

## 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:

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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:

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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:

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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:

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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:

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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:

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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:

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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:

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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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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 **Contact:** Dr. Ira Levin  
Diseases  
**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**Generic Name:** Aminosalicyclic 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

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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/mm<sup>3</sup>.  
**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

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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/mm<sup>3</sup>.

**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**Generic Name:** Centruroides immune F(ab)<sub>2</sub> **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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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 (involutional 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

<b>Generic Name:</b> Coagulation factor VIIa (recombinant)	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Coenzyme Q10
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Trade Name:
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**Orphan Indication:** For the treatment of Huntington's disease

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

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

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

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<b>Generic Name:</b> Colchicine
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Trade Name:
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**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:**

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<b>Generic Name:</b> Colfosceril palmitate, cetyl alcohol, tyloxapol	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Colfosceril palmitate, cetyl alcohol, tyloxapol	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Colfosceril palmitate, cetyl alcohol, tyloxapol	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Collagenase (lyophilized) for injection	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Corticorelin ovine triflutate	<b>Trade Name:</b> Acthrel
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**Orphan Indication:** For use in differentiating pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushing's 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

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<b>Generic Name:</b> Corticotropin-releasing factor, human	<b>Trade Name:</b> 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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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/mm<sup>3</sup>).**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:**

<b>Generic Name:</b> Gangliosides as sodium salts	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Gavilimomab
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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:**

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<b>Generic Name:</b> Gemtuzumab zogamicin	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Gene plasmid hVEGF165 driven by human cytomegalovirus, and [2,3-bis(oleoyl)propyl]trimethyl ammonium and dioleoyl phosphatidyl	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Gentamicin impregnated PMMA beads on surgical wire	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Gentamicin liposome injection	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Glatiramer acetate	<b>Trade Name:</b> Copaxone
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**Orphan Indication:** Treatment of multiple sclerosis.

**Sponsor:** Teva Pharmaceuticals USA **Contact:** Dr. Stanley Scheindlin

**Address:** Kulpsville, PA **Phone:** (800) 999-8382 **Fax:**

**Status:** Designated/Approved **Designation Date:** 09-Nov-87 **Marketing Approval Date:** 20-Dec-96

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<b>Generic Name:</b> Glatiramer acetate for injection	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Glutamine
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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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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<b>Generic Name:</b> Granulocyte macrophage-colony stimulating factor	<b>Trade Name:</b> 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:

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<b>Generic Name:</b> Group B streptococcus immune globulin
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Trade Name:
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**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:

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<b>Generic Name:</b> Growth hormone releasing factor
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Trade Name:
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**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:

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<b>Generic Name:</b> Guanethidine monosulfate	<b>Trade Name:</b> 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:

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<b>Generic Name:</b> Guanfacine	<b>Trade Name:</b> 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:

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<b>Generic Name:</b> Gusperimus	<b>Trade Name:</b> 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:

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<b>Generic Name:</b> h5G1.1-mAb
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Trade Name:
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**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:

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<b>Generic Name:</b> h5G1.1mAb
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Trade Name:
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**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:

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<b>Generic Name:</b> Halofantrine	<b>Trade Name:</b> 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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

<b>Generic Name:</b> Immune globulin intravenous (human)	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Immune globulin intravenous (human)	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Immune globulin intravenous, human	<b>Trade Name:</b> 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

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<b>Generic Name:</b> 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:**

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<b>Generic Name:</b> Indium In 111 murine monoclonal antibody FAB to myosin	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Indium In-111 altumomab pentetate	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Indium-In-111 murine MAb(2B8-MX-DTPA) & Yttrium-Y90 murine MAb(2B8-MX-DTPA)	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Infliximab	<b>Trade Name:</b> 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

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<b>Generic Name:</b> INH-A00021
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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:**

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**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:**

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**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

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**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:**

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**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:**

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**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

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**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:**

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**Generic Name:** Interferon alfa-2a (recombinant) **Trade Name:** Roferon-A

**Orphan Indication:** For the concomitant administration with Tecceleukin 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:**

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**Generic Name:** Interferon alfa-2a (recombinant) **Trade Name:** Roferon-A

**Orphan Indication:** For the treatment of metastatic malignant melanoma in combination with Tecceleukin.

**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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<b>Generic Name:</b> Interferon beta-1a (recombinant human)	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Interferon beta-1a (recombinant)	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Interferon beta-1a (recombinant)	<b>Trade Name:</b> 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 mm<sup>3</sup>.

