:** (609) 921-8082

Status: Designated/Approved **Designation Date:** 10-Jul-87 **Marketing Approval Date:** 20-Jun-00

Generic Name: Somatropin [rDNA] **Trade Name:** Genotropin

Orphan Indication: Treatment of short stature in patients with Prader-Willi syndrome.

Sponsor: Pharmacia & Upjohn **Contact:** Ms. Cynthia Blanchard

Address: Kalamazoo, MI **Phone:** (616) 833-6717 **Fax:**

Status: Designated/Approved **Designation Date:** 06-Jul-99 **Marketing Approval Date:** 20-Jun-00

Generic Name: somatropin [rDNA] **Trade Name:** Genotropin

Orphan Indication: Treatment of growth failure in children who were born small for gestational age.

Sponsor: Pharmacia and Upjohn Company **Contact:** Mr. Daniel Chirby

Address: Kalamazoo, MI **Phone:** (616) 833-9411 **Fax:**

Status: Designated/Approved **Designation Date:** 27-Dec-00 **Marketing Approval Date:** 25-Jul-01

Generic Name: Somatropin for injection **Trade Name:** Serostim

Orphan Indication: Treatment of AIDS-associated catabolism/weight loss.

Sponsor: Serono Laboratories, Inc. **Contact:** Mr. Thomas Lang

Address: Norwell, MA **Phone:** (617) 982-9000 **Fax:** (617) 871-6754

Status: Designated/Approved **Designation Date:** 15-Nov-91 **Marketing Approval Date:** 23-Aug-96

Generic Name: Somatropin for injection **Trade Name:** Nutropin

Orphan Indication: Treatment of growth retardation associated with chronic renal failure.

Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane

Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000

Status: Designated/Approved **Designation Date:** 04-Aug-89 **Marketing Approval Date:** 17-Nov-93

Generic Name: Somatropin for injection **Trade Name:** Humatrope

Orphan Indication: For the long-term treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone.

Sponsor: Eli Lilly and Company **Contact:** Dr. Timothy Franson

Address: Indianapolis, IN **Phone:** (317) 276-2000 **Fax:**

Status: Designated/Approved **Designation Date:** 12-Jun-86 **Marketing Approval Date:** 08-Mar-87

Generic Name: Somatropin for injection **Trade Name:** Nutropin

Orphan Indication: As replacement therapy for growth hormone deficiency in adults after epiphyseal closure.

Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane

Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000

Status: Designated/Approved **Designation Date:** 18-Nov-96 **Marketing Approval Date:** 15-Dec-97

Generic Name: Somatropin for injection **Trade Name:** Nutropin

Orphan Indication: Treatment of short stature associated with Turner's syndrome.

Sponsor: Genentech, Inc. **Contact:** Dr. M. David MacFarlane

Address: South San Francisco, CA **Phone:** (415) 225-1000 **Fax:** (415) 225-6000

Status: Designated/Approved **Designation Date:** 23-Mar-89 **Marketing Approval Date:** 30-Dec-96

Generic Name: Sorivudine **Trade Name:** BRAVAVIR

Orphan Indication: Treatment of herpes zoster (shingles) in immunocompromised patients.

Sponsor: Bristol-Myers Squibb **Contact:** Dr. Douglas Kriesel

Address: Wallingford, CT **Phone:** (203) 284-6883 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 09-Nov-95 **Marketing Approval Date:**

Generic Name: Sotalol HCl **Trade Name:** Betapace

Orphan Indication: Treatment of life-threatening ventricular tachyarrhythmias.

Sponsor: Berlex Laboratories, Inc. **Contact:** Dr. Suzanne Hampton

Address: Wayne, NJ **Phone:** (201) 305-5288 **Fax:**

Status: Designated/Approved **Designation Date:** 23-Sep-88 **Marketing Approval Date:** 30-Oct-92

Generic Name: Sotalol HCl **Trade Name:** Betapace

Orphan Indication: Prevention of life threatening ventricular tachyarrhythmias.

Sponsor: Berlex Laboratories, Inc. **Contact:** Dr. Suzanne Hampton

Address: Wayne, NJ **Phone:** (201) 305-5288 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 23-Sep-88 **Marketing Approval Date:**

Generic Name: Spiramycin **Trade Name:** Rovamycine

Orphan Indication: For symptomatic relief and parasitic cure of chronic cryptosporidiosis in patients with immunodeficiency.

Sponsor: Rhone-Poulenc Rorer Pharmaceuticals **Contact:** Dr. Thomas Donnelly

Address: Collegeville, PA **Phone:** (610) 454-3023 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 17-Oct-84 **Marketing Approval Date:**

Generic Name: squalamine lactate
Trade Name:

Orphan Indication: Treatment of ovarian cancer refractory or resistant to standard chemotherapy
Sponsor: Genaera Corporation **Contact:** Ms. Allyne Cheifet
Address: Plymouth Meeting, PA **Phone:** 6109415297 **Fax:** 6109415399
Status: Designated **Designation Date:** 11-May-01 Marketing Approval Date:

Generic Name: ST1-RTA immunotoxin (SR 44163)
Trade Name:

Orphan Indication: Treatment of patients with B-chronic lymphocytic leukemia.
Sponsor: Sanofi Winthrop, Inc. **Contact:** Ms. Jan Farrar
Address: Malvern, PA **Phone:** (610) 983-5000 Fax:
Status: Designated/Withdrawn **Designation Date:** 12-Aug-87 Marketing Approval Date:

Generic Name: ST1-RTA immunotoxin (SR 44163)
Trade Name:

Orphan Indication: Prevention of acute graft versus host disease in allogenic bone marrow transplantation.
Sponsor: Sanofi Winthrop, Inc. **Contact:** Ms. Jan Farrar
Address: Malvern, PA **Phone:** (610) 983-5000 Fax:
Status: Designated/Withdrawn **Designation Date:** 12-Aug-87 Marketing Approval Date:

Generic Name: Sterile talc **Trade Name:** Steritalc

Orphan Indication: Treatment of pneumothorax.
Sponsor: Novatech SA **Contact:** Ms. Sylvia White
Address: France, **Phone:** (302) 998-0595 **Fax:** (302) 998-7078
Status: Designated **Designation Date:** 08-Dec-97 Marketing Approval Date:

Generic Name: Sterile talc **Trade Name:** Steritalc

Orphan Indication: Treatment of malignant pleural effusion.
Sponsor: Novatech SA **Contact:** Ms. Sylvia White
Address: France, **Phone:** (302) 998-0595 **Fax:** (302) 998-7078
Status: Designated **Designation Date:** 08-Dec-97 Marketing Approval Date:

Generic Name: Sterile talc powder **Trade Name:** Sclerosol Intrapleural Aerosol

Orphan Indication: Treatment of malignant pleural effusion.
Sponsor: Bryan Corporation **Contact:** Mr. Frank Abrano
Address: Woburn, MA **Phone:** (781) 935-0004 **Fax:** (781) 935-7602
Status: Designated/Approved **Designation Date:** 18-Sep-95 **Marketing Approval Date:** 24-Dec-97

Generic Name: SU101
Trade Name:

Orphan Indication: Treatment of malignant glioma.
Sponsor: Sugen, Inc. **Contact:** Ms. Margie Nemcik-Cruz
Address: South San Francisco, CA **Phone:** (650) 553-8789 **Fax:** (650) 553-8312
Status: Designated **Designation Date:** 25-May-95 Marketing Approval Date:

Generic Name: SU101
Trade Name:

Orphan Indication: Treatment of ovarian cancer.
Sponsor: Sugen, Inc. **Contact:** Ms. Margie Nemcik-Cruz
Address: South San Francisco, CA **Phone:** (650) 553-8789 **Fax:** (650) 553-8312
Status: Designated **Designation Date:** 12-Mar-96 Marketing Approval Date:

Generic Name: Succimer **Trade Name:** Chemet

Orphan Indication: Prevention of cystine kidney stone formation in patients with homozygous cystinuria who are prone to stone development.
Sponsor: Sanofi Winthrop, Inc. **Contact:** Ms. Allyson Chambers
Address: New York, NY **Phone:** (212) 551-4233 Fax:
Status: Designated **Designation Date:** 05-Nov-90 Marketing Approval Date:

Generic Name: Succimer **Trade Name:** Chemet

Orphan Indication: Treatment of mercury intoxication.

