

List of Orphan Products Designated and Approved as of December 31, 2003

Total Number of Active Designations = 1087

Generic Name:
Bacitracin

Designated Indication:

Treatment of antibiotic-associated pseudomembranous enterocolitis caused by toxins A and B elaborated by Clostridium difficile

Trade Name (if present):
Altracm

Sponsor Contact Information

A. L. Laboratories, Inc.
One Executive Drive
P O. Box 1399
Fort Lee NJ 07024

Date Designated 3/13/1984

Date Approved

Generic Name:

Cells produced using the AastromReplicelle System and SC-I Therapy Kit

Designated Indication:

For use in patients receiving high dose chemotherapy who are unable to generate an acceptable dose of peripheral blood stem cells and who have a sufficient bone marrow aspirate without morphological evidence of tumor

Trade Name (if present):

Sponsor Contact Information

Aastrom Biosciences Incorporated
P O. Box 376
Ann Arbor MI 48106

Date Designated 7/10/2002

Date Approved

Generic Name:

Hemin

Designated 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.

Trade Name (if present):

Panhematm

Sponsor Contact Information

Abbott Laboratories
Diagnostics Division
Abbott Park IL 60064

Date Designated 3/16/1984

Date Approved 7/20/1983

Generic Name:

N-acetyl-sarcosyl-glycyl-L-valyl-D-alloisoleucyl-L-threonyl-L-norvalyl-L-isoleucyl-L-arginyl-L-prolylethylamine acetate

Designated Indication:

For the treatment of soft tissue sarcoma

Trade Name (if present):

Sponsor Contact Information

Abbott Laboratories
Pharmaceutical Products Division
200 Abbott Park Road
Abbott Park IL 60064

Date Designated 12/9/2003

Date Approved

Generic Name:

Gavilimomab

Designated Indication:

Acute graft-versus-host disease (aGVHD)

Trade Name (if present):

Sponsor Contact Information

Abgenix, Inc.
7601 Dumbarton Circle
Fremont CA 94555

Date Designated 11/20/2000

Date Approved

1984-2003

151 01

Generic Name:
Amiodarone

Designated Indication:
Treatment of incessant ventricular tachycardia.

Trade Name (if present):
Amio-Aqueous

Date Designated 8/17/1993
Date Approved

Sponsor Contact Information
Academic Pharmaceuticals, Inc
21 N Skokie Valley Highway
Suite G3
Lake Bluff IL 60044

Generic Name:
Fampridine

Designated Indication:
Relief of symptoms of multiple sclerosis

Trade Name (if present):
Neurelan

Date Designated 6/2/1987
Date Approved

Sponsor Contact Information
Acorda Therapeutics
15 Skyline Dr
Hawthorne NY 10532

Generic Name:
Fampridine

Designated Indication:
Treatment of chronic, incomplete spinal cord injury.

Trade Name (if present):
Neurelan

Date Designated 6/2/1997
Date Approved

Sponsor Contact Information
Acorda Therapeutics, Inc.
15 Skyline Dr
Hawthorne NY 10532

Generic Name:
miglustat

Designated Indication:
Treatment of Gaucher disease

Trade Name (if present):
Zavesca

Date Designated 5/29/1998
Date Approved 7/31/2003

Sponsor Contact Information
Actelion Pharmaceuticals Ltd
Gewerbstrasse 16
CH - 4123 Allschwi

SWITZERLAND

Generic Name:
Bosentan

Designated Indication:
Treatment of pulmonary arterial hypertension.

Trade Name (if present):
Tracleer

Date Designated 10/6/2000
Date Approved 11/20/2001
Date Approved 11/20/2001

Sponsor Contact Information
Actelion Life Sciences Ltd
1840 Gateway Dr
2nd Floor
San Mateo CA 94404

Generic Name:
myristoylated recombinant SCR1-3 of human
complement reseptor type I

Designated Indication:
Prevention of delayed graft function in solid organ transplant

Trade Name (if present):
APT070

Sponsor Contact Information
Adprotech, Ltd.
Chesterford Research Pk,
Little Chesterford, Saffron Walden,

Date Designated 5/21/2003
Date Approved

Generic Name:
Rifabutin

Designated Indication:
Prevention of disseminated Mycobacterium avium complex disease in patients
with advanced HIV infection

Trade Name (if present):
Mycobutin

Sponsor Contact Information
Adria Laboratories, Inc.
P O Box 16529
Columbus OH 43216

Date Designated 12/18/1989
Date Approved 12/23/1992

Generic Name:
Idarubicin HCl for injection

Designated Indication:
Treatment of acute myelogenous leukemia, also referred to as acute
nonlymphocytic leukemia

Trade Name (if present):
Idamycin

Sponsor Contact Information
Adria Laboratories, Inc.
P.O Box 16529
Columbus OH 43216

Date Designated 7/25/1988
Date Approved 9/27/1990

Generic Name:
Collagenase (lyophilized) for injection

Designated Indication:
Treatment of Peyronie's disease

Trade Name (if present):
Plaquase

Sponsor Contact Information
Advance Biofactures Corporation
35 Wilbur Street
Lynbrook NY 11563-2358

Date Designated 3/12/1996
Date Approved

Generic Name:
anti-interferon-gamma Fab from goats

Designated Indication:
For the treatment of immunologic corneal allograft rejection

Trade Name (if present):

Sponsor Contact Information
Advanced Biotherapy, Inc.
6355 Topanga Canyon Blvd.
Suite 510
Woodland Hills CA 91367

Date Designated 11/18/2003
Date Approved

Generic Name:
[5,10,15,20-tetrakis(1,3-diethylimidazolium-2-yl)porphyrinato] manganese(III)pentachloride

Trade Name (if present):

Date Designated 11/4/2003
Date Approved

Designated Indication:
Treatment of Amyotrophic Lateral Sclerosis

Sponsor Contact Information
Aeolus Pharmaceuticals, Inc
PO Box 14287, 79 T W. Alexander Dr.
4401 Research
Research Triangle Park NC 27709

Generic Name:
antiangiogenic components extracted from
marine cartilage

Trade Name (if present):
Neovastat (AE-941)

Date Designated 10/16/2002
Date Approved

Designated Indication:
Treatment of renal cell carcinoma

Sponsor Contact Information
AEterna Laboratories, Inc
Dr. Claude Hariton
Chief Medical Officer, VP, Cli
Quebec G1P 4P5, Canada
CANADA

Generic Name:
Lactoferrin alpha

Trade Name (if present):

Date Designated 8/20/2003
Date Approved

Designated Indication:
For the treatment of graft versus host disease

Sponsor Contact Information
Agennix, Inc
Greenway Plaza
Suite 910
Houston TX 77046

Generic Name:
Lactoferrin alpha

Trade Name (if present):

Date Designated 8/20/2003
Date Approved

Designated Indication:
For the prevention of graft-versus-host disease

Sponsor Contact Information
Agennix, Inc.
8 Greenway Plaza
Suite 910
Houston TX 77046

Generic Name:
T4 endonuclease V, liposome encapsulated

Trade Name (if present):

Date Designated 6/27/1989
Date Approved

Designated Indication:
To prevent cutaneous neoplasms and other skin abnormalities in xeroderma pigmentosum.

Sponsor Contact Information
AGI Dermatics
205 Buffalo Avenue
Freeport NY 11520

Generic Name:
Lodoxamide tromethamine

Designated Indication:
Treatment of vernal keratoconjunctivitis.

Trade Name (if present):
Alomide Ophthalmic Solution

Sponsor Contact Information
Alcon Laboratories, Inc
6201 South Freeway
Fort Worth TX 76134

Date Designated 10/16/1991
Date Approved 9/23/1993

Generic Name:
eculizumab

Designated Indication:
Idiopathic membranous glomerular nephropathy

Trade Name (if present):

Sponsor Contact Information
Alexion Pharmaceuticals, Inc.
352 Knotter Drive
Cheshire CT 06410

Date Designated 3/5/2001
Date Approved

Generic Name:
eculizumab

Designated Indication:
Treatment of paroxysmal nocturnal hemoglobinuria

Trade Name (if present):

Sponsor Contact Information
Alexion Pharmaceuticals, Inc.
352 Knotter Drive
Cheshire CT 06410

Date Designated 8/20/2003
Date Approved

Generic Name:
h5G1.1-mAb

Designated Indication:
Treatment of dermatomyositis

Trade Name (if present):

Sponsor Contact Information
Alexion Pharmaceuticals, Inc.
352 Knotter Drive
25 Science Park

Date Designated 9/21/2000
Date Approved

Alexion Pharmaceuticals, Inc.
Cheshire CT 06410

Generic Name:
bifidobacterium longum infantis 35624

Designated Indication:
Treatment of pediatric Crohn's disease

Trade Name (if present):

Sponsor Contact Information
Alimentary Health Limited
Guardwell, Kinsale
County Cork

Date Designated 1/16/2003
Date Approved

IRELAND

Generic Name:
Imported fire ant venom, allergenic extract

Designated 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.

Trade Name (if present):

Sponsor Contact Information
ALK Laboratories, Inc.
Research Center
27 Village Lane
Wallingford CT 06492

Date Designated 5/12/1992
Date Approved

Generic Name:
Brimonidine

Designated Indication:
Treatment of anterior ischemic optic neuropathy.

Trade Name (if present):
Alphagan

Sponsor Contact Information
Allergan, Inc.
2525 Dupont Dr
P.O. Box 19534
Irvine CA 92623-9534

Date Designated 2/7/2000
Date Approved

Generic Name:
Cyclosporine 2% ophthalmic ointment

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

Trade Name (if present):

Sponsor Contact Information
Allergan, Inc.
2525 Dupont Drive
P O Box 19534
Irvine CA 92623-9534

Date Designated 8/1/1991
Date Approved

Generic Name:
Botulinum toxin type A

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

Trade Name (if present):
Botox

Sponsor Contact Information
Allergan, Inc.
2525 Dupont Drive
P O. Box 19534
Irvine CA 92623-9534

Date Designated 12/6/1991
Date Approved

Generic Name:
Ofloxacin

Designated Indication:
Treatment of bacterial corneal ulcers

Trade Name (if present):
Ocuflox Ophthalmic Solution

Sponsor Contact Information
Allergan, Inc.
2525 Dupont Drive
P.O. Box 19534
Irvine CA 92713

Date Designated 4/18/1991
Date Approved 5/22/1996
Date Approved 5/22/1996

Generic Name:
Cyclosporine 2% ophthalmic ointment

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

Trade Name (if present):

Sponsor Contact Information

Allergan, Inc
2525 Dupont Drive
P.O. Box 19534
Irvine CA 92623-9534

Date Designated 8/1/1991

Date Approved

Generic Name:
Botulinum toxin type A

Designated Indication:
Treatment of cervical dystonia

Trade Name (if present):

Botox

Sponsor Contact Information

Allergan, Inc
2525 Dupont Drive
P O. Box 19534
Irvine CA 92623-9534

Date Designated 8/20/1986

Date Approved 12/21/2000

Generic Name:
Botulinum toxin type A

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

Trade Name (if present):

Botox

Sponsor Contact Information

Allergan, Inc.
2525 Dupont Drive
P O. Box 19534
Irvine CA 92713

Date Designated 3/22/1984

Date Approved 12/29/1989

Generic Name:
Botulinum toxin type A

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

Trade Name (if present):

Botox

Sponsor Contact Information

Allergan, Inc.
2525 Dupont Drive
P.O. Box 19534
Irvine CA 92713

Date Designated 3/22/1984

Date Approved 12/29/1989

Generic Name:
Perflubron

Designated Indication:
Treatment of acute respiratory distress disease (ARDS) in adults

Trade Name (if present):

LiquiVent

Sponsor Contact Information

Alliance Pharmaceutical Corp.
3040 Science Park Road
San Diego CA 92191

Date Designated 4/26/2001

Date Approved

Generic Name:
C1 esterase inhibitor (human)

Designated Indication:
Treatment and prevention of angioedema caused by C1-esterase inhibitor deficiency.

Trade Name (if present):

Sponsor Contact Information
Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles CA 90032

Date Designated 8/21/1996
Date Approved

Generic Name:
Antihemophilic factor (human)

Designated Indication:
Treatment of von Willebrand's disease.

Trade Name (if present):
Alphanate

Sponsor Contact Information
Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles CA 90032-3520

Date Designated 1/5/1996
Date Approved

Generic Name:
Fibrinogen (human)

Designated Indication:
For the control of bleeding and prophylactic treatment of patients deficient in fibrinogen

Trade Name (if present):

Sponsor Contact Information
Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles CA 90032

Date Designated 8/23/1995
Date Approved

Generic Name:
Isobutyramide

Designated Indication:
Treatment of sickle cell disease and beta thalassemia

Trade Name (if present):

Sponsor Contact Information
Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles CA 90032

Date Designated 5/25/1994
Date Approved

Generic Name:
Coagulation Factor IX (human)

Designated 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

Trade Name (if present):
AlphaNine

Sponsor Contact Information
Alpha Therapeutic Corporation
5555 Valley Boulevard
Los Angeles CA 90032

Date Designated 7/5/1990
Date Approved 12/31/1990

Generic Name:
Monoclonal antibody-B43.13

Designated Indication:
Treatment of epithelial ovarian cancer.

Trade Name (if present):
Ovarex MAb-B43.13

Sponsor Contact Information
AltaRex US Corp
610 Lincoln Street
Waltham MA 02451

Date Designated 11/25/1996
Date Approved

Generic Name:
lipase, amylase, and protease

Designated Indication:
Treatment of pancreatic insufficiency

Trade Name (if present):
TheraCLEC-Total

Sponsor Contact Information
Altus Biologics Inc
625 Putnam Avenue
Cambridge MA 02139

Date Designated 1/23/2002
Date Approved

Generic Name:
allantoin

Designated Indication:
Treatment of skin blistering and erosions associated with inherited epidermolysis bullosa

Trade Name (if present):
Alwextin

Sponsor Contact Information
Alwyn Company, Inc.
2301 Highway 60 East
Lake Crystal MN 56055

Date Designated 11/21/2002
Date Approved

Generic Name:
Doxorubicin liposome

Designated Indication:
Treatment of ovarian cancer

Trade Name (if present):
Doxil

Sponsor Contact Information
Alza Corporation
1550 Plymouth St
PO Box 7210
Mountain View CA 94039-7210

Date Designated 11/4/1998
Date Approved 6/28/1999

Generic Name:
Pentosan polysulfate sodium

Designated Indication:
Treatment of interstitial cystitis.