**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:**

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<b>Generic Name:</b> Interferon beta-1b	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Interferon gamma 1-b	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Interferon gamma-1b	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Interferon gamma-1b	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Interferon-alfa-1b	<b>Trade Name:</b>
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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:**

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<b>Generic Name:</b> Interleukin-1 alpha, human recombinant	<b>Trade Name:</b>
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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:**

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<b>Generic Name:</b> Interleukin-1 alpha, human recombinant	<b>Trade Name:</b>
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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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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')<sub>2</sub> 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:

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**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:

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**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:

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**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:

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**Generic Name:** L-baclofen

**Trade Name:** Neuralon

**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:

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**Generic Name:** L-baclofen

**Trade Name:** Neuralon

**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:

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**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:

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**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:

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**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:

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**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:**

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**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

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**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

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**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

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**  
**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:**  
**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:**  
**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:**

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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

**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:**

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**Generic Name:** Mitoguazone **Trade Name:** apep

**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:**

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**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:**

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**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:**

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**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:**

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**Generic Name:** Mitoxantrone **Trade Name:** Novantrone

**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

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**Generic Name:** Mitoxantrone **Trade Name:** Novantrone

**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

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**Generic Name:** Mitoxantrone **Trade Name:** Novantrone

**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

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**Generic Name:** Mitoxantrone HCl **Trade Name:** Novantrone

**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

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**Generic Name:** MN14 monoclonal antibody to carcinoembryonic antigen **Trade Name:** Cea-Cide



**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:** Mucoïd 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:** Mucoïd 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 Bourdakís  
**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**Generic Name:** Oprelvekin **Trade Name:** Neumega

**Orphan Indication:** Prevention of severe chemotherapy-induced thrombocytopenia.

**Sponsor:** Genetics Institute, Inc. **Contact:** Ms. Ingrid Bartinque

**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**Generic Name:** Poly I: poly C12U **Trade Name:** Ampligen

**Orphan Indication:** Treatment of renal cell carcinoma.

**Sponsor:** Hemisphere 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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

<b>Generic Name:</b> Porcine fetal neural dopaminergic cells and/or precursors aseptically prepared for intracerebral implantation.	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Porcine fetal neural gabaergic cells and/or precursors aseptically prepared and coated with anti-MHC-1 Ab for intracerebral implantation	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Porcine fetal neural gabaergic cells and/or precursors aseptically prepared for intracerebral implantation for Huntington's disease.	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Porcine Sertoli cells aseptically prepared for intracerebral co-implantation with fetal neural tissue	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> porfimer	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Porfimer sodium	<b>Trade Name:</b> 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

<b>Generic Name:</b> Porfimer sodium	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Porfiromycin	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Porfiromycin	<b>Trade Name:</b> 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:**

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**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

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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-1  
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-1 **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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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/mm<sup>3</sup>.**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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

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**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

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**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

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**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

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**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

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**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

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**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

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:

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**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:

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**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:

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**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:

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**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:

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**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

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**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:

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**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:

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**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:

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:

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**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  
**Status:** Designated **Designation Date:** 18-Jun-99 Marketing Approval Date:

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**Generic Name:** Synthetic porcine 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:** 18-Jun-99 Marketing Approval Date:

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**Generic Name:** Synthetic porcine 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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:

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**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:**

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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

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**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

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**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:**

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**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

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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:**

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**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 mm<sup>3</sup>.

**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 mm<sup>3</sup>.

**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:**

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**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:**

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**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:**

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**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

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**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:**

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**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:**

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**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

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**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:**

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**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:**

<b>Generic Name:</b> Valrubicin	<b>Trade Name:</b> 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

<b>Generic Name:</b> Vapreotide	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Vapreotide	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Vapreotide	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Vasoactive intestinal peptide	<b>Trade Name:</b>
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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:**

<b>Generic Name:</b> Vasoactive intestinal polypeptide	<b>Trade Name:</b>
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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:**

<b>Generic Name:</b> vigabatrin	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Viloxazine HCl	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Viloxazine HCl	<b>Trade Name:</b> 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:**

<b>Generic Name:</b> Virulizin	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Xenogeneic hepatocytes	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Yttrium-90 radiolabeled humanized monoclonal anti-carcinoembryonic antigen IgG antibody	<b>Trade Name:</b> 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:**

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<b>Generic Name:</b> Zalcitabine	<b>Trade Name:</b> 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

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<b>Generic Name:</b> 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:**

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<b>Generic Name:</b> Zidovudine	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Zidovudine	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Zinc acetate	<b>Trade Name:</b> 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

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<b>Generic Name:</b> Zoledronate	<b>Trade Name:</b> 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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