Sponsor: Sanofi Winthrop, Inc. **Contact:** Ms. Allyson Chambers

Address: New York, NY **Phone:** (212) 551-4233 **Fax:**

Status: Designated **Designation Date:** 22-Mar-91 **Marketing Approval Date:**

Generic Name: Succimer **Trade Name:** Chemet capsules

Orphan Indication: Treatment of lead poisoning in children.

Sponsor: Bock Pharmacal Company **Contact:** Mr. David Byron

Address: Saint Louis, MO **Phone:** (800) 727-2625 **Fax:**

Status: Designated/Approved **Designation Date:** 09-May-84 **Marketing Approval Date:** 22-Dec-88

Generic Name: Sucralfate

Trade Name:

Orphan Indication: Treatment of oral mucositis and stomatitis following radiation therapy for head and neck cancer.

Sponsor: Fuisz Technologies, Ltd. **Contact:** Dr. Mireille Peyrac

Address: Chantilly, VA **Phone:** (703) 803-3260 **Fax:** (703) 803-6460

Status: Designated/Withdrawn **Designation Date:** 15-Jul-93 **Marketing Approval Date:**

Generic Name: Sucralfate suspension

Trade Name:

Orphan Indication: Treatment of oral complications of chemotherapy in bone marrow transplant patients.

Sponsor: Darby Pharmaceuticals, Inc. **Contact:** Mr. Richard Scotland

Address: Rockville Centre, NY **Phone:** (516) 536-3636 **Fax:**

Status: Designated **Designation Date:** 12-Mar-90 **Marketing Approval Date:**

Generic Name: Sucralfate suspension

Trade Name:

Orphan Indication: Treatment of oral ulcerations and dysphagia in patients with epidermolysis bullosa.

Sponsor: Darby Pharmaceuticals, Inc. **Contact:** Mr. Richard Scotland

Address: Rockville Centre, NY **Phone:** (516) 536-3636 **Fax:**

Status: Designated **Designation Date:** 04-Mar-91 **Marketing Approval Date:**

Generic Name: Sulfadiazine

Trade Name:

Orphan Indication: For use in combination with pyrimethamine for the treatment of Toxoplasma gondii encephalitis in patients with and without AIDS.

Sponsor: Eon Labs Manufacturing, Inc. **Contact:** Ms. Carol Frankel

Address: Laurelton, NY **Phone:** (212) 755-2339 **Fax:**

Status: Designated/Approved **Designation Date:** 14-Mar-94 **Marketing Approval Date:** 29-Jul-94

Generic Name: Sulfapyridine

Trade Name:

Orphan Indication: Treatment of dermatitis herpetiformis.

Sponsor: Jacobus Pharmaceutical Company **Contact:** Dr. Neil Lewis

Address: Princeton, NJ **Phone:** (609) 921-7447 **Fax:**

Status: Designated **Designation Date:** 10-Sep-90 **Marketing Approval Date:**

Generic Name: Superoxide dismutase (human)

Trade Name:

Orphan Indication: 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.

Sponsor: Pharmacia-Chiron Partnership **Contact:** Dr. Bernardita Mendez

Address: Emeryville, CA **Phone:** (510) 655-8729 **Fax:**

Status: Designated **Designation Date:** 06-Mar-85 **Marketing Approval Date:**

Generic Name: Superoxide dismutase (recombinant human) **Trade Name:** Oxsodrol

Orphan Indication: Prevention of reperfusion injury to donor organ tissue.

Sponsor: Bio-Technology General Corp. **Contact:** Ms. Briti Kundu

Address: Iselin, NJ **Phone:** (732) 632-8800 **Fax:** (732) 632-8844

Status: Designated/Withdrawn **Designation Date:** 17-May-88 **Marketing Approval Date:**

Generic Name: Suramin **Trade Name:** Metaret

Orphan Indication: Treatment of hormone-refractory prostate cancer.
Sponsor: Warner-Lambert Company **Contact:** Dr. Margaret Uprichard
Address: Ann Arbor, MI **Phone:** (313) 996-4906 **Fax:** (313) 998-3283
Status: Designated **Designation Date:** 06-May-97 **Marketing Approval Date:**

Generic Name: Surface active extract of saline lavage of bovine lungs **Trade Name:** Infasurf

Orphan Indication: Treatment and prevention of respiratory failure due to pulmonary surfactant deficiency in preterm infants.
Sponsor: ONY, Inc. **Contact:** Dr. Edmund Egan
Address: Amherst, NY **Phone:** (716) 636-9096 **Fax:**
Status: Designated/Approved **Designation Date:** 07-Jun-85 **Marketing Approval Date:** 01-Jul-98

Generic Name: Surfactant (human) (amniotic fluid derived) **Trade Name:** Human Surf

Orphan Indication: Prevention and treatment of neonatal respiratory distress syndrome.
Sponsor: Merritt, T. Allen M.D. **Contact:** Dr. T. Allen Merritt
Address: Sacramento, CA **Phone:** (916) 734-7613 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 25-Mar-87 **Marketing Approval Date:**

Generic Name: Synsorb Pk
Trade Name:

Orphan Indication: Treatment of verocytotoxigenic E. coli infections.
Sponsor: Synsorb Biotech Inc. **Contact:** Mr. Gerald Swiss
Address: Canada T2N 3P5, CA **Phone:** (415) 854-7400 **Fax:**
Status: Designated **Designation Date:** 17-Jul-95 **Marketing Approval Date:**

Generic Name: Synthetic Human Parathyroid Hormone 1-34
Trade Name:

Orphan Indication: Treatment of hypoparathyroidism
Sponsor: Orphan Pharmaceuticals, U.S., Inc. **Contact:** Mr. Milton Ellis
Address: Nashville, TN **Phone:** 6153990700 **Fax:**
Status: Designated **Designation Date:** 26-Jan-01 **Marketing Approval Date:**

Generic Name: Synthetic human secretin
Trade Name:

Orphan Indication: For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.
Sponsor: ChiRhoClin, Inc. **Contact:** Dr. Edward Purich
Address: Silver Spring, MD **Phone:** (301) 384-1554 **Fax:** (301) 384-1565
Status: Designated **Designation Date:** 16-Jun-99 **Marketing Approval Date:**

Generic Name: Synthetic human secretin
Trade Name:

Orphan Indication: For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.
Sponsor: ChiRhoClin, Inc. **Contact:** Dr. Edward Purich
Address: Silver Spring, MD **Phone:** (301) 384-1554 **Fax:** (301) 384-1565
Status: Designated **Designation Date:** 07-Mar-00 **Marketing Approval Date:**

Generic Name: Synthetic human secretin
Trade Name:

Orphan Indication: For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.
Sponsor: ChiRhoClin, Inc. **Contact:** Dr. Edward Purich
Address: Silver Spring, MD **Phone:** (301) 384-1554 **Fax:** (301) 384-1565
Status: Designated **Designation Date:** 16-Jun-99 **Marketing Approval Date:**

Generic Name: Synthetic human secretin
Trade Name:

Orphan Indication: For use in the evaluation of exocrine pancreas function.
Sponsor: ChiRhoClin, Inc. **Contact:** Dr. Edward Purich

Address: Silver Spring, MD **Phone:** (301) 384-1554 **Fax:** (301) 384-1565
Status: Designated **Designation Date:** 16-Jun-99 **Marketing Approval Date:**

Generic Name: Synthetic porcine secretin
Trade Name:

Orphan Indication: For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.
Sponsor: ChiRhoClin, Inc. **Contact:** Dr. Edward Purich
Address: Silver Spring, MD **Phone:** (301) 384-1554 **Fax:** (301) 384-1565
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Sponsor: ChiRhoClin, Inc. **Contact:** Dr. Edward Purich
Address: Silver Spring, MD **Phone:** (301) 384-1554 **Fax:** (301) 384-1565
Status: Designated **Designation Date:** 07-Mar-00 **Marketing Approval Date:**