Trade Name (if present):
Elmiron

Sponsor Contact Information
Alza Corporation
950 Page Mill Rd.
PO Box 10950
Palo Alto CA 94303-0802

Date Designated 8/7/1985
Date Approved 9/26/1996

Generic Name:
Natural human lymphoblastoid interferon-alpha

Designated Indication:
Treatment of polycythemia vera

Trade Name (if present):

Sponsor Contact Information
Amarillo Biosciences, Inc

Date Designated 11/18/2002

Date Approved

800 West 9th Avenue
Amarillo TX 79101

Generic Name:
homoharringtonine

Designated Indication:
Treatment for chronic myelogenous leukemia

Trade Name (if present):

Sponsor Contact Information
American BioScience, Inc

Date Designated 2/8/2002

Date Approved

2730 Wilshire Blvd #110
Santa Monica CA 90403

Generic Name:
Antithrombin III human

Designated 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.

Trade Name (if present):

Antithrombin III human

Sponsor Contact Information

American National Red Cross
9312 Old Georgetown Road
Bethesda MD 20814

Date Designated 1/2/1986

Date Approved

Generic Name:
Recombinant human keratinocyte growth factor

Designated Indication:
Reducing the incidence and severity of radiation-induced xerostomia.

Trade Name (if present):

Sponsor Contact Information

Amgen Inc.
One Amgen Center Dr
Thousand Oaks CA 91320-1799

Date Designated 12/20/1999

Date Approved

Generic Name:
Recombinant secretory leucocyte protease inhibitor

Designated Indication:
Treatment of congenital alpha-1 antitrypsin deficiency.

Trade Name (if present):

Sponsor Contact Information

Amgen Inc.
3200 Walnut Street
Boulder CO 80301

Date Designated 3/29/1991

Date Approved

Generic Name:
AMG 531

Designated Indication:
Treatment of immune thrombocytopenic purpura

Trade Name (if present):

Sponsor Contact Information
Amgen, Inc.
One Amgen Center Drive
Thousand Oaks CA 91320-1799

Date Designated 3/27/2003

Date Approved

Generic Name:
cinacalcet

Designated Indication:
Treatment of hypercalcemia in patients with parathyroid carcinoma

Trade Name (if present):

Sensipar

Sponsor Contact Information
Amgen, Inc.

Date Designated 5/12/2003

Date Approved 3/8/2004

One Amgen Center Drive
Thousand Oaks CA 91320-1799

Generic Name:
metreleptin

Designated Indication:
Treatment of leptin deficiency secondary to generalized lipodystrophy and partial familial lipodystrophy

Trade Name (if present):

Sponsor Contact Information
Amgen, Inc.
One Amgen Center Drive
Thousand Oaks CA 91320-1799

Date Designated 8/22/2001

Date Approved

Generic Name:
Novel Acting Thrombolytic (NAT)

Designated Indication:
Treatment of peripheral arterial occlusion (PAO)

Trade Name (if present):

Sponsor Contact Information
Amgen, Inc.
One Amgen Center Drive
Thousand Oaks CA 91320-1799

Date Designated 1/26/2001

Date Approved

Generic Name:
Pegylated recombinant human megakaryocyte growth and development factor

Designated Indication:
For reducing the period of thrombocytopenia in patients undergoing hematopoietic stem cell transplantation.

Trade Name (if present):

MEGAGEN

Sponsor Contact Information
Amgen, Inc.
One Amgen Center Dr.
Thousand Oaks CA 91320-1789

Date Designated 10/20/1997

Date Approved

Generic Name:
Filgrastim

Designated Indication:

Reduction in the duration of neutropenia, fever, antibiotic use, and hospitalization, following induction and consolidation treatment for acute myeloid leukemia.

Trade Name (if present):
Neupogen

Sponsor Contact Information

Amgen, Inc
One Amgen Center Dr
Thousand Oaks CA 91320-1799

Date Designated 11/7/1996

Date Approved 4/2/1998

Generic Name:
Filgrastim

Designated Indication:

For use in the mobilization of peripheral blood progenitor cells for collection in patients who will receive myeloablative or myelosuppressive chemotherapy.

Trade Name (if present):
Neupogen

Sponsor Contact Information

Amgen, Inc
1840 Dehavilland Drive
Thousand Oaks CA 91320

Date Designated 7/17/1995

Date Approved 12/28/1995

Generic Name:
Recombinant methionyl human stem cell factor

Designated Indication:

Treatment of primary bone marrow failure

Trade Name (if present):

Sponsor Contact Information

Amgen, Inc
One Amgen Center Drive
Thousand Oaks CA 91320-1799

Date Designated 11/22/1995

Date Approved

Generic Name:
Recombinant methionyl brain-derived neurotrophic factor

Designated Indication:

Treatment of amyotrophic lateral sclerosis.

Trade Name (if present):

Sponsor Contact Information

Amgen, Inc.
One Amgen Center Dr.
Thousand Oaks CA 91320-1799

Date Designated 11/28/1994

Date Approved

Generic Name:
Ancestim

Designated 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.

Trade Name (if present):
Stemgen

Sponsor Contact Information

Amgen, Inc.
One Amgen Center Drive
Thousand Oaks CA 91320-1799

Date Designated 7/5/1995

Date Approved

Generic Name:
Interleukin-1 receptor antagonist, human
recombinant

Trade Name (if present):
Antril

Date Designated 10/16/1992
Date Approved

Designated Indication:
Prevention and treatment of graft versus host disease in transplant recipients

Sponsor Contact Information
Amgen, Inc
One Amgen Center Drive
Thousand Oaks CA 91320-1799

Generic Name:
Interleukin-1 receptor antagonist, human
recombinant

Trade Name (if present):
Antril

Date Designated 9/23/1991
Date Approved

Designated Indication:
Treatment of juvenile rheumatoid arthritis

Sponsor Contact Information
Amgen, Inc
One Amgen Center Drive
Thousand Oaks CA 91320-1799

Generic Name:
Epoetin alfa

Trade Name (if present):
Epogen

Date Designated 7/1/1991
Date Approved 12/31/1990

Designated Indication:
Treatment of anemia associated with HIV infection or HIV treatment

Sponsor Contact Information
Amgen, Inc.
1840 Dehavilland Drive
Thousand Oaks CA 91320

Generic Name:
Recombinant secretory leucocyte protease
inhibitor

Trade Name (if present):

Date Designated 3/29/1991
Date Approved

Designated Indication:
Treatment of cystic fibrosis

Sponsor Contact Information
Amgen, Inc
3200 Walnut Street
Boulder CO 80301

Generic Name:
Filgrastim

Trade Name (if present):
Neupogen

Date Designated 11/7/1990
Date Approved 12/19/1994

Designated Indication:
Treatment of patients with severe chronic neutropenia (absolute neutrophil count
less than 500/mm3).

Sponsor Contact Information
Amgen, Inc
1840 Dehavilland Drive
Thousand Oaks CA 91320

Generic Name:
Filgrastim

Designated Indication:

Treatment of patients with AIDS who, in addition, are afflicted with cytomegalovirus retinitis and are being treated with ganciclovir

Trade Name (if present):
Neupogen

Sponsor Contact Information

Amgen, Inc
One Amgen Center Dr.
Thousand Oaks CA 91320-1799

Date Designated 9/3/1991
Date Approved

Generic Name:
Filgrastim

Designated Indication:

Treatment of neutropenia associated with bone marrow transplants

Trade Name (if present):
Neupogen

Sponsor Contact Information

Amgen, Inc.
1840 Dehavilland Drive
Thousand Oaks CA 91320

Date Designated 10/1/1990
Date Approved 6/15/1994

Generic Name:
Epoetin alfa

Designated Indication:

Treatment of anemia associated with end stage renal disease

Trade Name (if present):
Epogen

Sponsor Contact Information

Amgen, Inc.
1840 Dehavilland Drive
Thousand Oaks CA 91320

Date Designated 4/10/1986
Date Approved 6/1/1989

Generic Name:
metreleptin

Designated Indication:

Treatment of metabolic disorders secondary to lipodystrophy

Trade Name (if present):

Sponsor Contact Information

Amgen, Inc ,
One Amgen Center Drive
Thousand Oaks CA 91320-1799

Date Designated 8/22/2001
Date Approved

Generic Name:
Imexon

Designated Indication:

Treatment of metastatic malignant melanoma

Trade Name (if present):
n/a

Sponsor Contact Information

AmpliMed Corporation
2321 Camino La Zorrela
Tucson AZ 85718

Date Designated 8/3/2001
Date Approved

Generic Name:
Imexon

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):

Sponsor Contact Information

AmpliMed Corporation
2321 Camino La Zorrela
Tucson AZ 85718

Date Designated 11/8/1996

Date Approved

Generic Name:
imexon

Designated Indication:
Treatment of pancreatic adenocarcinoma

Trade Name (if present):

Sponsor Contact Information

AmpliMed, CorporationAmpliMed, Corporation
2321 Camino La Zorrela
Tucson AZ 85718

Date Designated 11/1/2003

Date Approved

Generic Name:
Histrelin

Designated Indication:
Treatment of acute intermittent porphyria, hereditary coproporphyria, and
variegate porphyria.

Trade Name (if present):

Sponsor Contact Information

Anderson, Karl E., M.D.
University of Texas Medical Branch at Galveston
Route J-09, 700 The Strand
Galveston TX 77550

Date Designated 5/3/1991

Date Approved

Generic Name:
resiniferatoxin

Designated Indication:
Treatment of intractable pain at end-stage disease

Trade Name (if present):

Sponsor Contact Information

Andrew J. Mannes, Md
Bldg 10/Rm 2N236 - DASS/PPCS/NIDCR/NIH
10 Convent Drive
Bethesda MD 20892

Date Designated 5/13/2003

Date Approved

Generic Name:
Thalidomide

Designated Indication:
Treatment and prevention of recurrent aphthous ulcers in severely, terminally
immunocompromised patients.

Trade Name (if present):

Sponsor Contact Information

Andrulis Research Corporation
11800 Baltimore Avenue, Suite 113
Beltsville MD 20705

Date Designated 5/15/1995

Date Approved

Generic Name:
Thalidomide

Designated Indication:
Treatment of graft versus host disease

Trade Name (if present):

Sponsor Contact Information
Andrulis Research Corporation
11800 Baltimore Avenue, Suite 113
Beltsville MD 20705

Date Designated 3/5/1990

Date Approved

Generic Name:
Thalidomide

Designated Indication:
Prevention of graft versus host disease

Trade Name (if present):

Sponsor Contact Information
Andrulis Research Corporation
11800 Baltimore Avenue, Suite 113
Beltsville MD 20705

Date Designated 3/5/1990

Date Approved

Generic Name:
Benzylamine hydrochloride

Designated Indication:
Prophylactic treatment of oral mucositis resulting from radiation therapy for head and neck cancer.

Trade Name (if present):
Tantum

Sponsor Contact Information
Angelini Pharmaceuticals, Inc.
70 Grand Avenue
River Edge NJ 07661

Date Designated 5/18/1998

Date Approved

Generic Name:
Bindarit

Designated Indication:
Treatment of lupus nephritis.

Trade Name (if present):

Sponsor Contact Information
Angelini Pharmaceuticals, Inc.
70 Grand Avenue
River Edge NJ 07661

Date Designated 2/3/1998

Date Approved

Generic Name:
Tranilast

Designated Indication:
For the treatment of malignant glioma

Trade Name (if present):
Rizaben

Sponsor Contact Information
Angiogen Pharmaceuticals, Pty. Ltd.
Level 31, ABN AMRO Tower
88 Phillip Street Sydney, N S.W. 2000

Date Designated 12/2/2003

Date Approved

AUSTRALIA

Generic Name:
1,1'-[1,4-phenylenebis(methylene)-bis-1,4,8,11-tetraazacyclotetradecan

Trade Name (if present):

Date Designated 7/10/2003
Date Approved

Designated Indication:

For combination use with filgrastim to improve the yield of progenitor cells in the apheresis product for subsequent stem cell transplantation following myelosuppressive or myeloablative chemotherapy

Sponsor Contact Information

AnorMED Inc.
200-20353 64th Avenue
Langley, BC, V2Y 1N5

CANADA

Generic Name:
Valrubicin

Designated Indication:

Treatment of carcinoma in situ of the urinary bladder

Trade Name (if present):
Valstar

Date Designated 5/23/1994
Date Approved 9/25/1998

Sponsor Contact Information

Anthra Pharmaceuticals, Inc
103 Carnegie Center, Suite 102
Princeton NJ 08540

Generic Name:
Disodium clodronate tetrahydrate

Designated Indication:

Treatment of increased bone resorption due to malignancy.

Trade Name (if present):
Bonefos

Date Designated 3/5/1990
Date Approved

Sponsor Contact Information

Anthra Pharmaceuticals, Inc.
103 Carnegie Center, Suite 102
Princeton NJ 08540

Generic Name:
Liposomal-cis-bis-neodecanoato-trans-R,R-1,2-diaminocyclohexane-Pt (II)

Designated Indication:

Treatment of malignant mesothelioma.

Trade Name (if present):

Date Designated 9/1/1999
Date Approved

Sponsor Contact Information

Antigenics Incorporated
3 Forbes Road
Lexington MA 02421

Generic Name:
Tretinoin

Designated Indication:

Treatment of T-cell non-Hodgkin's lymphoma

Trade Name (if present):
ATRA-IV

Date Designated 4/11/2003
Date Approved

Sponsor Contact Information

Antigenics, Inc
34 Commerce Way
Woburn MA 01801

Generic Name:
autologous tumor-derived gp96 heat shock
protein-peptide complex

Designated Indication:
Treatment of metastatic melanoma

Trade Name (if present):
Oncophage

Sponsor Contact Information
Antigenics, Inc
34 Commerce Way
Woburn MA 01702

Date Designated 7/11/2002
Date Approved

Generic Name:
autologous tumor-derived gp96 heat shock
protein-peptide complex

Designated Indication:
Treatment of renal cell carcinoma

Trade Name (if present):
Oncophage

Sponsor Contact Information
Antigenics, Inc.
34 Commerce Way
Woburn MA 01702

Date Designated 5/10/2002
Date Approved

Generic Name:
Liposomal nystatin

Designated Indication:
Treatment of invasive fungal infections.

Trade Name (if present):
Nyotran

Sponsor Contact Information
Antigenics, Inc
3 Forbes Road
Lexington MA 02421

Date Designated 6/13/2000
Date Approved

Generic Name:
Tretinoin

Designated Indication:
Treatment of acute and chronic leukemia

Trade Name (if present):
ATRA-IV

Sponsor Contact Information
Antigenics, Inc.
34 Commerce Way
Woburn MA 01801

Date Designated 1/14/1993
Date Approved

Generic Name:
TGF(beta)2-specific phosphorothioate antisense
oligodeoxynucleotide

Designated Indication:
Treatment of malignant glioma

Trade Name (if present):
Oncomun

Sponsor Contact Information
Antisense Pharma GmbH
Josef-Engert-Str. 9
93053 Regensburg

Date Designated 6/5/2002
Date Approved

GERMANY

Generic Name:
Murine MAb to polymorphic epithelial mucin,
human milk fat globule 1

Designated Indication:
Adjuvant treatment of ovarian cancer.

Trade Name (if present):
Theragyn

Sponsor Contact Information
Antisoma plc
West Africa House
Hanger Lane Ealing
London W5 3QR
UNITED KINGDOM

Date Designated 3/22/1999
Date Approved

Generic Name:
G17DT Immunogen

Designated Indication:
Treatment of gastric cancer

Trade Name (if present):

Sponsor Contact Information
Aphtron Corporation
26 Harter Avenue
Suite 14
Woodland CA 95776

Date Designated 7/18/2002
Date Approved

Generic Name:
G17DT Immunogen

Designated Indication:
Treatment of adenocarcinoma of the pancreas

Trade Name (if present):

Sponsor Contact Information
Aphtron Corporation
26 Harter Avenue
Suite 14
Woodland CA 95776

Date Designated 7/10/2002
Date Approved

Generic Name:
deferiprone

Designated Indication:
Treatment of iron overload in patients with hematologic disorders requiring
chronic transfusion therapy

Trade Name (if present):
Ferriprox

Sponsor Contact Information
Apotex Research Inc.
150 Signet Drive
Toronto, Canada M9L 1T9

Date Designated 12/12/2001
Date Approved

CANADA

Generic Name:
recombinant adeno-associated virus alpha 1-
antitrypsin vector

Designated Indication:
Treatment of alpha1-antitrypsin deficiency

Trade Name (if present):
rAAV-AAT

Sponsor Contact Information
Applied Genetic Technologies Corp
12085 Research Drive
Suite 110
Alachua FL 32615

Date Designated 1/27/2003
Date Approved

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

Trade Name (if present):
CYTOIMPLANT

Date Designated 6/13/1997
Date Approved

Designated Indication:
Treatment of pancreatic cancer

Sponsor Contact Information
Applied Immunotherapeutics, LLC
14132 E. Firestone Boulevard
Santa Fe Springs CA 90670

Generic Name:
Anti-thymocyte serum

Trade Name (if present):
Nashville Rabbit Anti-thymocyte Serum

Date Designated 6/2/1993
Date Approved

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

Sponsor Contact Information
Applied Medical Research
1600 Hayes Street
Nashville TN 37203

Generic Name:
AP1903

Trade Name (if present):

Date Designated 11/24/1999
Date Approved

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

Sponsor Contact Information
Ariad Gene Therapeutics, Inc
26 Landsdowne St
Cambridge MA 02139-4234

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

Trade Name (if present):

Date Designated 7/31/2001
Date Approved

Designated Indication:
Use with gancyclovir in the treatment of malignant glioma

Sponsor Contact Information
Ark Therapeutics Ltd
6 Warren Mews
London W1T6AR
London
UNITED KINGDOM

Generic Name:
Gene plasmid hVEGF165 driven by human cytomegalovirus, and [2,3-bis(oleoyl)propyl]trimethyl ammonium and dioleoyl phosphatidyl ethanolamine

Trade Name (if present):
Trinam

Date Designated 10/24/2000
Date Approved

Designated Indication:
Prevention of complications due to neointimal hyperplasia disease in certain vascular anastomoses.

Sponsor Contact Information
Ark Therapeutics Ltd.
1 Fitzroy Mews
London W1T6DE

UNITED KINGDOM

Generic Name:
Coagulation factor IX

Designated Indication:
Replacement treatment and prophylaxis of the hemorrhagic complications of hemophilia B

Trade Name (if present):
Mononine

Sponsor Contact Information
Armour Pharmaceutical Company
500 Arcola Road, P O Box 1200
Collegeville PA 19426

Date Designated 6/27/1989
Date Approved 8/20/1992

Generic Name:
recombinant human alpha 1-antitrypsin (rAAT)

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Sponsor Contact Information
Arriva Pharmaceuticals, Inc
2020 Challenger Drive
Alameda CA 94501

Date Designated 11/20/2001
Date Approved

Generic Name:
Mesna

Designated Indication:
Inhibition of the urotoxic effects induced by oxazaphosphorine compounds such as cyclophosphamide.

Trade Name (if present):

Sponsor Contact Information
Asta Medica , Inc.
890 East St
Tewksbury MA 01876-1496

Date Designated 12/16/1987
Date Approved

Generic Name:
Multi-vitamin infusion (neonatal formula)

Designated Indication:
For establishment and maintenance of total parenteral nutrition in very low birth weight infants

Trade Name (if present):

Sponsor Contact Information
Astra Pharmaceuticals, L.P.
725 Chesterbrook Blvd.
Wayne PA 19087-5677

Date Designated 12/12/1989
Date Approved

Generic Name:
Remacemide

Designated Indication:
Treatment of Huntington's disease.

Trade Name (if present):
Ecovia

Sponsor Contact Information
AstraZeneca LP
725 Chesterbrook Blvd.
Wayne PA 19087-5677

Date Designated 3/6/2000
Date Approved

Generic Name:
Recombinant human antithrombin III

Designated Indication:
Treatment of antithrombin III dependent heparin resistance requiring anticoagulation.

Trade Name (if present):

Sponsor Contact Information
AT III LLC
c/o Genzyme Corporation
15 Pleasant St Connector, P.O. Box 9322
Framingham MA 01701

Date Designated 4/6/2000
Date Approved

Generic Name:
Tizanidine HCl

Designated Indication:
Treatment of spasticity associated with multiple sclerosis and spinal cord injury.

Trade Name (if present):
Zanaflex

Sponsor Contact Information
Athena Neurosciences, Inc.
800 Gateway Boulevard
South San Francisco CA 94080

Date Designated 1/31/1994
Date Approved

Generic Name:
suberoylanilide hydroxamic acid

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):

Sponsor Contact Information
Aton Pharma, Inc
777 Old Saw Mill River Road
Tarrytown NY 10591-6717

Date Designated 6/12/2003
Date Approved

Generic Name:
Natural human lymphoblastoid interferon-alpha

Designated Indication:
Treatment of papillomavirus warts in the oral cavity of HIV positive patients.

Trade Name (if present):

Sponsor Contact Information
Atrix Laboratories, Inc
2579 Midpoint Drive
Fort Collins CO 80525-4417

Date Designated 8/10/2000
Date Approved

Generic Name:
Natural human lymphoblastoid interferon-alpha

Designated Indication:
Treatment of Behcet's disease

Trade Name (if present):

Sponsor Contact Information
Atrix Laboratories, Inc.
2579 Midpoint Dr
Fort Collins CO 80525-4417

Date Designated 1/18/2000
Date Approved

Generic Name:
Purified type II collagen

Designated Indication:
Treatment of juvenile rheumatoid arthritis.

Trade Name (if present):
Colloral

Sponsor Contact Information
AutoImmune, Inc.
128 Spring Street
Lexington MA 02421

Date Designated 2/9/1995
Date Approved

Generic Name:
Soluble complement receptor type 1

Designated Indication:
Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass

Trade Name (if present):

Sponsor Contact Information
Avant Immunotherapeutics, Inc.
119 Fourth Ave.
Needham MA 02494-2725

Date Designated 3/6/2000
Date Approved

Generic Name:
retroviral gamma-c cDNA containing vector

Designated Indication:
Treatment of X linked severe combined immune deficiency disease

Trade Name (if present):

Sponsor Contact Information
AVAX technologies, Inc.
9200 Indian Creek Parkway
Building 9, Suite 200
Overland Park KS 66210

Date Designated 4/29/2002
Date Approved

Generic Name:
DNP-Modified autologous tumor vaccine

Designated Indication:
Adjuvant therapy for the treatment of ovarian cancer

Trade Name (if present):
O-Vax

Sponsor Contact Information
AVAX Technologies, Inc.
9200 Indian Creek Parkway
Building 9, Suite 200
Overland Park KS 66210

Date Designated 9/21/2000
Date Approved

Generic Name:
Autologous DNP-conjugated tumor vaccine

Designated Indication:
For adjuvant therapy in melanoma patients with surgically resectable lymph node metastasis (Stage III and limited Stage IV disease).

Trade Name (if present):
M-Vax

Sponsor Contact Information
Avax Technologies, Inc.
9200 Indian Creek Parkway
Building 9, Suite 200
Overland Park KS 66210

Date Designated 2/23/1999
Date Approved

Generic Name:
Alpha1-proteinase inhibitor (human)

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

Trade Name (if present):

Date Designated 11/24/1999
Date Approved

Sponsor Contact Information
Aventis Behring L.L.C.
1020 First Ave.
PO Box 61501
King of Prussia PA 19406-0901

Generic Name:
C1-esterase-inhibitor, human, pasteurized

Designated Indication:
Prevention and/or treatment of acute attacks of hereditary angioedema

Trade Name (if present):
Bernert P

Date Designated 10/16/1992
Date Approved

Sponsor Contact Information
Aventis Behring L.L.C.
1020 First Ave
PO Box 61501
King of Prussia PA 19406-0901

Generic Name:
Antihemophilic factor/von Willebrand factor complex (human), dried, pasteurized

Designated 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

Trade Name (if present):

Humate-P

Date Designated 10/16/1992
Date Approved 4/1/1999

Sponsor Contact Information
Aventis Behring L.L.C.
1020 First Avenue
PO Box 61501
King Of Prussia PA 19406-0901

Generic Name:
Desmopressin acetate

Designated Indication:
Treatment of mild hemophilia A and von Willebrand's disease

Trade Name (if present):

Date Designated 1/22/1991
Date Approved 3/7/1994

Sponsor Contact Information
Aventis Behring L.L.C.
1020 First Avenue
PO Box 61501
King of Prussia PA 19406-0901

Generic Name:
Pentamidine isethionate

Designated Indication:
Treatment of Pneumocystis carinii pneumonia.

Trade Name (if present):

Date Designated 10/29/1984
Date Approved

Sponsor Contact Information
Aventis Behring L.L.C.
1020 First Avenue
PO Box 61501
King of Prussia PA 19406-0901

Generic Name:
factor XIII concentrate (human), pasteurized

Designated Indication:
Treatment of congenital factor XIII deficiency.

Trade Name (if present):
Fibrogammin P

Date Designated 1/16/1985
Date Approved

Sponsor Contact Information
Aventis Behring L.L.C.
1020 First Ave
PO Box 61501
King of Prussia PA 19406-0901

Generic Name:
Antithrombin III (human) concentrate IV

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

Trade Name (if present):
Kyberlin P

Date Designated 7/2/1985
Date Approved

Sponsor Contact Information
Aventis Behring L L C
1020 First Ave
PO Box 61501
King of Prussia PA 19406-0901

Generic Name:
vigabatrin

Designated Indication:
Treatment of infantile spasms

Trade Name (if present):
Sabril

Date Designated 6/12/2000
Date Approved

Sponsor Contact Information
Aventis Pharmaceuticals Inc
P.O Box 9627
Kansas City MO 64137

Generic Name:
creatine

Designated Indication:
Treatment of amyotrophic lateral sclerosis

Trade Name (if present):
Creapure

Date Designated 2/12/2002
Date Approved

Sponsor Contact Information
Avicena Group, Inc.
580 California St
Suite 1600
San Francisco CA 94104

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

Designated Indication:
Intrahepatic treatment of patients with moderate to severe hemophilia

Trade Name (if present):
Coagulin-B

Date Designated 6/13/2001
Date Approved

Sponsor Contact Information
Avigen, Inc.
1301 Harbor Bay Parkway
Alameda CA 94502

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

Designated Indication:
Intramuscular treatment of patients with moderate to severe hemophilia

Trade Name (if present):
Coagulum-B

Sponsor Contact Information
Avigen, Inc
1301 Harbor Bay Parkway
Alameda CA 94502

Date Designated 6/13/2001
Date Approved

Generic Name:
Ursodiol

Designated Indication:
Treatment of patients with primary biliary cirrhosis.

Trade Name (if present):
URSO

Sponsor Contact Information
Axcen Pharma Inc
597 Laurier Blvd
Mount St. Hilaire Quebec H7L 4S3

Date Designated 6/20/1991
Date Approved 12/10/1997

Generic Name:
porfimer

Designated Indication:
For the ablation of High-Grade Dysplasia in Barrett's Esophagus in patients who
are not considered to be candidates for esophagectomy

Trade Name (if present):
Photofrin

Sponsor Contact Information
Axcen Scandipharm Inc
22 Inverness Parkway
Suite 310

Date Designated 10/19/2001
Date Approved 8/1/2003
Birmingham AL 35242

Generic Name:
Paclitaxel

Designated Indication:
Treatment of AIDS-related Kaposi's sarcoma.

Trade Name (if present):
Paxene

Sponsor Contact Information
Baker Norton Pharmaceuticals, Inc.
4400 Biscayne Boulevard
Miami FL 33137

Date Designated 4/15/1997
Date Approved

Generic Name:
Flucinolone

Designated Indication:
Treatment uveitis involving the posterior segment of the eye

Trade Name (if present):

Sponsor Contact Information
Bausch & Lomb Pharmaceuticals, Inc
8500 Hidden River Parkway
Tampa FL 33637

Date Designated 7/31/2000
Date Approved

Generic Name:
Ganciclovir intravitreal implant

Designated Indication:
Treatment of cytomegalovirus retinitis.