Generic Name: Synthetic porcine secretin
Trade Name:

Orphan Indication: For use in the evaluation of exocrine pancreas function.
Sponsor: ChiRhoClin, Inc. **Contact:** Dr. Edward Purich
Address: Silver Spring, MD **Phone:** (301) 384-1554 **Fax:** (301) 384-1565
Status: Designated **Designation Date:** 18-Jun-99 **Marketing Approval Date:**

Generic Name: T-cell depleted stem cell enriched cellular product from peripheal blood stem cells
Trade Name:

Orphan Indication: Treatment of chronic granulomatous disease
Sponsor: Nexell Therapeutics Inc. **Contact:** Ms. Tung Koh
Address: Irvine, CA **Phone:** 9494706451 **Fax:** 9495862420
Status: Designated **Designation Date:** 01-Nov-01 **Marketing Approval Date:**

Generic Name: T4 endonuclease V, liposome encapsulated
Trade Name:

Orphan Indication: To prevent cutaneous neoplasms and other skin abnormalities in xeroderma pigmentosum.
Sponsor: AGI Dermatics **Contact:** Mr. Jonathan Klein
Address: Freeport, NY **Phone:** (516) 868-9026 **Fax:** (516) 868-9143
Status: Designated **Designation Date:** 27-Jun-89 **Marketing Approval Date:**

Generic Name: Tacrolimus **Trade Name:** Prograf

Orphan Indication: Prophylaxis of graft-versus-host-disease.
Sponsor: Fujisawa USA, Inc. **Contact:** Dr. Jerry Johnson
Address: Deerfield, IL **Phone:** (847) 317-8800 **Fax:** (847) 317-7286
Status: Designated **Designation Date:** 06-Apr-98 **Marketing Approval Date:**

Generic Name: TAK-603
Trade Name:

Orphan Indication: Treatment of Crohn's disease.
Sponsor: Tap Holdings Inc. **Contact:** Ms. Marilyn Bergland
Address: Deerfield, IL **Phone:** (847) 236-2366 **Fax:** (847) 317-5795
Status: Designated/Withdrawn **Designation Date:** 13-May-98 **Marketing Approval Date:**

Generic Name: Technetium Tc 99m pterotetramide

Trade Name: **Orphan Indication:** For the identification of ovarian carcinomas.**Sponsor:** Endocyte, Inc. **Contact:** Mr. P. Ron Ellis**Address:** Lafayette, IN **Phone:** (765) 463-7175 **Fax:****Status:** Designated **Designation Date:** 16-Feb-00 **Marketing Approval Date:****Generic Name:** Technetium Tc99m anti-melanoma murine monoclonal antibody **Trade Name:** Oncotrac Melanoma Imaging Kit**Orphan Indication:** For use in detecting, by imaging, metastases of malignant melanoma.**Sponsor:** NeoRx Corporation **Contact:** Ms. Becky Bottino**Address:** Seattle, WA **Phone:** (206) 286-2516 **Fax:** (206) 284-7112**Status:** Designated/Withdrawn **Designation Date:** 02-Jun-87 **Marketing Approval Date:****Generic Name:** Technetium Tc99m murine monoclonal antibody (IgG2a) to B cell **Trade Name:** LymphoScan**Orphan Indication:** 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.**Sponsor:** Immunomedics, Inc. **Contact:** Dr. Irene Wei**Address:** Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282**Status:** Designated **Designation Date:** 07-Apr-92 **Marketing Approval Date:****Generic Name:** Technetium Tc99m murine monoclonal antibody to hCG **Trade Name:** Immuraid, hCG-Tc-99m**Orphan Indication:** Detection of hCG producing tumors such as germ cell and trophoblastic cell tumors.**Sponsor:** Immunomedics, Inc. **Contact:** Dr. Joseph Presslitz**Address:** Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282**Status:** Designated **Designation Date:** 07-Aug-89 **Marketing Approval Date:****Generic Name:** Technetium Tc99m murine monoclonal antibody to human AFP **Trade Name:** AFP-Scan**Orphan Indication:** Detection of alpha-fetoprotein producing germ cell tumors.**Sponsor:** Immunomedics, Inc. **Contact:** Dr. Irene Wei**Address:** Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282**Status:** Designated **Designation Date:** 01-Aug-89 **Marketing Approval Date:****Generic Name:** Technetium Tc99m murine monoclonal antibody to human alpha-fetoprotein **Trade Name:** Immuraid, AFP-Scan**Orphan Indication:** Detection of hepatocellular carcinoma and hepatoblastoma.**Sponsor:** Immunomedics, Inc. **Contact:** Dr. Irene Wei**Address:** Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-8282**Status:** Designated **Designation Date:** 01-Aug-89 **Marketing Approval Date:****Generic Name:** Technetium Tc99m rh-Annexin V **Trade Name:** Apomate**Orphan Indication:** Diagnosis or assessment of rejection status in heart, heart-lung, single lung, or bilateral lung transplants.**Sponsor:** Theseus Imaging Corporation **Contact:** Mr. Philip Fantasia**Address:** Cambridge, MA **Phone:** (508) 359-1300 **Fax:** (508) 359-9932**Status:** Designated **Designation Date:** 03-Nov-00 **Marketing Approval Date:****Generic Name:** Temoporfin **Trade Name:** Foscan**Orphan Indication:** 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.**Sponsor:** Scotia Pharmaceuticals Ltd. **Contact:** Mr. Frank Sasinowski**Address:** Scotland FK9 4TZ, GB **Phone:** 2027374287 **Fax:** (202) 737-9329**Status:** Designated **Designation Date:** 28-Oct-99 **Marketing Approval Date:****Generic Name:** Temozolomide **Trade Name:** Temodar**Orphan Indication:** Treatment of recurrent malignant glioma.**Sponsor:** Schering-Plough Research Institute **Contact:** Dr. Joseph Lamendola**Address:** Kenilworth, NJ **Phone:** (908) 298-2628 **Fax:****Status:** Designated/Approved **Designation Date:** 05-Oct-98 **Marketing Approval Date:** 11-Aug-99**Generic Name:** Temozolomide **Trade Name:** Temodal

Orphan Indication: Treatment of advanced metastatic melanoma.
Sponsor: Schering-Plough Research Institute **Contact:** Dr. Joseph Lamendola
Address: Kenilworth, NJ **Phone:** (908) 298-2628 **Fax:**
Status: Designated **Designation Date:** 14-Oct-98 **Marketing Approval Date:**

Generic Name: Teniposide **Trade Name:** Vumon for injection

Orphan Indication: Treatment of refractory childhood acute lymphocytic leukemia.
Sponsor: Bristol-Myers Squibb Pharmaceutical Research **Contact:** Dr. Douglas Kriesel
 Institute
Address: Wallingford, CT **Phone:** (203) 284-6051 **Fax:**
Status: Designated/Approved **Designation Date:** 01-Nov-84 **Marketing Approval Date:** 14-Jul-92

Generic Name: Teriparatide **Trade Name:** Parathar

Orphan Indication: Treatment of idiopathic osteoporosis.
Sponsor: Henri Beaufour Institute USA, Inc. **Contact:** Mr. Steven Scott
Address: Milford, MA **Phone:** (508) 478-0144 **Fax:** (508) 473-3531
Status: Designated **Designation Date:** 28-Oct-99 **Marketing Approval Date:**

Generic Name: Teriparatide **Trade Name:** Parathar

Orphan Indication: Diagnostic agent to assist in establishing the diagnosis in patients presenting with clinical and laboratory evidence of hypocalcemia due to either hypoparathyroidism or pseudohypoparathyroidism.
Sponsor: Rhone-Poulenc Rorer Pharmaceuticals, Inc. **Contact:** Dr. Thomas Donnelly
Address: Collegeville, PA **Phone:** (610) 454-3023 **Fax:**
Status: Designated/Approved **Designation Date:** 09-Jan-87 **Marketing Approval Date:** 23-Dec-87