Trade Name (if present):
Vitrasert Implant

Date Designated 6/7/1995
Date Approved 3/4/1996

Sponsor Contact Information
Bausch & Lomb Surgical, Chiron Vision Products
9342 Jeronimo Road
Irvine CA 92718-1903

Generic Name:
Mafosfamide

Designated Indication:
Treatment of neoplastic meningitis

Trade Name (if present):

Date Designated 1/21/2003
Date Approved

Sponsor Contact Information
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake IL 60073-0490

Generic Name:
recombinant human alpha-1 antitrypsin (rAAT)

Designated Indication:
To delay progression of chronic obstructive pulmonary disease resulting from AAT deficiency-mediated emphysema and bronchiectasis

Trade Name (if present):

Date Designated 8/28/2001
Date Approved

Sponsor Contact Information
Baxter Healthcare Corporation
550 N Brand Blvd.
Glendale CA 91203

Generic Name:
Icodextrin 7.5% with Electrolytes Peritoneal
Dialysis Solution

Designated Indication:
Treatment of those patients having end stage renal disease and requiring peritoneal dialysis treatment

Trade Name (if present):
Extraneal (with 7.5% Icodextrin)

Date Designated 7/18/1997
Date Approved 12/20/2002

Sponsor Contact Information
Baxter Healthcare Corporation
Renal Division
1620 Waukegan Road
McGaw Park IL 60085

Generic Name:
Protein C concentrate

Designated Indication:
For replacement therapy in congenital protein C deficiency for the prevention and treatment of thrombosis, pulmonary emboli, and purpura fulminans

Trade Name (if present):
Protein C Concentrate (human) Vapor

Date Designated 6/23/1992
Date Approved

Sponsor Contact Information
Baxter Healthcare Corporation
Hyland Division (Baxter Hyland)
550 North Brand Blvd
Glendale CA 91203

Generic Name:
Dianeal peritoneal dialysis solution with 1.1% amino acids

Trade Name (if present):
Nutrimeal (Peritoneal Dialysis Solution)

Date Designated 6/11/1992
Date Approved

Designated Indication:
For use as a nutritional supplement for the treatment of malnourishment in patients undergoing continuous ambulatory peritoneal dialysis

Sponsor Contact Information
Baxter Healthcare Corporation
1620 Waukegan Road
McGaw Park IL 60085

Generic Name:
Immune globulin intravenous, human

Trade Name (if present):
Gamunite N

Date Designated 2/18/1993
Date Approved 12/27/1993

Designated Indication:
Infection prophylaxis in pediatric patients affected with the human immunodeficiency virus

Sponsor Contact Information
Bayer Corporation
Pharmaceutical Division, Biological Products
400 Morgan Lane
New Haven CT 06516

Generic Name:
Aprotinin

Trade Name (if present):

Trasylol

Date Designated 11/17/1993
Date Approved 12/29/1993

Designated 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 Contact Information
Bayer Corporation
Pharmaceutical Division
400 Morgan Lane
West Haven CT 06516

Generic Name:
Cytomegalovirus immune globulin intravenous (human)

Trade Name (if present):

Date Designated 1/28/1991
Date Approved

Designated Indication:
For use in conjunction with ganciclovir sodium for the treatment of cytomegalovirus pneumonia in bone marrow transplant patients.

Sponsor Contact Information
Bayer Corporation
Pharmaceutical Division, Biological Products
400 Morgan Lane
New Haven CT 06516

Generic Name:
Antihemophilic factor (recombinant)

Trade Name (if present):
Kogenate

Date Designated 9/25/1989
Date Approved 2/25/1993

Designated Indication:
Prophylaxis and treatment of bleeding in individuals with hemophilia A or for prophylaxis when surgery is required in individuals with hemophilia A.

Sponsor Contact Information
Bayer Corporation
1884 Miles Avenue
Elkhart IN 46515

Generic Name:
Alpha1-proteinase inhibitor (human)

Designated Indication:
For replacement therapy in the alpha-1-proteinase inhibitor congenital deficiency state.

Trade Name (if present):
Prolastin

Sponsor Contact Information
Bayer Corporation
Pharmaceutical Division, Biological Products
400 Morgan Lane
New Haven CT 06516

Date Designated 12/7/1984
Date Approved 12/2/1987

Generic Name:
Antithrombin III (human)

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

Trade Name (if present):
Thrombate III

Sponsor Contact Information
Bayer Corporation
Pharmaceutical Division, Biological Products
400 Morgan Lane
New Haven CT 06516

Date Designated 11/26/1984
Date Approved 12/30/1991

Generic Name:
dextran 1

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Sponsor Contact Information
BCY LifeSciences Inc
160 Eglinton Ave. East
Suite 600
Toronto, Ontario M4P 3B
CANADA

Date Designated 3/21/2003
Date Approved

Generic Name:
4-aminosalicylic acid

Designated Indication:
Treatment of mild to moderate ulcerative colitis in patients intolerant to sulfasalazine

Trade Name (if present):
Pamisyl (P-D), Rezipas (Squibb)

Sponsor Contact Information
Becken, Warren M.D.
University Of Vermont
Given C-317
Burlington VT 05405

Date Designated 12/13/1989
Date Approved

Generic Name:
Fludarabine phosphate

Designated Indication:
Treatment and management of patients with non-Hodgkins lymphoma.

Trade Name (if present):
Fludara

Sponsor Contact Information
Berlex Laboratories, Inc
15049 San Pablo Avenue
P.O. Box 4099
Richmond CA 94804-0099

Date Designated 4/18/1989
Date Approved

Generic Name:
Sotalol HCl

Designated Indication:
Treatment of life-threatening ventricular tachyarrhythmias

Trade Name (if present):
Betapace

Sponsor Contact Information
Berlex Laboratories, Inc
300 Fairfield Road
Wayne NJ 07470

Date Designated 9/23/1988
Date Approved 10/30/1992

Generic Name:
Fludarabine phosphate

Designated Indication:
Treatment of chronic lymphocytic leukemia (CLL), including refractory CLL

Trade Name (if present):
Fludara

Sponsor Contact Information
Berlex Laboratories, Inc.
15049 San Pablo Avenue, P O Box 4099
Richmond CA 94804

Date Designated 4/18/1989
Date Approved 4/18/1991

Generic Name:
Gamma hydroxybutyrate

Designated Indication:
Treatment of narcolepsy and the auxiliary symptoms of cataplexy, sleep paralysis, hypnagogic hallucinations and automatic behavior.

Trade Name (if present):

Sponsor Contact Information
Biocraft Laboratories, Inc
18-01 River Road
Fair Lawn NJ 07410

Date Designated 12/3/1987
Date Approved

Generic Name:
Peldesine

Designated Indication:
Treatment of cutaneous T-cell lymphoma

Trade Name (if present):

Sponsor Contact Information
BioCryst Pharmaceuticals, Inc
2190 Parkway Lake Drive
Birmingham AL 35244

Date Designated 10/5/1993
Date Approved

Generic Name:
Levomethadyl acetate hydrochloride

Designated Indication:
Treatment of heroin addicts suitable for maintenance on opiate agonists

Trade Name (if present):
Orlaam

Sponsor Contact Information
Biodevelopment Corporation
8180 Greensboro Drive, Suite 1000
McLean VA 22102

Date Designated 1/24/1985
Date Approved 7/9/1993

Generic Name:
ibritumomab tiuxetan

Designated Indication:
Treatment of B-cell non-Hodgkin's lymphoma

Trade Name (if present):
Zevalin

Sponsor Contact Information
Biogen IDEC Inc.
3030 Callan Road
San Diego CA 92121

Date Designated 9/6/1994
Date Approved 2/19/2002

Generic Name:
anti-CD23 IgG1, kappa monoclonal antibody

Designated Indication:
Treatment of chronic lymphocytic leukemia

Trade Name (if present):

Sponsor Contact Information
Biogen IDEC, Inc

Date Designated 2/12/2003
Date Approved

3030 Callan Road
San Diego CA 92121

Generic Name:
Rituximab

Designated Indication:
Treatment of non-Hodgkin's B-cell lymphoma.

Trade Name (if present):
Rituxan

Sponsor Contact Information
Biogen IDEC, Inc
3030 Callan Road
San Diego CA 92121

Date Designated 6/13/1994
Date Approved 11/26/1997

Generic Name:
Recombinant humanized MAb 5c8

Designated Indication:
Prevention of rejection of pancreatic islet cell transplants

Trade Name (if present):

Sponsor Contact Information
Biogen, Inc.
14 Cambridge Center
Cambridge MA 02142

Date Designated 3/22/1999
Date Approved

Generic Name:
Recombinant humanized MAb 5c8

Designated Indication:
Prevention of rejection of solid organ transplants.

Trade Name (if present):

Sponsor Contact Information
Biogen, Inc
14 Cambridge Center
Cambridge MA 02142

Date Designated 3/22/1999
Date Approved

Generic Name:
Interferon Beta-1a

Designated Indication:
Treatment of juvenile rheumatoid arthritis

Trade Name (if present):
Avonex

Sponsor Contact Information
Biogen, Inc
14 Cambridge Center
Cambridge MA 02142

Date Designated 10/14/1998
Date Approved

Generic Name:
Recombinant humanized MAb 5c8

Designated Indication:
Prevention and treatment of Factor VIII/Factor IX inhibitors in patients with hemophilia A or B

Trade Name (if present):

Sponsor Contact Information
Biogen, Inc
14 Cambridge Center
Cambridge MA 02142

Date Designated 10/14/1998
Date Approved

Generic Name:
Recombinant humanized monoclonal antibody 5c8

Designated Indication:
Treatment of systemic lupus erythematosus.

Trade Name (if present):

Sponsor Contact Information
Biogen, Inc.
14 Cambridge Center
Cambridge MA 02142

Date Designated 2/18/1998
Date Approved

Generic Name:
Interferon beta-1a (recombinant human)

Designated Indication:
Treatment of pulmonary fibrosis.

Trade Name (if present):
Avonex

Sponsor Contact Information
Biogen, Inc.
14 Cambridge Center
Cambridge MA 02142

Date Designated 1/7/1999
Date Approved

Generic Name:
Recombinant humanized monoclonal antibody 5c8

Designated Indication:
Treatment of immune thrombocytopenic purpura

Trade Name (if present):

Sponsor Contact Information
Biogen, Inc
14 Cambridge Center
Cambridge MA 02142

Date Designated 2/3/1998
Date Approved

Generic Name:
Recombinant human gelsolin

Designated Indication:
Treatment of acute and chronic respiratory symptoms of bronchiectasis.

Trade Name (if present):

Sponsor Contact Information

Biogen, Inc.
14 Cambridge Center
Cambridge MA 02142

Date Designated 3/6/1995

Date Approved

Generic Name:
Recombinant human gelsolin

Designated Indication:
Treatment of the respiratory symptoms of cystic fibrosis.

Trade Name (if present):

Sponsor Contact Information

Biogen, Inc.
14 Cambridge Center
Cambridge MA 02142

Date Designated 1/12/1994

Date Approved

Generic Name:
Interferon beta (recombinant human)

Designated Indication:
Treatment of primary brain tumors.

Trade Name (if present):

Avonex

Sponsor Contact Information

Biogen, Inc.
14 Cambridge Center
Cambridge MA 02142

Date Designated 1/13/1993

Date Approved

Generic Name:
Interferon beta-1a

Designated Indication:
Treatment of multiple sclerosis.

Trade Name (if present):

Avonex

Sponsor Contact Information

Biogen, Inc.
14 Cambridge Center
Cambridge MA 02142

Date Designated 12/16/1991

Date Approved 5/17/1996

Generic Name:
Interferon beta-1a (recombinant human)

Designated Indication:
Treatment of acute non-A, non-B hepatitis

Trade Name (if present):

Sponsor Contact Information

Biogen, Inc.
14 Cambridge Center
Cambridge MA 02142

Date Designated 7/24/1992

Date Approved

Generic Name:
N-acetylgalactosamine-4-sulfatase, recombinant human

Designated Indication:
Treatment of mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome)

Trade Name (if present):

Sponsor Contact Information
BioMarin Pharmaceutical, Inc
11 Pimental Court
Novato CA 94949-5608

Date Designated 2/17/1999
Date Approved

Generic Name:
Iaronidase

Designated Indication:
Treatment of patients with mucopolysaccharidosis-I.

Trade Name (if present):
Aldurazyme

Sponsor Contact Information
BioMarin Pharmaceutical, Inc.
371 Bel Marin Keys Boulevard, Suite 210
Novato CA 94949-5608

Date Designated 9/24/1997
Date Approved 4/30/2003

Generic Name:
40SD02

Designated Indication:
Treatment of chronic iron overload resulting from conventional transfusional treatment of beta-thalassemia major and sickle cell anemia

Trade Name (if present):

Sponsor Contact Information
Biomedical Frontiers, Inc
1095 10th Ave , S.E.
Minneapolis MN 55414

Date Designated 12/21/1998
Date Approved

Generic Name:
Dextran and deferoxamine

Designated Indication:
Treatment of acute iron poisoning.

Trade Name (if present):
Bio-Rescue

Sponsor Contact Information
Biomedical Frontiers, Inc
1095 10th Avenue S.E
Minneapolis MN 55414

Date Designated 3/8/1991
Date Approved

Generic Name:
(+/-)-7-[3-(4-acetyl-3-methoxy-2-propylphenoxy)propoxy]-3,4-dihydro-8-propyl-2H-1-benzopyran-2-carboxylic acid

Designated Indication:
Prevention of serious adverse events associated with vascular leak syndrome caused by Interleukin-2 therapy

Trade Name (if present):

Sponsor Contact Information
BioMedicines, Inc
2000 Powell Street, Suite 1640
Emeryville CA 94608

Date Designated 3/31/2003
Date Approved

Generic Name:
Liposome encapsulated recombinant interleukin-2

Designated Indication:
Treatment of cancers of the kidney and renal pelvis

Trade Name (if present):

Sponsor Contact Information
Biomira USA, Inc.
1002 Eastpark Boulevard
Cranbury NJ 08512

Date Designated 6/20/1994
Date Approved

Generic Name:
Liposome encapsulated recombinant interleukin-2

Designated Indication:
Treatment of brain and CNS tumors

Trade Name (if present):

Sponsor Contact Information
Biomira USA, Inc.
1002 Eastpark Boulevard
Cranbury NJ 08512

Date Designated 11/25/1991
Date Approved

Generic Name:
Bovine whey protein concentrate

Designated Indication:
Treatment of cryptosporidiosis caused by the presence of *Cryptosporidium parvum* in the gastrointestinal tract of patients who are immunodeficient/immunocompromised or immunocompetent

Trade Name (if present):
Immuno-C

Sponsor Contact Information
Biomune Systems, Inc.
540 Arapeen Drive, Suite 202
Salt Lake City UT 84108

Date Designated 9/30/1993
Date Approved

Generic Name:
Mitolactol

Designated Indication:
As adjuvant therapy in the treatment of primary brain tumors.

Trade Name (if present):

Sponsor Contact Information
Biopharmaceutics, Inc.
990 Station Road
Bellport NY 11713

Date Designated 7/12/1995
Date Approved

Generic Name:
Mitolactol

Designated Indication:
Treatment of recurrent invasive or metastatic squamous carcinoma of the cervix

Trade Name (if present):

Sponsor Contact Information
Biopharmaceutics, Inc.
990 Station Road
Bellport NY 11713

Date Designated 1/23/1989
Date Approved

Generic Name:
Protaxel

Designated Indication:
Treatment of ovarian cancer

Trade Name (if present):

Date Designated 5/21/2003
Date Approved

Sponsor Contact Information
Biophysica, Inc.
3333 North Torrey Pines Court
Suite 100
La Jolla CA 92037

Generic Name:
Chimeric, humanized monoclonal antibody to
staphylococcus

Designated Indication:
Prophylaxis of Staphylococcus epidermidis sepsis in low birth weight (1500 grams
or less) infants.

Trade Name (if present):

Date Designated 8/3/2000
Date Approved

Sponsor Contact Information
Biosynexus, Inc.
9610 Medical Center Drive
Suite 100
Rockville MD 20850

Generic Name:
Oxandrolone

Designated Indication:
Treatment of patients with Duchenne's muscular dystrophy and Becker's muscular
dystrophy

Trade Name (if present):
Oxandrin

Date Designated 4/22/1997
Date Approved

Sponsor Contact Information
Bio-Technology General Corp.
One Tower Center Boulevard, 12th floor
East Brunswick NJ 08816

Generic Name:
Oxandrolone

Designated Indication:
Adjunctive therapy for AIDS patients suffering from HIV-wasting syndrome.

Trade Name (if present):
Oxandrin

Date Designated 9/6/1991
Date Approved

Sponsor Contact Information
Bio-Technology General Corp.
One Tower Center Boulevard, 12 th floor
East Brunswick NJ 08816

Generic Name:
Polyethylene glycol (PEG)-uricase

Designated Indication:
To control the clinical consequences of hyperuricemia in patients with severe gout
in whom conventional therapy is contraindicated or has been ineffective.

Trade Name (if present):

Date Designated 2/21/2001
Date Approved

Sponsor Contact Information
Bio-Technology General Corporation
One Tower Center Boulevard, 12th floor
East Brunswick NJ 08816

Generic Name:
Humanized anti-human CD2 MAb

Trade Name (if present):
MEDI-507

Date Designated 9/17/1998
Date Approved

Designated 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 Contact Information
Biotransplant, Inc
Building 75, 3rd Ave
Charlestown Navy Yard
Charlestown MA 02129

Generic Name:
Ethanalamine oleate

Trade Name (if present):
Ethanolin

Date Designated 3/22/1984
Date Approved 12/22/1988

Designated Indication:
Treatment of patients with esophageal varices that have recently bled, to prevent rebleeding

Sponsor Contact Information
Block Drug Company, Inc
257 Cornelison Avenue
Jersey City NJ 07302

Generic Name:
Succimer

Trade Name (if present):
Chemet capsules

Date Designated 5/9/1984
Date Approved 12/22/1988

Designated Indication:
Treatment of lead poisoning in children.

Sponsor Contact Information
Bock Pharmacal Company
P.O. Box 419056
Saint Louis MO 63141-9056

Generic Name:
carbamic acid, [[4-[[3-[[4-[1-(4-hydroxyphenyl)-1-methyl-ethyl]phenoxy]methyl]phenyl]methoxy]-

Trade Name (if present):

Date Designated 1/15/2002
Date Approved

Designated Indication:
Management of cystic fibrosis

Sponsor Contact Information
Boehringer Ingelheim Pharmaceuticals, Inc
900 Ridgebury Road
P.O. Box 368
Ridgefield CT 06877

Generic Name:
meloxicam

Trade Name (if present):
Mobic

Date Designated 11/22/2002
Date Approved

Designated Indication:
Treatment of juvenile rheumatoid arthritis

Sponsor Contact Information
Boehringer Ingelheim Pharmaceuticals, Inc
900 Ridgebury Road
P. O. Box 368
Ridgefield CT 06877-0368

Generic Name:
Porfiromycin

Designated Indication:
Treatment of cervical cancer

Trade Name (if present):
Promycin

Date Designated 3/13/1997
Date Approved

Sponsor Contact Information
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
PO Box 368
Ridgefield CT 06877

Generic Name:
Porfiromycin

Designated Indication:
Treatment of head and neck cancer

Trade Name (if present):
Promycin

Date Designated 9/19/1995
Date Approved

Sponsor Contact Information
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
PO Box 368
Ridgefield CT 06877

Generic Name:
Bromhexine

Designated Indication:
Treatment of mild to moderate keratoconjunctivitis sicca in patients with Sjogren's syndrome

Trade Name (if present):
Bisolvon

Date Designated 5/15/1989
Date Approved

Sponsor Contact Information
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road, Box 368
Ridgefield CT 06877-0368

Generic Name:
Digoxin immune fab(ovine)

Designated Indication:
Treatment of life-threatening acute cardiac glycoside intoxication manifested by conduction disorders, ectopic ventricular activity and (in some cases) hyperkalemia.

Trade Name (if present):
Digidote

Date Designated 3/11/1985
Date Approved

Sponsor Contact Information
Boehringer Mannheim Corp.
1301 Piccard Drive
Rockville MD 20850

Generic Name:
Hemin and zinc mesoporphyrin

Designated Indication:
Treatment of acute porphyric syndromes.

Trade Name (if present):
Hemex

Date Designated 12/20/1993
Date Approved

Sponsor Contact Information
Bonkovsky, Herbert L. M.D
University Of Massachusetts Medical Center
55 Lake Avenue North
Worcester MA 01655

Generic Name:
Japanese encephalitis vaccine (live, attenuated)

Designated Indication:
Prevention of Japanese encephalitis.

Trade Name (if present):

Sponsor Contact Information
Boran Pharmaceuticals
3F, Koryo Academytel, 437-3
Ahyun-Dong, Mapo-Gu, Seoul 121-010

Date Designated 5/19/1999

Date Approved

Generic Name:
Botulinum toxin type A

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

Trade Name (if present):

Sponsor Contact Information
Botulinum Toxin Research Associates, Inc
1261 Furnace Brook Parkway
Quincy MA 02169

Date Designated 9/15/1992

Date Approved

Generic Name:
Calcium acetate

Designated Indication:
Treatment of hyperphosphatemia in end stage renal failure.

Trade Name (if present):
Phos-Lo

Sponsor Contact Information
Braintree Laboratories
60 Columbian Street
P O Box 361
Braintree MA 02184

Date Designated 12/22/1988

Date Approved 12/10/1990

Generic Name:
Ammonium tetrathiomolybdate

Designated Indication:
Treatment of Wilson's disease

Trade Name (if present):

Sponsor Contact Information
Brewer, George J. , M D.
University Of Michigan Medical School
4708 Medical Science Building II 0618
Ann Arbor MI 48109

Date Designated 1/31/1994

Date Approved

Generic Name:
Acetylcysteine

Designated Indication:
Intravenous treatment of patients presenting with moderate to severe acetaminophen overdose.

Trade Name (if present):
Mucomyst/Mucomyst 10 IV

Sponsor Contact Information
Bristol-Myers Squibb Company
P.O. Box 4500
Princeton NJ 08543-4500

Date Designated 8/13/1987

Date Approved

Generic Name:
Paclitaxel

Designated Indication:
Treatment of AIDS-related Kaposi's sarcoma

Trade Name (if present):
Taxol

Sponsor Contact Information
Bristol-Myers Squibb Pharmaceutical Research Institute
5 Research Parkway
P O. Box 5100
Wallingford CT 06492-7660

Date Designated 3/25/1997
Date Approved 8/4/1997

Generic Name:
Bleomycin sulfate

Designated Indication:
Treatment of malignant pleural effusion.

Trade Name (if present):
Blenoxane

Sponsor Contact Information
Bristol-Myers Squibb Pharmaceutical Research Institute
P O. Box 4000
Princeton NJ 08543

Date Designated 9/17/1993
Date Approved 2/20/1996

Generic Name:
Hydroxyurea

Designated Indication:
Treatment of patients with sickle cell anemia as shown by the presence of hemoglobin S

Trade Name (if present):
Droxia

Sponsor Contact Information
Bristol-Myers Squibb Pharmaceutical Research Institute
P.O. Box 4000
Princeton NJ 08543

Date Designated 10/1/1990
Date Approved 2/25/1998

Generic Name:
Megestrol acetate

Designated Indication:
Treatment of patients with anorexia, cachexia, or significant weight loss ($\geq 10\%$ of baseline body weight) and confirmed diagnosis of AIDS.

Trade Name (if present):
Megace

Sponsor Contact Information
Bristol-Myers Squibb Pharmaceutical Research Institute
2400 West Lloyd Expressway
Evansville IN 47721

Date Designated 4/13/1988
Date Approved 9/10/1993

Generic Name:
Ifosfamide

Designated Indication:
Treatment of testicular cancer

Trade Name (if present):
Ifex

Sponsor Contact Information
Bristol-Myers Squibb Pharmaceutical Research Institute
5 Research Parkway, P.O. Box 5100
Wallingford CT 06492

Date Designated 1/20/1987
Date Approved 12/30/1988

Generic Name:
Ifosfamide

Designated Indication:
Treatment of bone sarcomas

Trade Name (if present):
Ifex

Sponsor Contact Information
Bristol-Myers Squibb Pharmaceutical Research Institute
P O Box 4000
Princeton NJ 08543-4000

Date Designated 8/7/1985
Date Approved

Generic Name:
Ifosfamide

Designated Indication:
Treatment of soft tissue sarcomas.

Trade Name (if present):
Ifex

Sponsor Contact Information
Bristol-Myers Squibb Pharmaceutical Research Institute
P O Box 4000
Princeton NJ 08543

Date Designated 8/7/1985
Date Approved

Generic Name:
Teniposide

Designated Indication:
Treatment of refractory childhood acute lymphocytic leukemia.

Trade Name (if present):
Vumon for injection

Sponsor Contact Information
Bristol-Myers Squibb Pharmaceutical Research Institute
5 Research Parkway
P.O. Box 5100
Wallingford CT 06492

Date Designated 11/1/1984
Date Approved 7/14/1992

Generic Name:
Clotrimazole

Designated Indication:
Treatment of sickle cell disease.

Trade Name (if present):

Sponsor Contact Information
Brugnara, Carlo M.D.
The Children's Hospital
300 Longwood Avenue, Bader 760
Boston MA 02115

Date Designated 4/24/1995
Date Approved

Generic Name:
Sterile talc powder

Designated Indication:
Treatment of malignant pleural effusion.

Trade Name (if present):
Sclerosol Intrapleural Aerosol

Sponsor Contact Information
Bryan Corporation
4 Plympton Street
Woburn MA 01801

Date Designated 9/18/1995
Date Approved 12/24/1997

Generic Name:
BW 12C

Designated Indication:
Treatment of sickle cell disease

Trade Name (if present):

Sponsor Contact Information
Burroughs Wellcome Company
3030 Cornwallis Road
P.O. Box 12700
Research Triangle Pk NC 27709

Date Designated 10/23/1987

Date Approved

Generic Name:
rSP-C lung surfactant

Designated Indication:
Treatment of adult respiratory distress syndrome

Trade Name (if present):

Venticute

Sponsor Contact Information
Byk Gulden Pharmaceuticals
Byk-Gulden StraBe 2
78467 Konstanz

Date Designated 4/3/2000

Date Approved

GERMANY

Generic Name:
Calcium gluconate

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

Trade Name (if present):

Calgonate

Sponsor Contact Information
Calgonate Corp.
190 Commerce Drive
Warwick RI 02886

Date Designated 11/20/1997

Date Approved

Generic Name:
Botulism immune globulin

Designated Indication:
Treatment of infant botulism.

Trade Name (if present):

BabyBIG

Sponsor Contact Information
California Department of Health Services
2151 Berkeley Way
Berkeley CA 94704-1011

Date Designated 1/31/1989

Date Approved 10/23/2003

Generic Name:
2-(3-diethylaminopropyl)-8,8-dipropyl-2-azaspiro
[4,5] decan dimaleate

Designated Indication:
Treatment of multiple myeloma and associated bone resorption

Trade Name (if present):

Atiprimod

Sponsor Contact Information
Callisto Pharmaceuticals, Inc
2 Executive Drive
Suite 450
Somerset NJ 08873

Date Designated 12/2/2003

Date Approved

Generic Name:
Dimethylsulfoxide

Designated Indication:
Treatment of palmar-plantar erythrodysesthesia syndrome.

Trade Name (if present):

Sponsor Contact Information

Cancer Technologies, Inc
7301 East 22nd Street
Suite 10E
Tucson AZ 85710

Date Designated 4/6/1998

Date Approved

Generic Name:
Dimethylsulfoxide

Designated Indication:
Topical treatment for the prevention of soft tissue injury following extravasation of cytotoxic drugs.

Trade Name (if present):

Sponsor Contact Information

Cancer Technologies, Inc
7301 East 22nd Street
Suite 10E
Tucson AZ 85710

Date Designated 4/15/1997

Date Approved

Generic Name:
Melanoma cell vaccine

Designated Indication:
Treatment of invasive melanoma.