Generic Name: Terlipressin **Trade Name:** Glypressin

Orphan Indication: Treatment of bleeding esophageal varices.
Sponsor: Ferring Laboratories, Inc. **Contact:** Mr. Isidoro Nudelman
Address: Suffern, NY **Phone:** (888) 793-6367 **Fax:**
Status: Designated **Designation Date:** 06-Mar-86 **Marketing Approval Date:**

Generic Name: Testosterone **Trade Name:** Androgel

Orphan Indication: Treatment of weight loss in AIDS patients with HIV-associated wasting.
Sponsor: Unimed Pharmaceuticals, Inc. **Contact:** Dr. Margaret Hurley
Address: Deerfield, IL **Phone:** 9737011596 **Fax:** 9736359881
Status: Designated **Designation Date:** 05-Feb-96 **Marketing Approval Date:**

Generic Name: Testosterone **Trade Name:** TheraDerm Testosterone Transdermal System

Orphan Indication: For use as physiologic testosterone replacement in androgen deficient HIV+ patients with an associated weight loss.
Sponsor: Watson Laboratories **Contact:** Ms. Dorothy Frank
Address: Salt Lake City, UT **Phone:** (801) 588-6200 **Fax:** (801) 583-8135
Status: Designated **Designation Date:** 22-Sep-97 **Marketing Approval Date:**

Generic Name: Testosterone propionate ointment 2%
 Trade Name:

Orphan Indication: Treatment of vulvar dystrophies.
Sponsor: Star Pharmaceuticals, Inc. **Contact:** Mr. Scott Davidson
Address: Pompano Beach, FL **Phone:** (954) 971-9704 **Fax:**
Status: Designated **Designation Date:** 31-Jul-91 **Marketing Approval Date:**

Generic Name: Testosterone sublingual
 Trade Name:

Orphan Indication: Treatment of constitutional delay of growth and puberty in boys.
Sponsor: Bio-Technology General Corp. **Contact:** Mr. Briti Kundu
Address: Iselin, NJ **Phone:** (732) 632-8800 **Fax:** (732) 632-8844
Status: Designated/Withdrawn **Designation Date:** 16-Jan-91 **Marketing Approval Date:**

Generic Name: Tetrabenazine
 Trade Name:

Orphan Indication: Treatment of Huntington's disease.
Sponsor: Lifehealth Limited **Contact:** Mr. Robert Rosen
Address: SL4 4BA, UK **Phone:** (415) 332-6753 **Fax:** (415) 332-6751
Status: Designated **Designation Date:** 11-Dec-97 Marketing Approval Date:

Generic Name: Tetrabenazine
Trade Name:

Orphan Indication: Treatment of moderate/severe tardive dyskinesia.
Sponsor: Lifehealth Limited **Contact:** Mr. Robert Rosen
Address: SL4 4BA, UK **Phone:** (415) 332-6753 **Fax:** (415) 332-6751
Status: Designated **Designation Date:** 12-May-98 Marketing Approval Date:

Generic Name: Tetraiodothyroacetic acid
Trade Name:

Orphan Indication: Suppression of thyroid stimulating hormone in patients with well-differentiated cancer of the thyroid gland.
Sponsor: Danforth, Jr., MD, Elliot **Contact:** Dr. Elliot Danforth, Jr.
Address: Underhill, VT **Phone:** (802) 899-2349 **Fax:**
Status: Designated **Designation Date:** 01-May-00 Marketing Approval Date:

Generic Name: Thalidomide **Trade Name:** Thalomid

Orphan Indication: Treatment of multiple myeloma.
Sponsor: Celgene Corporation **Contact:** Dr. Steve Thomas
Address: Warren, NJ **Phone:** (732) 805-3914 **Fax:**
Status: Designated **Designation Date:** 14-Oct-98 Marketing Approval Date:

Generic Name: Thalidomide
Trade Name:

Orphan Indication: Treatment of Kaposi's sarcoma.
Sponsor: Celgene Corporation **Contact:** Dr. Steve Thomas
Address: Warren, NJ **Phone:** (732) 805-3914 **Fax:** (908) 271-4184
Status: Designated **Designation Date:** 29-Jul-98 Marketing Approval Date:

Generic Name: Thalidomide
Trade Name:

Orphan Indication: Treatment of graft versus host disease in patients receiving bone marrow transplantation.
Sponsor: Pediatric Pharmaceuticals, Inc. **Contact:** Mr. R.C. Stites
Address: Westfield, NJ **Phone:** (908) 225-0989 **Fax:**
Status: Designated **Designation Date:** 19-Sep-88 Marketing Approval Date:

Generic Name: Thalidomide
Trade Name:

Orphan Indication: Treatment and maintenance of reactional lepromatous leprosy.
Sponsor: Pediatric Pharmaceuticals, Inc. **Contact:** Mr. R.C. Stites
Address: Westfield, NJ **Phone:** (908) 225-0989 **Fax:**
Status: Designated **Designation Date:** 15-Nov-88 Marketing Approval Date:

Generic Name: Thalidomide
Trade Name:

Orphan Indication: Treatment of primary brain malignancies.
Sponsor: Celgene Corporation **Contact:** Dr. Steve Thomas
Address: Warren, NJ **Phone:** (732) 805-3914 **Fax:** (908) 271-4184
Status: Designated **Designation Date:** 27-Feb-98 Marketing Approval Date:

Generic Name: Thalidomide **Trade Name:** Thalomid

Orphan Indication: Treatment of Crohn's disease.
Sponsor: Celgene Corporation **Contact:** Dr. Steve Thomas
Address: Warren, NJ **Phone:** (732) 805-3914 **Fax:**
Status: Designated **Designation Date:** 06-Apr-99 Marketing Approval Date:

Generic Name: Thalidomide

Trade Name:

Orphan Indication: Prevention of graft versus host disease.**Sponsor:** Andrulis Research Corporation **Contact:** Dr. Murray Drulak**Address:** Beltsville, MD **Phone:** (301) 419-2400 **Fax:****Status:** Designated **Designation Date:** 05-Mar-90 **Marketing Approval Date:****Generic Name:** Thalidomide

Trade Name:

Orphan Indication: Prevention of graft versus host disease in patients receiving bone marrow transplantation.**Sponsor:** Pediatric Pharmaceuticals, Inc. **Contact:** Mr. R.C. Stites**Address:** Westfield, NJ **Phone:** (908) 225-0989 **Fax:****Status:** Designated **Designation Date:** 19-Sep-88 **Marketing Approval Date:****Generic Name:** Thalidomide **Trade Name:** Synovir**Orphan Indication:** Treatment of HIV-associated wasting syndrome.**Sponsor:** Celgene Corporation **Contact:** Dr. Steve Thomas**Address:** Warren, NJ **Phone:** (732) 805-3914 **Fax:** (732) 271-4184**Status:** Designated **Designation Date:** 11-Mar-96 **Marketing Approval Date:****Generic Name:** Thalidomide **Trade Name:** Thalomid**Orphan Indication:** Treatment of erythema nodosum leprosum.**Sponsor:** Celgene Corporation **Contact:** Dr. Steve Thomas**Address:** Warren, NJ **Phone:** (732) 805-3914 **Fax:** (732) 271-4184**Status:** Designated/Approved **Designation Date:** 26-Jul-95 **Marketing Approval Date:** 16-Jul-98**Generic Name:** Thalidomide

Trade Name:

Orphan Indication: Treatment and prevention of recurrent aphthous ulcers in severely, terminally immunocompromised patients.**Sponsor:** Andrulis Research Corporation **Contact:** Dr. Murray Drulak**Address:** Beltsville, MD **Phone:** (301) 419-2400 **Fax:****Status:** Designated **Designation Date:** 15-May-95 **Marketing Approval Date:****Generic Name:** Thalidomide

Trade Name:

Orphan Indication: Treatment of severe recurrent aphthous stomatitis in severely, terminally immunocompromised patients.**Sponsor:** Celgene Corporation **Contact:** Dr. Steve Thomas**Address:** Warren, NJ **Phone:** (732) 805-3914 **Fax:** () -**Status:** Designated **Designation Date:** 01-May-95 **Marketing Approval Date:****Generic Name:** Thalidomide

Trade Name:

Orphan Indication: Treatment of the clinical manifestations of mycobacterial infection caused by Mycobacterium tuberculosis and non-tuberculous mycobacteria.**Sponsor:** Celgene Corporation **Contact:** Dr. Steve Thomas**Address:** Warren, NJ **Phone:** (732) 805-3914 **Fax:** () -**Status:** Designated **Designation Date:** 12-Jan-93 **Marketing Approval Date:****Generic Name:** Thalidomide

Trade Name:

Orphan Indication: Treatment of graft versus host disease.**Sponsor:** Andrulis Research Corporation **Contact:** Dr. Murray Drulak**Address:** Beltsville, MD **Phone:** (301) 419-2400 **Fax:****Status:** Designated **Designation Date:** 05-Mar-90 **Marketing Approval Date:****Generic Name:** Thymalfasin **Trade Name:** Zadaxin**Orphan Indication:** Treatment of DiGeorge anomaly with immune defects.**Sponsor:** SciClone Pharmaceuticals, Inc. **Contact:** Mr. David Wilgus**Address:** San Mateo, CA **Phone:** 6503583456 **Fax:** (650) 358-3469**Status:** Designated **Designation Date:** 08-Jan-98 **Marketing Approval Date:**

Generic Name: Thymalfasin **Trade Name:** Zadaxin**Orphan Indication:** Treatment of chronic active hepatitis B.**Sponsor:** SciClone Pharmaceuticals, Inc. **Contact:** Ms. Eda Cook**Address:** San Mateo, CA **Phone:** (650) 358-1444 **Fax:** (415) 358-3469**Status:** Designated **Designation Date:** 03-May-91 **Marketing Approval Date:****Generic Name:** Thymalfasin **Trade Name:** Zadaxin**Orphan Indication:** Treatment of hepatocellular carcinoma.**Sponsor:** SciClone Pharmaceuticals, Inc. **Contact:** Mr. Shawn Singh**Address:** San Mateo, CA **Phone:** (650) 358-3456 **Fax:** (650) 358-3469**Status:** Designated **Designation Date:** 06-Mar-00 **Marketing Approval Date:****Generic Name:** Thymoxamine HCl

Trade Name:

Orphan Indication: Reversal of phenylephrine-induced mydriasis in patients who have narrow anterior angles and are at risk of developing an acute attack of angle-closure glaucoma following mydriasis.**Sponsor:** Iolab Pharmaceuticals **Contact:** Susan Caballa**Address:** Claremont, CA **Phone:** (714) 399-1278 **Fax:****Status:** Designated/Withdrawn **Designation Date:** 16-Nov-87 **Marketing Approval Date:****Generic Name:** Thyrotropin alfa **Trade Name:** Thyrogen**Orphan Indication:** Treatment of well-differentiated papillary, follicular or combined papillary/follicular carcinomas of the thyroid**Sponsor:** Genzyme Corporation **Contact:** Ms. Patricia Thomas**Address:** Cambridge, MA **Phone:** 6177618239 **Fax:** 6172527600**Status:** Designated **Designation Date:** 03-Aug-01 **Marketing Approval Date:****Generic Name:** Thyrotropin alpha **Trade Name:** Thyrogen**Orphan Indication:** As an adjunct in the diagnosis of thyroid cancer.**Sponsor:** Genzyme Corporation **Contact:** Ms. Allison Lawton**Address:** Cambridge, MA **Phone:** (617) 252-7500 **Fax:** (617) 252-7600**Status:** Designated/Approved **Designation Date:** 24-Feb-92 **Marketing Approval Date:** 30-Nov-98**Generic Name:** Tiapride

Trade Name:

Orphan Indication: Treatment of Tourette's syndrome.**Sponsor:** Sanofi-Synthelabo, Inc. **Contact:** Dr. Debra Gayda**Address:** Malvern, PA **Phone:** (610) 889-8645 **Fax:** (610) 889-6993**Status:** Designated/Withdrawn **Designation Date:** 21-Apr-98 **Marketing Approval Date:****Generic Name:** Tiazofurin (2-Beta-D-ribofuranosyl-4-thiazolecarboxamide)

Trade Name:

Orphan Indication: Chronic myelogenous leukemia (CML)**Sponsor:** ICN Pharmaceuticals, Inc. (ICN) **Contact:** Dr. Jane Fang**Address:** Costa Mesa, CA **Phone:** 8005485100 **Fax:****Status:** Designated **Designation Date:** 27-Dec-00 **Marketing Approval Date:****Generic Name:** Tiopronin **Trade Name:** Thiola**Orphan Indication:** Prevention of cystine nephrolithiasis in patients with homozygous cystinuria.**Sponsor:** Pak, Charles Y.C. M.D. **Contact:** Dr. Charles Y.C. Pak**Address:** Dallas, TX **Phone:** 6214) 688-2100 **Fax:****Status:** Designated/Approved **Designation Date:** 17-Jan-86 **Marketing Approval Date:** 11-Aug-88**Generic Name:** Tiratricol **Trade Name:** Triacana**Orphan Indication:** 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.**Sponsor:** Laphal Laboratoires **Contact:** Ms. Valerie Laigle**Address:** France, FR **Phone:** () - **Fax:****Status:** Designated **Designation Date:** 13-Aug-91 **Marketing Approval Date:**

Generic Name: Tizanidine HCl **Trade Name:** Zanaflex

Orphan Indication: Treatment of spasticity associated with multiple sclerosis and spinal cord injury.

Sponsor: Athena Neurosciences, Inc. **Contact:** Ms. Kathleen Dumas

Address: South San Francisco, CA **Phone:** (415) 877-0900 **Fax:** (415) 877-8370

Status: Designated **Designation Date:** 31-Jan-94 **Marketing Approval Date:**

Generic Name: Tobramycin **Trade Name:** Tobl

Orphan Indication: Treatment of bronchiectasis patients infected with *Pseudomonas aeruginosa*.

Sponsor: Chiron Corporation **Contact:** Ms. Connie Spooner

Address: Seattle, WA **Phone:** 2065056916 **Fax:** (206) 282-5065

Status: Designated **Designation Date:** 18-Jun-99 **Marketing Approval Date:**

Generic Name: Tobramycin for inhalation **Trade Name:** TOBI

Orphan Indication: Treatment of bronchopulmonary infections of *Pseudomonas aeruginosa* in cystic fibrosis patients.

Sponsor: Pathogenesis Corporation **Contact:** Dr. A. Bruce Montgomery

Address: Seattle, WA **Phone:** (206) 467-8100 **Fax:** (206) 282-5065

Status: Designated/Approved **Designation Date:** 13-Oct-94 **Marketing Approval Date:** 22-Dec-97

Generic Name: Tocophersolan oral solution (vitamin E-tpgs)

Trade Name:

Orphan Indication: Treatment of vitamin E deficiency resulting from malabsorption due to prolonged cholestatic hepatobiliary disease.

Sponsor: Sterling Winthrop **Contact:** Linda Harver

Address: Malvern, PA **Phone:** (215) 889-8600 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 15-Apr-88 **Marketing Approval Date:**

Generic Name: Topiramate **Trade Name:** Topamax

Orphan Indication: Treatment of Lennox-Gastaut syndrome.

Sponsor: R. W. Johnson Pharmaceutical Research Institute **Contact:** Ms. Catherine Glamkowski

Address: Raritan, NJ **Phone:** (908) 704-5360 **Fax:**

Status: Designated/Approved **Designation Date:** 25-Nov-92 **Marketing Approval Date:** 28-Aug-01

Generic Name: Toremifene

Trade Name:

Orphan Indication: Treatment of desmoid tumors.

Sponsor: Orion Corporation **Contact:** Mr. Daniel Azarnoff

Address: Finland, **Phone:** (650) 588-9187 **Fax:**

Status: Designated **Designation Date:** 17-Aug-93 **Marketing Approval Date:**

Generic Name: Toremifene **Trade Name:** Fareston

Orphan Indication: Hormonal therapy of metastatic carcinoma of the breast.