Trade Name (if present):

Sponsor Contact Information

CancerVax Corporation
2110 Rutherford Road
Carlsbad CA 92008

Date Designated 10/13/1994

Date Approved

Generic Name:
Polymeric oxygen

Designated Indication:
Treatment of sickle cell anemia

Trade Name (if present):

Sponsor Contact Information

Capmed USA
P O Box 14
Bryn Mawr PA 19010

Date Designated 3/25/1992

Date Approved

Generic Name:
Oxypurinol

Designated Indication:
Treatment of hyperuricemia in patients intolerant to allopurinol

Trade Name (if present):

Sponsor Contact Information

Cardiome Pharma Corp.
3650 Westbrook Mall
Vancouver, B.C.
CANADA

Date Designated 11/9/1998

Date Approved

Generic Name:
Allopurinol sodium

Designated 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.

Trade Name (if present):
Aloprim for Injection

Sponsor Contact Information
Catalytica Pharmaceuticals, Inc
PO Box 1887
Greenville NC 27835-1887

Date Designated 10/16/1992
Date Approved 5/17/1996

Generic Name:
Microbubble contrast agent

Designated Indication:
Intraoperative aid in the identification and localization of intracranial tumors.

Trade Name (if present):
Filmix Neurosonographic Contrast Agent

Sponsor Contact Information
Cav-Con, Inc.
55 Knollwood Road
Farmington CT 06032

Date Designated 11/16/1990
Date Approved

Generic Name:
3-(4'aminoisindoline-1'-one)-1-piperidine-2,6-dione

Designated Indication:
Treatment for multiple myeloma

Trade Name (if present):
Revimid (proposed)

Sponsor Contact Information
Celgene Corporation
7 Powder Horn Drive
Warren NJ 07059

Date Designated 9/20/2001
Date Approved

Generic Name:
a-(3-aminophthalimido) glutaramide

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):
Actimid

Sponsor Contact Information
Celgene Corporation

Date Designated 1/15/2003
Date Approved

7 Powder Horn Drive
Warren NJ 07059

Generic Name:
Thalidomide

Designated Indication:
Treatment of Crohn's disease.

Trade Name (if present):
Thalomid

Sponsor Contact Information
Celgene Corporation
7 Powder Horn Dr.
Warren NJ 07059

Date Designated 4/6/1999
Date Approved

Generic Name:
Thalidomide

Designated Indication:
Treatment of multiple myeloma.

Trade Name (if present):
Thalomid

Sponsor Contact Information
Celgene Corporation
7 Powder Horn Dr
Warren NJ 07059

Date Designated 10/14/1998
Date Approved

Generic Name:
Thalidomide

Designated Indication:
Treatment of Kaposi's sarcoma.

Trade Name (if present):

Sponsor Contact Information
Celgene Corporation
7 Powder Horn Dr.
Warren NJ 07059

Date Designated 7/29/1998
Date Approved

Generic Name:
Thalidomide

Designated Indication:
Treatment of primary brain malignancies.

Trade Name (if present):

Sponsor Contact Information
Celgene Corporation
7 Powder Horn Dr.
Warren NJ 07059

Date Designated 2/27/1998
Date Approved

Generic Name:
Thalidomide

Designated Indication:
Treatment of HIV-associated wasting syndrome

Trade Name (if present):
Synovir

Sponsor Contact Information
Celgene Corporation
P.O. Box 4914
7 Powder Horn Drive
Warren NJ 07059

Date Designated 3/11/1996
Date Approved

Generic Name:
Thalidomide

Designated Indication:
Treatment of erythema nodosum leprosum

Trade Name (if present):
Thalomid

Sponsor Contact Information
Celgene Corporation
P O. Box 4914
7 Powder Horn Drive
Warren NJ 07059

Date Designated 7/26/1995
Date Approved 7/16/1998

Generic Name:
Thalidomide

Designated Indication:
Treatment of severe recurrent aphthous stomatitis in severely, terminally immunocompromised patients.

Trade Name (if present):

Sponsor Contact Information

Celgene Corporation
P.O. Box 4914
7 Powder Horn Drive
Warren NJ 07059

Date Designated 5/1/1995
Date Approved

Generic Name:
Thalidomide

Designated Indication:
Treatment of the clinical manifestations of mycobacterial infection caused by Mycobacterium tuberculosis and non-tuberculous mycobacteria

Trade Name (if present):

Sponsor Contact Information

Celgene Corporation
P.O. Box 4914
7 Powder Horn Drive
Warren NJ 07059

Date Designated 1/12/1993
Date Approved

Generic Name:
Serratia marcescens extract (polyribosomes)

Designated Indication:
Treatment of primary brain malignancies.

Trade Name (if present):

Imuvert

Sponsor Contact Information

Cell Technology, Inc.
1668 Valtec Lane
Boulder CO 80306

Date Designated 9/7/1988
Date Approved

Generic Name:
arsenic trioxide

Designated Indication:
Treatment of chronic lymphocytic leukemia

Trade Name (if present):

Trisenox

Sponsor Contact Information

Cell Therapeutics, Inc.
501 Elliott Avenue West
Suite 400
Seattle WA 98119

Date Designated 5/13/2003
Date Approved

Generic Name:
arsenic trioxide

Designated Indication:
Treatment of liver cancer

Trade Name (if present):

Trisenox

Sponsor Contact Information

Cell Therapeutics, Inc.
501 Elliott Avenue West
Suite 400
Seattle WA 98119

Date Designated 6/13/2003
Date Approved

Generic Name:
arsenic

Designated Indication:

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

Trade Name (if present):
Trisenox

Sponsor Contact Information

Cell Therapeutics, Inc
501 Elliott Avenue West
Suite 400
Seattle WA 98119

Date Designated 11/2/2001
Date Approved

Generic Name:
arsenic trioxide

Designated Indication:

Treatment of chronic myeloid leukemia

Trade Name (if present):
Trisenox

Sponsor Contact Information

Cell Therapeutics, Inc
501 Elliott Avenue West
Suite 400
Seattle WA 98119

Date Designated 10/18/2001
Date Approved

Generic Name:
Arsenic trioxide

Designated Indication:

Treatment of multiple myeloma

Trade Name (if present):
Trisenox

Sponsor Contact Information

Cell Therapeutics, Inc
201 Elliott Ave West, Suite 400
Seattle WA 98119

Date Designated 4/28/2000
Date Approved

Generic Name:
arsenic trioxide

Designated Indication:

Treatment of myelodysplastic syndrome.

Trade Name (if present):
Trisenox

Sponsor Contact Information

Cell Therapeutics, Inc.
201 Elliott Avenue West
Suite 400
Seattle WA 98119

Date Designated 7/17/2000
Date Approved

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

Designated Indication:

Treatment of hormone refractory prostate carcinoma.

Trade Name (if present):

Sponsor Contact Information

Cell Therapeutics, Inc.
201 Elliott Avenue West
Suite 400
Seattle WA 98119

Date Designated 1/18/2000
Date Approved

Generic Name:
Lisofylline

Designated Indication:
Treatment of patients undergoing induction therapy for acute myeloid leukemia

Trade Name (if present):

Sponsor Contact Information

Cell Therapeutics, Inc.
201 Elliot Avenue West
Suite 400
Seattle WA 98119

Date Designated 6/10/1999

Date Approved

Generic Name:
CT-2584 mesylate

Designated Indication:
Treatment of malignant mesothelioma

Trade Name (if present):

Sponsor Contact Information

Cell Therapeutics, Inc.
501 Elliott Avenue West, #400
Seattle WA 98119

Date Designated 4/16/1999

Date Approved

Generic Name:
CT-2584 Mesylate

Designated Indication:
Treatment of adult soft tissue sarcoma.

Trade Name (if present):

Sponsor Contact Information

Cell Therapeutics, Inc.
501 Elliott Ave. West
Suite 400
Seattle WA 98119

Date Designated 4/16/1999

Date Approved

Generic Name:
Arsenic trioxide

Designated Indication:
Treatment of acute promyelocytic leukemia.

Trade Name (if present):

Trisenox

Sponsor Contact Information

Cell Therapeutics, Inc.
201 Elliott Ave. West
Suite 400
Seattle WA 98119

Date Designated 3/3/1998

Date Approved 9/25/2000

Generic Name:
tri-antennary glycotripeptide derivative of 5-
fluorodeoxyuridine monophosphate

Designated Indication:
Treatment for hepatocellular carcinoma

Trade Name (if present):

Sponsor Contact Information

Cell Works Inc.
6200 Seaforth Street
Baltimore MD 21224-6506

Date Designated 11/23/2001

Date Approved

Generic Name:
ACA125

Designated Indication:
Treatment of epithelial ovarian cancer

Trade Name (if present):

Sponsor Contact Information
CellControl Biomedical Laboratories AG
Am Klopferspitz 19
D-82152

Date Designated 11/25/2003

Date Approved

GERMANY

Generic Name:
CDP571

Designated Indication:
Treatment of Crohn's disease.

Trade Name (if present):

Sponsor Contact Information
Celltech Chiroscience Limited
216 Bath Road
Slough SL1 4EN

Date Designated 12/11/1997

Date Approved

UNITED KINGDOM

Generic Name:
Pyruvate

Designated Indication:
Treatment of interstitial lung disease.

Trade Name (if present):

Sponsor Contact Information
Cellular Sciences, Inc
84 park Avenue
P.O. Box 968
Flemington NJ 08822

Date Designated 2/21/2001

Date Approved

Generic Name:
Sodium pyruvate

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Sponsor Contact Information
Cellular Sciences, Inc.
84 Park Avenue
P. O. Box 968
Flemington NJ 08822

Date Designated 3/31/2003

Date Approved

Generic Name:
4,5-dibromorhodamine 123

Designated Indication:
Treatment of chronic myelogenous leukemia

Trade Name (if present):
Theralux Irradiation Device

Sponsor Contact Information
Celmed BioSciences Inc.
2310 boul Alfred-Nobel
Saint-Laurent, Quebec
CANADA

Date Designated 4/10/2003

Date Approved

Generic Name:
Recombinant human insulin-like growth factor-
I/insulin-like growth factor binding protein-3

Designated Indication:
Treatment of major burns that require hospitalization

Trade Name (if present):

Sponsor Contact Information

Celtrix Pharmaceuticals, Inc
P O. Box 2400
Glen Allen VA 23058-2400

Date Designated 6/15/1999

Date Approved

Generic Name:
Transforming growth factor-beta 2

Designated Indication:
Treatment of full thickness macular holes

Trade Name (if present):

Sponsor Contact Information

Celtrix Pharmaceuticals, Inc.
3055 Patrick Henry Drive
Santa Clara CA 95054

Date Designated 12/18/1992

Date Approved

Generic Name:
recombinant human insulin-like growth factor-
I/insulin-like growth factor binding protein-3

Designated Indication:
Treatment of growth hormone insensitivity syndrome

Trade Name (if present):

SomatoKine

Sponsor Contact Information

Celtrix Pharmaceuticals, Inc a subsidiary of Inmed, Inc
4851 Lake Brook Drive
Glen Allen VA 23060

Date Designated 5/17/2002

Date Approved

Generic Name:
infliximab

Designated Indication:
Treatment of chronic sarcoidosis

Trade Name (if present):

Remicade

Sponsor Contact Information

Centocor, Inc.
200 Great Valley Parkway
Malvern PA 19355-1307

Date Designated 5/21/2003

Date Approved

Generic Name:
infliximab

Designated Indication:
Treatment of giant cell arteritis

Trade Name (if present):

Remicade

Sponsor Contact Information

Centocor, Inc.
200 Great Valley Parkway
Malvern PA 19355-1307

Date Designated 5/6/2003

Date Approved

Generic Name:
Human Anti-tumor Necrosis factor alpha
monoclonal antibody

Trade Name (if present):

Date Designated 1/16/2003
Date Approved

Designated Indication:
Treatment of uveitis of the posterior segment of non-infectious etiology, and
uveitis of the anterior segment of non-infectious etiology and refractory to
conventional therapy

Sponsor Contact Information
Centocor, Inc
200 Great Valley Parkway
Malvern PA 19355-1307

Generic Name:
infliximab

Trade Name (if present):
Remicade

Date Designated 10/23/2002
Date Approved

Designated Indication:
Treatment of juvenile rheumatoid arthritis

Sponsor Contact Information
Centocor, Inc.

200 Great Valley Parkway
Malvern PA 19355-1307

Generic Name:
Infliximab

Trade Name (if present):
Remicade

Date Designated 11/14/1995
Date Approved 8/24/1998

Designated 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 Contact Information
Centocor, Inc
200 Great Valley Parkway
Malvern PA 19355-1307

Generic Name:
Indium In 111 murine monoclonal antibody FAB
to myosin

Trade Name (if present):
Myoscint

Date Designated 8/7/1989
Date Approved

Designated Indication:
To aid in the diagnosis of myocarditis

Sponsor Contact Information
Centocor, Inc.
244 Great Valley Parkway
Malvern PA 19355

Generic Name:
Imciromab pentetate

Trade Name (if present):
Myoscint

Date Designated 1/25/1989
Date Approved

Designated Indication:
Detecting early necrosis as an indication of rejection of orthotopic cardiac
transplants.

Sponsor Contact Information
Centocor, Inc.
244 Great Valley Parkway
Malvern PA 19355

Generic Name:
Nebacumab

Designated Indication:
Treatment of patients with gram-negative bacteremia which has progressed to endotoxin shock

Trade Name (if present):
Centoxin

Sponsor Contact Information
Centocor, Inc
200 Great Valley Parkway
Malvern PA 19355

Date Designated 10/1/1986
Date Approved

Generic Name:
infliximab

Designated Indication:
Treatment of pediatric (0 to 16 years of age) Crohn's Disease

Trade Name (if present):
REMICADE

Sponsor Contact Information
Centocor, Inc.
200 Great Valley Parkway
Malvern PA 19355-1307

Date Designated 11/12/2003
Date Approved

Generic Name:
infliximab

Designated Indication:
Treatment of pediatric (0 to 16 years of age) ulcerative colitis

Trade Name (if present):
REMICADE

Sponsor Contact Information
Centocor, Inc.
200 Great Valley Parkway
Malvern PA 19355-1307

Date Designated 11/12/2003
Date Approved

Generic Name:
Recombinant human insulin-like growth factor-I

Designated Indication:
Treatment of post-poliomyelitis syndrome.

Trade Name (if present):

Sponsor Contact Information
Cephalon, Inc.
145 Brandywine Parkway
West Chester PA 19380-4245

Date Designated 10/13/1995
Date Approved

Generic Name:
Modafinil

Designated Indication:
Treatment of excessive daytime sleepiness in narcolepsy

Trade Name (if present):
Provigil

Sponsor Contact Information
Cephalon, Inc.
145 Brandywine Parkway
West Chester PA 19380

Date Designated 3/15/1993
Date Approved 12/24/1998

Generic Name:
Mecasermin

Designated Indication:
Treatment of amyotrophic lateral sclerosis

Trade Name (if present):
Myotrophin

Date Designated 8/5/1991
Date Approved

Sponsor Contact Information
Cephalon, Inc
145 Brandywine Parkway
West Chester PA 19380-4245

Generic Name:
Trisaccharides A and B

Designated Indication:
Prevention of ABO medical hemolytic reactions arising from ABO-incompatible bone marrow transplantation.

Trade Name (if present):
Biosynject

Date Designated 4/15/1988
Date Approved

Sponsor Contact Information
Chembiomed, Ltd
P.O. Box 8050
Edmonton, Alberta

CANADA

Generic Name:
Trisaccharides A and B

Designated Indication:
For use in ABO-incompatible solid organ transplantation, including kidney, heart, liver and pancreas.

Trade Name (if present):
Biosynject

Date Designated 4/20/1987
Date Approved

Sponsor Contact Information
Chembiomed, Ltd
P.O. Box 8050
Edmonton, Alberta

CANADA

Generic Name:
Trisaccharides A and B

Designated 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.

Trade Name (if present):
Biosynject

Date Designated 4/12/1987
Date Approved

Sponsor Contact Information
Chembiomed, Ltd
P.O. Box 8050, Station F
Edmonton, Alberta

CANADA

Generic Name:
Antiepilepsirine

Designated Indication:
Treatment of drug resistant generalized tonic-clonic epilepsy in children and adults.

Trade Name (if present):

Date Designated 3/23/1989
Date Approved

Sponsor Contact Information
Children's Hospital
700 Children's Drive
Columbus OH 43205

Generic Name:
Synthetic human secretin

Designated Indication:
For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.

Trade Name (if present):

Sponsor Contact Information
ChiRhoCln, Inc
15500 Gallaudet Ave
Silver Spring MD 20905-4176

Date Designated 3/7/2000
Date Approved

Generic Name:
Synthetic porcine secretin

Designated Indication:
For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion

Trade Name (if present):

Sponsor Contact Information
ChiRhoClin, Inc
15500 Gallaudet Ave.
Silver Spring MD 20905-4176

Date Designated 3/7/2000
Date Approved 4/4/2002

Generic Name:
Synthetic porcine secretin

Designated Indication:
For use in the evaluation of exocrine pancreas function.

Trade Name (if present):

Sponsor Contact Information
ChiRhoClin, Inc
15500 Gallaudet Ave.
Silver Spring MD 20905-4176

Date Designated 6/18/1999
Date Approved 11/1/2002

Generic Name:
Synthetic porcine secretin

Designated Indication:
For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.

Trade Name (if present):

Sponsor Contact Information
ChiRhoCln, Inc.
15500 Gallaudet Ave.
Silver Spring MD 20905-4176

Date Designated 6/18/1999
Date Approved

Generic Name:
Synthetic porcine secretin

Designated Indication:
For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.

Trade Name (if present):

Sponsor Contact Information
ChiRhoClin, Inc.
15500 Gallaudet Ave.
Silver Spring MD 20905-4176

Date Designated 6/18/1999
Date Approved 4/4/2002

Generic Name:
Synthetic human secretin

Designated Indication:
For use in the evaluation of exocrine pancreas function

Trade Name (if present):

Sponsor Contact Information

ChiRhoClin, Inc
1550 Gallaudet Ave
Silver Spring MD 20905-4176

Date Designated 6/16/1999

Date Approved

Generic Name:
Synthetic human secretin

Designated Indication:
For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma

Trade Name (if present):

Sponsor Contact Information

ChiRhoClin, Inc
15500 Gallaudet Ave.
Silver Spring MD 20905-4176

Date Designated 6/16/1999

Date Approved

Generic Name:
Synthetic human secretin

Designated Indication:
For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.

Trade Name (if present):

Sponsor Contact Information

ChiRhoClin, Inc
15500 Gallaudet Ave
Silver Spring MD 20905-4176

Date Designated 6/16/1999

Date Approved

Generic Name:
Tezacitabine

Designated Indication:
Treatment of adenocarcinoma of the esophagus and stomach

Trade Name (if present):

Sponsor Contact Information

Chiron Corporation
4560 Horton Street
Emeryville CA 94608-2916

Date Designated 1/27/2003

Date Approved

Generic Name:
Interferon beta-1b

Designated Indication:
Treatment of multiple sclerosis.

Trade Name (if present):

Betaseron

Sponsor Contact Information

Chiron Corp. & Berlex Laboratories
4560 Horton Street
Emeryville CA 94608

Date Designated 11/17/1988

Date Approved 7/23/1993

Generic Name:
Tobramycin

Designated Indication:
Treatment of bronchiectasis patients infected with Pseudomonas aeruginosa

Trade Name (if present):
Tobi

Sponsor Contact Information
Chiron Corporation
201 Elliott Avenue West
Suite 150
Seattle WA 98119

Date Designated 6/18/1999
Date Approved

Generic Name:
Aldesleukin

Designated Indication:
For the treatment non-Hodgkin's lymphoma.

Trade Name (if present):
Proleukin

Sponsor Contact Information
Chiron Corporation
4560 Horton St.
Emeryville CA 94608-2916

Date Designated 11/24/1998
Date Approved

Generic Name:
Aldesleukin

Designated Indication:
Treatment of acute myelogenous leukemia

Trade Name (if present):
Proleukin

Sponsor Contact Information
Chiron Corporation
4560 Horton St
Emeryville CA 94608-2916

Date Designated 7/31/1998
Date Approved

Generic Name:
Aldesleukin

Designated Indication:
Treatment of metastatic melanoma

Trade Name (if present):
Proleukin

Sponsor Contact Information
Chiron Corporation
4560 Horton Street
Emeryville CA 94608-2916

Date Designated 9/10/1996
Date Approved 1/9/1998

Generic Name:
PEG-interleukin-2

Designated Indication:
Treatment of primary immunodeficiencies associated with T-cell defects.

Trade Name (if present):

Sponsor Contact Information
Chiron Corporation
4560 Horton Street
Emeryville CA 94608

Date Designated 2/1/1990
Date Approved

Generic Name:
Aldesleukin

Designated Indication:
Treatment of metastatic renal cell carcinoma

Trade Name (if present):
Proleukin

Sponsor Contact Information
Chiron Corporation
4560 Horton Street
Emeryville CA 94608-2916

Date Designated 9/14/1988
Date Approved 5/5/1992

Generic Name:
Aldesleukin

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

Trade Name (if present):
Proleukin

Sponsor Contact Information
Chiron Corporation
4560 Horton Street
Emeryville CA 94608-2916

Date Designated 3/22/1989
Date Approved

Generic Name:
cyclosporine

Designated Indication:
For the treatment of refractory acute rejection in patients requiring allogenic lung transplants

Trade Name (if present):

Sponsor Contact Information
Chiron Corporation
4560 Horton Street
Emeryville CA 94608

Date Designated 11/25/2003
Date Approved

Generic Name:
cyclosporin

Designated Indication:
Prophylaxis of acute rejection in patients requiring allogenic lung transplant

Trade Name (if present):

Sponsor Contact Information
Chiron Corporation
4560 Horton Street
Emeryville CA 94608

Date Designated 11/25/2003
Date Approved

Generic Name:
Epidermal growth factor (human)

Designated Indication:
For acceleration of corneal epithelial regeneration and the healing of stromal tissue in the condition of non-healing corneal defects

Trade Name (if present):

Sponsor Contact Information
Chiron Vision
500 Iolab Drive
Claremont CA 91711

Date Designated 10/5/1987
Date Approved

Generic Name:
Urogastrone

Designated Indication:

For acceleration of corneal epithelial regeneration and healing of stromal incisions from corneal transplant surgery.

Trade Name (if present):

Sponsor Contact Information

Chiron Vision
500 Iolab Drive
Claremont CA 91711

Date Designated 11/1/1984

Date Approved

Generic Name:
Epoetin beta

Designated Indication:

Treatment of anemia associated with end stage renal disease

Trade Name (if present):

Marogen

Sponsor Contact Information

Chugai-USA, Inc
3780 Hawthorn Court
Waukegan IL 60087

Date Designated 10/22/1987

Date Approved

Generic Name:
Xenogeneic hepatocytes

Designated Indication:

Treatment of severe liver failure

Trade Name (if present):

HepatAssist Liver Assist System

Sponsor Contact Information

Circe Biomedical, Inc
99 Hayden Ave.
Lexington MA 02421-7995

Date Designated 11/27/1998

Date Approved

Generic Name:
Recombinant human Clara Cell 10kDa protein

Designated Indication:

Prevention of neonatal bronchopulmonary dysplasia in premature neonates with respiratory distress syndrome

Trade Name (if present):

Sponsor Contact Information

Claragen, Inc
335 Paint Branch Drive
College Park MD 20742

Date Designated 7/13/1998

Date Approved

Generic Name:
Halofuginone

Designated Indication:

Treatment of systemic sclerosis.

Trade Name (if present):

Stenorol

Sponsor Contact Information

Collgard Biopharmaceuticals Ltd
Textile House, 2 Koifman St
Tel-Aviv 68012

Date Designated 2/7/2000

Date Approved

ISRAEL

Generic Name:
Mazindol

Designated Indication:
Treatment of Duchenne muscular dystrophy.

Trade Name (if present):
Sanorex

Sponsor Contact Information
Collipp, Platon J M D
176 Memorial Drive
Jesup GA 31545

Date Designated 12/8/1986

Date Approved

Generic Name:
Diethyldithiocarbamate

Designated Indication:
Treatment of AIDS

Trade Name (if present):
Imuthiol

Sponsor Contact Information
Connaught Laboratories
Route 611, P O Box 187
Swiftwater PA 18370

Date Designated 4/3/1986

Date Approved

Generic Name:
Recombinant human relaxin

Designated Indication:
Treatment of progressive systemic sclerosis

Trade Name (if present):

Sponsor Contact Information
Connetics Corporation
3400 West Bayshore Road
Palo Alto CA 94303

Date Designated 11/3/1995

Date Approved

Generic Name:
Tositumomab and iodine I 131 tositumomab

Designated Indication:
Treatment of non-Hodgkin's B-cell lymphoma

Trade Name (if present):
Bexxar

Sponsor Contact Information
Corixa Corporation
1124 Columbia St
Suite 200
Seattle WA 98104

Date Designated 5/16/1994

Date Approved 6/27/2003

Generic Name:
aztreonam

Designated Indication:
Inhalation therapy for control of gram-negative bacteria in the respiratory tract of patients with cystic fibrosis

Trade Name (if present):

Sponsor Contact Information
Corus Pharma
2025 First Ave., Suite 800
Seattle WA 98121

Date Designated 3/12/2002

Date Approved

Generic Name:
heat killed mycobacterium with
immunomodulator

Designated Indication:
Adjuvant to multi-drug therapy in the management of multibacillary leprosy

Trade Name (if present):
CADI Mw

Sponsor Contact Information
CPL, Inc
16020 Swingley Ridge Road
Suite 145
Chesterfield MO 63017

Date Designated 11/21/2002
Date Approved

Generic Name:
Defibrotide

Designated Indication:
Treatment of thrombotic thrombocytopenic purpura

Trade Name (if present):

Sponsor Contact Information
Crinos International
Via Belvedere 1
Villa Guardia, Italy 22079

Date Designated 7/5/1985
Date Approved

Generic Name:
acetylcysteine

Designated Indication:
For the intravenous treatment of moderate to severe acetaminophen overdose

Trade Name (if present):
Acetadote

Sponsor Contact Information
Cumberland Pharmaceuticals, Inc.
209 10th Street South
Suite 332
Nashville TN 37203

Date Designated 10/19/2001
Date Approved 1/23/2004

Generic Name:
Chondrocyte-alginate gel suspension

Designated Indication:
For use in correcting vesicoureteral reflux in the pediatric population

Trade Name (if present):

Sponsor Contact Information
Curis, Inc.
61 Moulton Street
Cambridge MA 02138

Date Designated 12/1/1997
Date Approved

Generic Name:
CY-1503

Designated Indication:
Treatment of neonates and infants undergoing cardiopulmonary bypass during surgical repair of congenital heart lesions.

Trade Name (if present):
Cylexin

Sponsor Contact Information
Cytel Corporation
3525 John Hopkins Court
San Diego CA 92121

Date Designated 7/18/1997
Date Approved

Generic Name:
CY-1503

Designated Indication:

Treatment of post-ischemic pulmonary reperfusion edema following surgical treatment for chronic thromboembolic pulmonary hypertension

Trade Name (if present):
Cylexin

Sponsor Contact Information

Cytel Corporation
3525 John Hopkins Court
San Diego CA 92121

Date Designated 12/22/1993
Date Approved

Generic Name:
CY-1899

Designated Indication:

Treatment of chronic active hepatitis B infection in HLA-A2 positive patients.

Trade Name (if present):

Sponsor Contact Information

Cytel Corporation
3525 John Hopkins Court
San Diego CA 92121

Date Designated 3/16/1994
Date Approved

Generic Name:
Autolymphocyte therapy

Designated Indication:

Treatment of renal cell carcinoma.

Trade Name (if present):

Sponsor Contact Information

Cytogen Corporation
600 College Road East
CN 5308
Princeton NJ 08540-5308

Date Designated 7/12/1994
Date Approved

Generic Name:
Oncorad Ov103

Designated Indication:

Treatment of ovarian cancer.

Trade Name (if present):

Sponsor Contact Information

Cytogen Corporation
600 College Road East
Princeton NJ 08540

Date Designated 4/24/1990
Date Approved

Generic Name:
Satumomab pendetide

Designated Indication:

Detection of ovarian carcinoma.

Trade Name (if present):
Oncoscint CR/OV

Sponsor Contact Information

Cytogen Corporation
600 College Road East
Princeton NJ 08540

Date Designated 9/25/1989
Date Approved 12/29/1992

Generic Name:
L-glutamyl-L-tryptophan

Designated Indication:
Treatment of AIDS-related Kaposi's sarcoma.