Sponsor: Orion Corporation **Contact:** Dr. Daniel Azarnoff

Address: Finland, **Phone:** (415) 340-8222 **Fax:**

Status: Designated/Approved **Designation Date:** 19-Sep-91 **Marketing Approval Date:** 29-May-97

Generic Name: Tositumomab and iodine I 131 tositumomab **Trade Name:** Bexxar

Orphan Indication: Treatment of non-Hodgkin's B-cell lymphoma.

Sponsor: Coulter Pharmaceutical, Inc. **Contact:** Ms. Patricia Oto

Address: Palo Alto, CA **Phone:** (650) 553-1917 **Fax:** (650) 553-1910

Status: Designated **Designation Date:** 16-May-94 **Marketing Approval Date:**

Generic Name: Tranexamic acid **Trade Name:** Cyklokapron

Orphan Indication: Treatment of patients undergoing prostatectomy where there is hemorrhage or risk of hemorrhage as a result of increased fibrinolysis or fibrinogenolysis.

Sponsor: Pharmacia Inc. **Contact:** Robert Watson

Address: Columbus, OH **Phone:** (614) 764-8100 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 23-Jul-87 **Marketing Approval Date:**

Generic Name: Tranexamic acid **Trade Name:** Cyklokapron

Orphan Indication: Treatment of hereditary angioneurotic edema.
Sponsor: Pharmacia Inc. **Contact:** Mr. Robert Watson
Address: Columbus, OH **Phone:** (614) 764-8100 **Fax:**
Status: Designated/Withdrawn **Designation Date:** 09-Sep-85 **Marketing Approval Date:**

Generic Name: Tranexamic acid **Trade Name:** Cyklokapron

Orphan Indication: Treatment of patients with congenital coagulopathies who are undergoing surgical procedures (e.g. dental extractions).
Sponsor: Pharmacia Inc. **Contact:** Mr. Robert Watson
Address: Columbus, OH **Phone:** (614) 764-8100 **Fax:**
Status: Designated/Approved/With **Designation Date:** 29-Oct-85 **Marketing Approval Date:** 30-Dec-86
drawn

Generic Name: Transforming growth factor-beta 2
Trade Name:

Orphan Indication: Treatment of full thickness macular holes.
Sponsor: Celtrix Pharmaceuticals, Inc. **Contact:** Dr. Meggi Raeder
Address: Santa Clara, CA **Phone:** (408) 450-4724 **Fax:**
Status: Designated **Designation Date:** 18-Dec-92 **Marketing Approval Date:**

Generic Name: Transgenic human alpha 1 antitrypsin
Trade Name:

Orphan Indication: Treatment of emphysema secondary to alpha 1 antitrypsin deficiency.
Sponsor: PPL Therapeutics (Scotland) Limited **Contact:** Dr. Julian Cooper
Address: EH25 9PP Scotland, GB **Phone:** (540) 961-5559 **Fax:**
Status: Designated **Designation Date:** 19-May-99 **Marketing Approval Date:**

Generic Name: Trastuzumab **Trade Name:** Herceptin

Orphan Indication: Treatment of patients with pancreatic cancer that overexpress p185HER2.
Sponsor: Genentech, Inc. **Contact:** Dr. Robert Garnick
Address: South San Francisco, CA **Phone:** (650) 225-1201 **Fax:** (650) 225-6000
Status: Designated **Designation Date:** 14-Dec-99 **Marketing Approval Date:**

Generic Name: Treosulfan **Trade Name:** Ovastat

Orphan Indication: Treatment of ovarian cancer.
Sponsor: Medac GmbH **Contact:** Mr. Thomas Becze
Address: Germany, DE **Phone:** (609) 737-3131 **Fax:**
Status: Designated **Designation Date:** 16-May-94 **Marketing Approval Date:**

Generic Name: Tretinoin **Trade Name:** Atragen

Orphan Indication: Treatment of acute and chronic leukemia.
Sponsor: Aronex Pharmaceuticals, Inc. **Contact:** Ms. Helene Marshall
Address: The Woodlands, TX **Phone:** (281) 367-1666 **Fax:** (281) 367-1676
Status: Designated **Designation Date:** 14-Jan-93 **Marketing Approval Date:**

Generic Name: Tretinoin
Trade Name:

Orphan Indication: Treatment of squamous metaplasia of the ocular surface epithelia (conjunctiva and/or cornea) with mucous deficiency and keratinization.
Sponsor: Hannan Ophthalmic Marketing Services, Inc **Contact:** Mr. James Hannan
Address: Marshfield, MA **Phone:** (781) 834-8111 **Fax:** (781) 834-3917
Status: Designated **Designation Date:** 15-Apr-85 **Marketing Approval Date:**

Generic Name: Tretinoin **Trade Name:** Vesanoïd

Orphan Indication: Treatment of acute promyelocytic leukemia.
Sponsor: Hoffmann-La Roche, Inc. **Contact:** Dr. David Parkinson
Address: Nutley, NJ **Phone:** (201) 496-8798 **Fax:**
Status: Designated/Approved **Designation Date:** 24-Oct-90 **Marketing Approval Date:** 22-Nov-95

Generic Name: Trientine HCl **Trade Name:** Syprine

Orphan Indication: Treatment of patients with Wilson's disease who are intolerant, or inadequately responsive to penicillamine.

Sponsor: Merck Sharp & Dohme Research **Contact:** Dr. Robert Zeldin

Address: West Point, PA **Phone:** (610) 397-3149 **Fax:**

Status: Designated/Approved **Designation Date:** 24-Dec-84 **Marketing Approval Date:** 08-Nov-85

Generic Name: Trimetrexate **Trade Name:** Neutrexin

Orphan Indication: Treatment of metastatic osteogenic sarcoma.

Sponsor: Medimmune Oncology, Inc. **Contact:** Ms. Eve Damiano

Address: West Conshohocken, PA **Phone:** (610) 832-4580 **Fax:** (610) 832-4571

Status: Designated **Designation Date:** 10-Aug-00 **Marketing Approval Date:**

Generic Name: Trimetrexate glucuronate **Trade Name:** Neutrexin

Orphan Indication: Treatment of Pneumocystis carinii pneumonia in AIDS patients.

Sponsor: Medimmune Oncology, Inc. **Contact:** Ms. Eve Damiano

Address: West Conshohocken, PA **Phone:** (610) 832-4580 **Fax:** (610) 832-4571

Status: Designated/Approved **Designation Date:** 15-May-86 **Marketing Approval Date:** 17-Dec-93

Generic Name: Trimetrexate glucuronate

Trade Name:

Orphan Indication: Treatment of patients with advanced non-small cell carcinoma of the lung.

Sponsor: Medimmune Oncology, Inc. **Contact:** Ms. Eve Damiano

Address: West Conshohocken, PA **Phone:** (610) 832-4580 **Fax:** (610) 832-4571

Status: Designated **Designation Date:** 13-Jan-88 **Marketing Approval Date:**

Generic Name: Trimetrexate glucuronate

Trade Name:

Orphan Indication: Treatment of pancreatic adenocarcinoma.

Sponsor: Medimmune Oncology, Inc. **Contact:** Ms. Eve Damiano

Address: West Conshohocken, PA **Phone:** (610) 832-4580 **Fax:** (610) 832-4571

Status: Designated **Designation Date:** 25-Jul-85 **Marketing Approval Date:**

Generic Name: Trimetrexate glucuronate

Trade Name:

Orphan Indication: Treatment of metastatic colorectal adenocarcinoma.

Sponsor: Medimmune Oncology, Inc. **Contact:** Ms. Eve Damiano

Address: West Conshohocken, PA **Phone:** (610) 832-4580 **Fax:** (610) 832-4571

Status: Designated **Designation Date:** 25-Jul-85 **Marketing Approval Date:**

Generic Name: Trimetrexate glucuronate

Trade Name:

Orphan Indication: Treatment of metastatic carcinoma of the head and neck (i.e. buccal cavity, pharynx, and larynx).

Sponsor: Medimmune Oncology, Inc. **Contact:** Ms. Eve Damiano

Address: Gaithersburg, MD **Phone:** 3015274261 **Fax:** 3012285161

Status: Designated **Designation Date:** 25-Jul-85 **Marketing Approval Date:**

Generic Name: Triptorelin pamoate **Trade Name:** Decapeptyl Injection

Orphan Indication: For use in the palliative treatment of advanced ovarian carcinoma of epithelial origin.

Sponsor: Debio R.A. Inc. **Contact:** Peter Kostopoulos

Address: Mclean, VA **Phone:** (703) 749-1029 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 10-Aug-90 **Marketing Approval Date:**

Generic Name: Trisaccharides A and B **Trade Name:** Biosynject

Orphan Indication: Prevention of ABO medical hemolytic reactions arising from ABO-incompatible bone marrow transplantation.

Sponsor: Chembiomed, Ltd. **Contact:** Dr. G.H. Worsley

Address: Canada T6H 4NP, CA **Phone:** (403) 450-6800 **Fax:**

Status: Designated **Designation Date:** 15-Apr-88 **Marketing Approval Date:**

Generic Name: Trisaccharides A and B

Trade Name:

Orphan Indication: Treatment of moderate to very severe clinical forms of transfusion reactions arising from ABO incompatible transfusions of blood, blood products, and blood derivatives.

Sponsor: Chembiomed, Ltd. **Contact:**

Address: Alberta, CA **Phone:** Fax:

Status: Designated/Withdrawn **Designation Date:** 03-Aug-87 **Marketing Approval Date:**

Generic Name: Trisaccharides A and B **Trade Name:** Biosynject

Orphan Indication: 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.

Sponsor: Chembiomed, Ltd. **Contact:** Dr. G.H. Worsley

Address: Canada T6H 4NP, CA **Phone:** (403) 450-6800 **Fax:**

Status: Designated **Designation Date:** 12-Apr-87 **Marketing Approval Date:**

Generic Name: Trisaccharides A and B **Trade Name:** Biosynject

Orphan Indication: For use in ABO-incompatible solid organ transplantation, including kidney, heart, liver and pancreas.

Sponsor: Chembiomed, Ltd. **Contact:** Dr. G.H. Worsley

Address: Canada T6H 4NP, CA **Phone:** (403) 450-6800 **Fax:**

Status: Designated **Designation Date:** 20-Apr-87 **Marketing Approval Date:**

Generic Name: Trisodium citrate concentration **Trade Name:** Hemocitrate

Orphan Indication: For use in leukapheresis procedures.

Sponsor: Hemotec Medical Products, Inc. **Contact:** Dr. Vincent DiSpigno

Address: Johnston, RI **Phone:** (401) 934-2571 **Fax:**

Status: Designated **Designation Date:** 15-Jun-95 **Marketing Approval Date:**

Generic Name: Troleandomycin

Trade Name:

Orphan Indication: Treatment of severe steroid-requiring asthma.

Sponsor: Szeffler, Stanley M. M.D. **Contact:** Dr. Stanley Szeffler

Address: Denver, CO **Phone:** (303) 388-4461 **Fax:**

Status: Designated **Designation Date:** 21-Sep-89 **Marketing Approval Date:**

Generic Name: Tumor necrosis factor-binding protein I

Trade Name:

Orphan Indication: Treatment of symptomatic patients with AIDS including all patients with CD4 counts less than 200 cells per mm³.

Sponsor: Serono Laboratories, Inc. **Contact:** Ms. Pamela Williamson Joyce

Address: Norwell, MA **Phone:** (800) 283-8088 **Fax:** (781) 871-6754

Status: Designated **Designation Date:** 06-Jan-93 **Marketing Approval Date:**

Generic Name: Tumor necrosis factor-binding protein II

Trade Name:

Orphan Indication: Treatment of symptomatic patients with the AIDS including all patients with CD4 T-cell counts less than 200 cells per mm³.

Sponsor: Serono Laboratories, Inc. **Contact:** Mr. Dennis Bucceri

Address: Norwell, MA **Phone:** (800) 283-8088 **Fax:** (781) 871-6754

Status: Designated **Designation Date:** 06-Jan-93 **Marketing Approval Date:**

Generic Name: Tyloxapol **Trade Name:** Supervent

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: Kennedy & Hoidal, M.D.'s **Contact:** Dr. Thomas Kennedy

Address: Salt Lake City, UT **Phone:** (801) 581-7806 **Fax:** (801) 585-3355

Status: Designated **Designation Date:** 08-Mar-95 **Marketing Approval Date:**

Generic Name: Ubiquinone **Trade Name:** Ubiquigel

Orphan Indication: Treatment of mitochondrial cytopathies.

Sponsor: Gel-Tec, Division of Tishcon Corp. **Contact:** Mr. Raj Chopra

Address: Westbury, NY **Phone:** (516) 333-3050 **Fax:** (516) 997-1052

Status: Designated **Designation Date:** 14-Dec-99 **Marketing Approval Date:**

Generic Name: Unconjugated Chimeric (human-murine) G250 IgG monoclonal antibody
Trade Name:

Orphan Indication: Treatment of renal cell carcinoma.

Sponsor: Wilex Biotechnology GmbH **Contact:** Dr. MaryJane Rafii

Address: Germany, DE **Phone:** 2124501536 **Fax:** 2124501535

Status: Designated **Designation Date:** 22-Mar-01 **Marketing Approval Date:**

Generic Name: Uridine 5'-triphosphate
Trade Name:

Orphan Indication: Treatment of cystic fibrosis.

Sponsor: Inspire Pharmaceuticals, Inc. **Contact:** Ms. JoAnn Gorden

Address: Durham, NC **Phone:** (919) 941-9777 **Fax:** (919) 941-9797

Status: Designated/Withdrawn **Designation Date:** 04-Dec-95 **Marketing Approval Date:**

Generic Name: Uridine 5'-triphosphate
Trade Name:

Orphan Indication: To facilitate the removal of lung secretions in the treatment of patients with primary ciliary dyskinesia.

Sponsor: Inspire Pharmaceuticals, Inc. **Contact:** Dr. Donald Kellerman

Address: Durham, NC **Phone:** (919) 941-9777 **Fax:** (919) 941-9797

Status: Designated/Withdrawn **Designation Date:** 26-Jun-96 **Marketing Approval Date:**

Generic Name: Urofollitropin **Trade Name:** Metrodin

Orphan Indication: 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.

Sponsor: Serono Laboratories, Inc. **Contact:** Mr. Thomas Lang

Address: Norwell, MA **Phone:** (617) 982-9000 **Fax:** (617) 871-6754

Status: Designated/Approved **Designation Date:** 25-Nov-87 **Marketing Approval Date:** 18-Sep-86

Generic Name: Urofollitropin **Trade Name:** Fertinex

Orphan Indication: For the initiation and re-initiation of spermatogenesis in adult males with reproductive failure due to hypothalamic or pituitary dysfunction, hypogonadotropic hypogonadism.

Sponsor: Serono Laboratories, Inc. **Contact:** Mr. Dennis Bucceri

Address: Norwell, MA **Phone:** (800) 283-8088 **Fax:** (781) 871-6754

Status: Designated **Designation Date:** 05-Dec-97 **Marketing Approval Date:**

Generic Name: Urogastrone
Trade Name:

Orphan Indication: For acceleration of corneal epithelial regeneration and healing of stromal incisions from corneal transplant surgery.

Sponsor: Chiron Vision **Contact:** Mr. Mark Stavro

Address: Claremont, CA **Phone:** (909) 399-1343 **Fax:**

Status: Designated **Designation Date:** 01-Nov-84 **Marketing Approval Date:**

Generic Name: Ursodiol **Trade Name:** URSO

Orphan Indication: Treatment of patients with primary biliary cirrhosis.

Sponsor: Axcan Pharma Inc. **Contact:** Ms. Quyen Vinh

Address: Canada, CA **Phone:** 4504675138 **Fax:** (514) 669-5161

Status: Designated/Approved **Designation Date:** 20-Jun-91 **Marketing Approval Date:** 10-Dec-97

Generic Name: Ursodiol **Trade Name:** Actigall

Orphan Indication: Management of the clinical signs and symptoms associated with primary biliary cirrhosis.

Sponsor: Novartis Pharmaceuticals Corporation **Contact:** Mr. Robert Miranda

Address: East Hanover, NJ **Phone:** (908) 277-5744 **Fax:**

Status: Designated/Withdrawn **Designation Date:** 19-Feb-91 **Marketing Approval Date:**

Generic Name: Valine, isoleucine and leucine **Trade Name:** VIL

Orphan Indication: Treatment of hyperphenylalaninemia.

Sponsor: Leas Research Products **Contact:** Ms. Terri Shawhan

Address: North Haven, CT **Phone:** (203) 239-2021 **Fax:** (203) 288-8411

Status: Designated **Designation Date:** 05-Jan-96 **Marketing Approval Date:**

Generic Name: Valrubicin	Trade Name: Valstar
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Orphan Indication: Treatment of carcinoma in situ of the urinary bladder.

Sponsor: Anthra Pharmaceuticals, Inc. **Contact:** Dr. Nabila Turjman

Address: Princeton, NJ **Phone:** (609) 514-1060 **Fax:** 6095141360

Status: Designated/Approved **Designation Date:** 23-May-94 **Marketing Approval Date:** 25-Sep-98

Generic Name: Vapreotide	Trade Name: Octastatin
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Orphan Indication: Prevention of early postoperative complications following pancreatic resection.

Sponsor: Debiopharm S.A. **Contact:** Dr. J. Kay Noel

Address: Switzerland, CH **Phone:** (510) 525-4250 **Fax:** (510) 528-0374

Status: Designated **Designation Date:** 06-Mar-00 **Marketing Approval Date:**

Generic Name: Vapreotide	Trade Name: Octastatin
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Orphan Indication: Treatment of gastrointestinal and pancreatic fistulas.

Sponsor: Debiopharm S.A. **Contact:** Dr. J. Kay Noel

Address: Switzerland, CH **Phone:** (510) 525-4250 **Fax:** (510) 528-0374

Status: Designated **Designation Date:** 10-Jan-00 **Marketing Approval Date:**

Generic Name: Vapreotide	Trade Name: Octastatin
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Orphan Indication: Treatment of esophageal variceal hemorrhage patients with portal hypertension.

Sponsor: Debiopharm S.A. **Contact:** Dr. J. Kay Noel

Address: Switzerland, CH **Phone:** (510) 525-4250 **Fax:** (510) 528-0374

Status: Designated **Designation Date:** 10-Jan-00 **Marketing Approval Date:**

Generic Name: Vasoactive intestinal peptide	Trade Name:
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Orphan Indication: Treatment of Acute Respiratory Distress Syndrome.

Sponsor: Sami I. Said, M.D. **Contact:** Dr. Sami Said

Address: Stony Brook, NY **Phone:** 6314441754 **Fax:**

Status: Designated **Designation Date:** 09-Mar-01 **Marketing Approval Date:**

Generic Name: Vasoactive intestinal polypeptide	Trade Name:
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Orphan Indication: Treatment of acute esophageal food impaction.

Sponsor: Research Triangle Pharmaceuticals **Contact:** Dr. David Shoemaker

Address: Durham, NC **Phone:** (919) 361-2286 **Fax:** (919) 361-2290

Status: Designated **Designation Date:** 23-Jun-93 **Marketing Approval Date:**

Generic Name: vigabatrin	Trade Name: Sabril
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Orphan Indication: Treatment of infantile spasms.

Sponsor: Aventis Pharmaceuticals Inc. **Contact:** Ms. M. Lorie Stewart

Address: Kansas City, MO **Phone:** (816) 767-6605 **Fax:** (816) 767-7369

Status: Designated **Designation Date:** 12-Jun-00 **Marketing Approval Date:**

Generic Name: Viloxazine HCl	Trade Name: Catatrol
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Orphan Indication: Treatment of narcolepsy.

Sponsor: Stuart Pharmaceuticals **Contact:**

Address: Wilmington, DE **Phone:** **Fax:**

Status: Designated/Withdrawn **Designation Date:** 11-Jun-84 **Marketing Approval Date:**

Generic Name: Viloxazine HCl	Trade Name: Catatrol
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Orphan Indication: Treatment of cataplexy.

Sponsor: Stuart Pharmaceuticals **Contact:**

Address: Wilmington, DE **Phone:** **Fax:**

Status: Designated/Withdrawn **Designation Date:** 11-Jun-84 **Marketing Approval Date:**

Generic Name: Virulizin	Trade Name: Virulizin
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Orphan Indication: Treatment of pancreatic cancer.

Sponsor: Lorus Therapeutics Inc. **Contact:** Ms. Anne Tomalin

Address: Canada, **Phone:** 8478378824 **Fax:** 8478278825

Status: Designated **Designation Date:** 01-Feb-01 **Marketing Approval Date:**

Generic Name: Xenogeneic hepatocytes	Trade Name: HepatAssist Liver Assist System
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Orphan Indication: Treatment of severe liver failure.

Sponsor: Circe Biomedical, Inc. **Contact:** Ms. Zorina Pitkin

Address: Lexington, MA **Phone:** (781) 863-8720 **Fax:** (781) 863-6140

Status: Designated **Designation Date:** 27-Nov-98 **Marketing Approval Date:**

Generic Name: Yttrium-90 radiolabeled humanized monoclonal anti-carcinoembryonic antigen IgG antibody	Trade Name: Cea-Cide
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Orphan Indication: Treatment of ovarian carcinoma.

Sponsor: Immunomedics, Inc. **Contact:** Dr. Nabila Turjman

Address: Morris Plains, NJ **Phone:** (973) 605-8200 **Fax:** (973) 605-1103

Status: Designated **Designation Date:** 03-Aug-99 **Marketing Approval Date:**

Generic Name: Zalcitabine	Trade Name: Hivid
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Orphan Indication: Treatment of AIDS.

Sponsor: Hoffmann-La Roche, Inc. **Contact:** Ms. Lisa Luther

Address: Nutley, NJ **Phone:** (201) 235-4135 **Fax:**

Status: Designated/Approved **Designation Date:** 28-Jun-88 **Marketing Approval Date:** 19-Jun-92

Generic Name: Zalcitabine	Trade Name:
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Orphan Indication: Treatment of AIDS.

Sponsor: National Cancer Institute, DCT **Contact:** Dr. Jay Greenblatt

Address: Bethesda, MD **Phone:** (301) 496-7912 **Fax:**

Status: Designated **Designation Date:** 09-Dec-86 **Marketing Approval Date:**

Generic Name: Zidovudine	Trade Name: Retrovir
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Orphan Indication: Treatment of AIDS.

Sponsor: Glaxo Wellcome Inc. **Contact:** Dr. Michael Dalton

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Designated/Approved **Designation Date:** 17-Jul-85 **Marketing Approval Date:** 19-Mar-87

Generic Name: Zidovudine	Trade Name: Retrovir
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Orphan Indication: Treatment of AIDS related complex.

Sponsor: Glaxo Wellcome Inc. **Contact:** Dr. Michael Dalton

Address: Research Triangle Park, NC **Phone:** (919) 483-2100 **Fax:**

Status: Designated/Approved **Designation Date:** 12-May-87 **Marketing Approval Date:** 19-Mar-87

Generic Name: Zinc acetate	Trade Name: Galzin
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Orphan Indication: Treatment of Wilson's disease.

Sponsor: Lemmon Company **Contact:** Ms. Deborah Jaskot

Address: Kulpsville, PA **Phone:** (215) 256-8400 **Fax:** (215) 721-8796

Status: Designated/Approved **Designation Date:** 06-Nov-85 **Marketing Approval Date:** 28-Jan-97

Generic Name: Zoledronate	Trade Name: Zometa, Zabel
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Orphan Indication: Treatment of tumor induced hypercalcemia.

Sponsor: Novartis Pharmaceuticals Corp. **Contact:** Ms. Ellen Cutler

Address: East Hanover, NJ **Phone:** (973) 781-8180 **Fax:** (973) 781-6325

Status: Designated/Approved **Designation Date:** 18-Aug-00 **Marketing Approval Date:** 20-Aug-01

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