Trade Name (if present):

Sponsor Contact Information

Cytran Incorporated
10230 N.E. Points Dr.
Suite 530
Kirkland WA 98033-7869

Date Designated 10/20/1999

Date Approved

Generic Name:
oglufanide disodium

Designated Indication:
Treatment of ovarian cancer

Trade Name (if present):

Sponsor Contact Information

Cytran, Inc.
10230 NE Points Dr., NE
Suite 530
Kirkland WA 98033-7869

Date Designated 9/24/2001

Date Approved

Generic Name:
Poloxamer 188

Designated Indication:
Treatment of vasospasm in subarachnoid hemorrhage patients following surgical repair of a ruptured cerebral aneurysm

Trade Name (if present):

Sponsor Contact Information

CytRx Corporation
154 Technology Parkway
Norcross GA 30092

Date Designated 8/5/1997

Date Approved

Generic Name:
Poloxamer 331

Designated Indication:
Initial therapy of toxoplasmosis in patients with AIDS.

Trade Name (if present):

Protex

Sponsor Contact Information

CytRx Corporation
154 Technology Parkway
Norcross GA 30092

Date Designated 3/21/1991

Date Approved

Generic Name:
Poloxamer 188

Designated Indication:
Treatment of severe burns requiring hospitalization.

Trade Name (if present):

Florcor

Sponsor Contact Information

CytRx Corporation
154 Technology Parkway
Norcross GA 30092

Date Designated 2/22/1990

Date Approved

Generic Name:
Poloxamer 188

Designated Indication:
Treatment of sickle cell crisis

Trade Name (if present):
FloCor

Sponsor Contact Information
CytRx Corporation
154 Technology Parkway
Norcross GA 30092

Date Designated 6/27/1989

Date Approved

Generic Name:
Tetraiodothyroacetic acid

Designated Indication:
Suppression of thyroid stimulating hormone in patients with well-differentiated cancer of the thyroid gland.

Trade Name (if present):

Sponsor Contact Information
Danforth, Jr., MD, Elliot
University of Vermont
84 Beartown Rd.
Underhill VT 05489

Date Designated 5/1/2000

Date Approved

Generic Name:
alteplase

Designated Indication:
Treatment of intraventricular hemorrhage associated with intracerebral hemorrhage

Trade Name (if present):
Activase

Sponsor Contact Information
Daniel F. Hanley, MD
Johns Hopkins University
600 N. Wolfe St., Jefferson 1-109
Baltimore MD 21287

Date Designated 1/27/2003

Date Approved

Generic Name:
Sucralfate suspension

Designated Indication:
Treatment of oral ulcerations and dysphagia in patients with epidermolysis bullosa.

Trade Name (if present):

Sponsor Contact Information
Darby Pharmaceuticals, Inc.
100 Banks Avenue
Rockville Centre NY 11570

Date Designated 3/4/1991

Date Approved

Generic Name:
Sucralfate suspension

Designated Indication:
Treatment of oral complications of chemotherapy in bone marrow transplant patients

Trade Name (if present):

Sponsor Contact Information
Darby Pharmaceuticals, Inc.
100 Banks Avenue
Rockville Centre NY 11570

Date Designated 3/12/1990

Date Approved

Generic Name:
Iodine 131 6B-iodomethyl-19-norcholesterol

Designated Indication:
For use in adrenal cortical imaging

Trade Name (if present):

Date Designated 8/1/1984

Date Approved

Sponsor Contact Information

David E. Kuhl, M.D.
University of Michigan Medical Center/1500 E. Med
B1G412 /0028 University Hospital
Ann Arbor MI 48109-0028

Generic Name:
Oxaliplatin

Designated Indication:
Treatment of ovarian cancer

Trade Name (if present):

Date Designated 10/6/1992

Date Approved

Sponsor Contact Information

Debio Pharm S.A.
Rue des Terreaux 17
Pronova Biocare S.A
CH-1000
SWITZERLAND

Generic Name:
vapeotide

Designated Indication:
Treatment of esophageal variceal hemorrhage patients with portal hypertension.

Trade Name (if present):

Octastatin

Date Designated 1/10/2000

Date Approved

Sponsor Contact Information

Debiopharm S.A.
17 rue des Terreaux
Pronova Biocare S.A.
CH-1000
SWITZERLAND

Generic Name:
vapeotide

Designated Indication:
Treatment of gastrointestinal and pancreatic fistulas.

Trade Name (if present):

Octastatin

Date Designated 1/10/2000

Date Approved

Sponsor Contact Information

Debiopharm S.A.
17 rue des Terreaux
CH-1000 Lausanne 9

SWITZERLAND

Generic Name:
vapeotide

Designated Indication:
Prevention of early postoperative complications following pancreatic resection.

Trade Name (if present):

Octastatin

Date Designated 3/6/2000

Date Approved

Sponsor Contact Information

Debiopharm S.A.
17 rue des Terreaux
CH-1000 Lausanne 9

SWITZERLAND

Generic Name:
ferric hexacyanoferrate (II) "Prussian Blue"

Designated Indication:
Treatment of patients with known or suspected internal contamination with radioactive or non-radioactive cesium or thallium

Trade Name (if present):

Sponsor Contact Information

Degussa AG
Weissfrauenstr.9
D-60287
Frankfurt
GERMANY

Date Designated 6/26/2003

Date Approved

Generic Name:

Mesna

Designated Indication:

For use as a prophylactic agent in reducing the incidence of ifosfamide-induced hemorrhagic cystitis

Trade Name (if present):

Mesnex

Sponsor Contact Information

Degussa Corporation
65 Challenger Road
Ridgefield Park NJ 07660

Date Designated 11/14/1985

Date Approved 12/30/1988

Generic Name:

D-peptide of the sequence AKRHHGYKRKFH - NH₂

Designated Indication:

Treatment of cystic fibrosis

Trade Name (if present):

PulmaDex

Sponsor Contact Information

Demegen, Inc.
100 Technology Drive
Suite 440 B
Pittsburgh PA 15219

Date Designated 10/23/2002

Date Approved

Generic Name:

autologous antigen presenting cells pulsed with autologous tumor Ig idiotype

Designated Indication:

Treatment of multiple myeloma

Trade Name (if present):

Mylovenge

Sponsor Contact Information

Dendreon Corporation
3005 First Avenue
Seattle WA 98121

Date Designated 4/18/2002

Date Approved

Generic Name:

Cytarabine liposomal

Designated Indication:

Treatment of neoplastic meningitis

Trade Name (if present):

DepoCyt

Sponsor Contact Information

DepoTech Corporation
10450 Science Center Drive
San Diego CA 92121

Date Designated 6/2/1993

Date Approved 4/1/1999

Generic Name:
Alpha-galactosidase A

Designated Indication:
Treatment of Fabry's disease

Trade Name (if present):
Fabrase

Date Designated 7/20/1990
Date Approved

Sponsor Contact Information
Desnick, Robert J M.D.
The Mount Sinai School Of Medicine
Fifth Avenue at 100th Street, Box 1203
New York NY 10029

Generic Name:
Pulmonary surfactant replacement, porcine

Designated Indication:
For the treatment and prevention of respiratory distress syndrome in premature infants

Trade Name (if present):
Curosurf

Date Designated 8/2/1993
Date Approved

Sponsor Contact Information
Dey Laboratories
2751 Napa Valley Corporate Drive
Napa CA 94558

Generic Name:
S-adenosylmethionine

Designated Indication:
Treatment of AIDS-myelopathy

Trade Name (if present):

Date Designated 4/30/1998
Date Approved

Sponsor Contact Information
Di Rocco, Alessandro M.D.
Beth Israel Medical Center, Phillips Ambulatory Ca
Philips Building, Suite 2Q, 10 Union Square East
New York NY 10003

Generic Name:
Methionine/L-methionine

Designated Indication:
Treatment of AIDS myelopathy

Trade Name (if present):

Date Designated 8/21/1996
Date Approved

Sponsor Contact Information
Di Rocco, Alessandro M.D.
Beth Israel Medical Center, Phillips Ambulatory Ca
Philips Building, Suite 2R; 10 Union Square East
New York NY 10003

Generic Name:
Porcine fetal neural dopaminergic cells and/or precursors aseptically prepared and coated with anti-MHC-1 Ab for intracerebral implantation

Designated Indication:
Treatment of Hoehn and Yahr stage 4 and 5 Parkinson's disease

Trade Name (if present):
NeuroCell-PD

Date Designated 12/17/1996
Date Approved

Sponsor Contact Information
Diacrin/Genzyme LLC
One Kendall Square
Cambridge MA 02139-1562

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

Designated Indication:
Treatment of Huntington's disease.

Trade Name (if present):
NeuroCell-HD

Sponsor Contact Information
Diacrin/Genzyme LLC
One Kendall Square
Cambridge MA 02129-1562

Date Designated 12/10/1996

Date Approved

Generic Name:
Porcine fetal neural dopaminergic cells and/or
precursors aseptically prepared for intracerebral
implantation.

Designated Indication:
Treatment of Hoehn and Yahr stage 4 and 5 Parkinson's disease

Trade Name (if present):
NeuroCell-PD

Sponsor Contact Information
Diacrin/Genzyme LLC
One Kendall Square
Cambridge MA 02139-1562

Date Designated 12/17/1996

Date Approved

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

Designated Indication:
Treatment of Huntington's disease.

Trade Name (if present):
NeuroCell-HD

Sponsor Contact Information
Diacrin/Genzyme LLC
One Kendall Square
Cambridge MA 02139-1562

Date Designated 12/10/1996

Date Approved

Generic Name:
Intraoral fluoride releasing system

Designated Indication:
Prevention of dental caries due to radiation-induced xerostomia in patients with
head and neck cancer

Trade Name (if present):
IFRS

Sponsor Contact Information
Digestive Care, Inc.
1120 Win Drive
Bethlehem PA 18017

Date Designated 7/31/2001

Date Approved

Generic Name:
Carmustine

Designated Indication:
Treatment of intracranial malignancies.

Trade Name (if present):

Sponsor Contact Information
Direct Therapeutics, Inc.
460 Seaport Court
Suite 220
Redwood CA 94063

Date Designated 7/3/2000

Date Approved

Generic Name:
Disodium clodronate

Designated Indication:
Treatment of hypercalcemia of malignancy

Trade Name (if present):

Sponsor Contact Information
Discovery Experimental & Development, Inc.
29949 S R 54 West
Wesley Chapel FL 33543

Date Designated 6/16/1993

Date Approved

Generic Name:
Lucinactant

Designated Indication:
Treatment of meconium aspiration syndrome in newborn infants.

Trade Name (if present):

Surfaxin

Sponsor Contact Information
Discovery Laboratories, Inc
350 South Main Street
Suite 307
Doylestown PA 18901

Date Designated 7/30/1996

Date Approved

Generic Name:
Lucinactant

Designated Indication:
Treatment of respiratory distress syndrome in premature infants.

Trade Name (if present):

Surfaxin

Sponsor Contact Information
Discovery Laboratories, Inc
350 South Main Street
Suite 307
Doylestown PA 18901

Date Designated 10/18/1995

Date Approved

Generic Name:
Lucinactant

Designated Indication:
Treatment of acute respiratory distress syndrome in adults.

Trade Name (if present):

Surfaxin

Sponsor Contact Information
Discovery Laboratories, Inc.
350 South Main Street
Suite 307
Doylestown PA 18901

Date Designated 7/17/1995

Date Approved

Generic Name:
repertaxin

Designated Indication:
Prevention of delayed graft function in solid organ transplant

Trade Name (if present):

Sponsor Contact Information
Dompe s p a.
Via Campo di Pile
67100 - L'Aquila

Date Designated 1/27/2003

Date Approved

ITALY

Generic Name:
Beta alethine

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):
Betathine

Sponsor Contact Information
Dovetail Technologies, Inc.
Bldg. 337, Paint Branch Drive
College Park MD 20742

Date Designated 3/24/1997
Date Approved

Generic Name:
Beta alethine

Designated Indication:
Treatment of metastatic melanoma.

Trade Name (if present):
Betathine

Sponsor Contact Information
Dovetail Technologies, Inc.
Bldg 337, Paint Branch Drive
College Park MD 20742

Date Designated 3/24/1997
Date Approved

Generic Name:
cholic acid (3 alpha, 7 alpha, 12 alpha trihydroxy
5-beta cholanoic acid)

Designated Indication:
Treatment of inborn errors of cholesterol and bile acid synthesis and metabolism

Trade Name (if present):
Falkochol

Sponsor Contact Information
Dr Falk Pharma GmbH
Leinenweberstrasse 5
Postfach 6529

Date Designated 7/18/2003
Date Approved

GERMANY

Generic Name:
Coumarin

Designated Indication:
Treatment of renal cell carcinoma.

Trade Name (if present):
Onkolox

Sponsor Contact Information
Drossapharm LTD
4002 Basel

Date Designated 12/22/1994
Date Approved

SWITZERLAND

Generic Name:
Pentastarch

Designated Indication:
As an adjunct in leukapheresis to improve the harvesting and increase the yield of leukocytes by centrifugal means.

Trade Name (if present):
Pentaspán

Sponsor Contact Information
Du Pont Pharmaceuticals
E.I Du Pont De Nemours & Co
Wilmington DE 19898

Date Designated 8/28/1985
Date Approved 5/19/1987

Generic Name:
cultured, partially T-Cell depleted, allogenic
thymic tissue for transplantation

Designated Indication:

As a therapy for primary immune deficiency resulting from athymia associated
with complete DiGeorge Syndrome

Trade Name (if present):

Sponsor Contact Information

Duke University Medical Center
Division of Pediatric Allergy & Immunology
Erwin Road
Durham NC 27710

Date Designated 8/15/2003

Date Approved

Generic Name:
Oxymorphone

Designated Indication:

For relief of severe intractable pain in narcotic-tolerant patients.

Trade Name (if present):

Numorphan H.P

Sponsor Contact Information

DuPont Merck Pharmaceutical Company
P.O. Box 80027
Wilmington DE 19880

Date Designated 3/19/1985

Date Approved

Generic Name:
Naltrexone HCl

Designated 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.

Trade Name (if present):

Trexan

Sponsor Contact Information

DuPont Pharmaceuticals
E.I. Du Pont De Nemours & Co.
Wilmington DE 19880

Date Designated 3/11/1985

Date Approved 11/30/1984

Generic Name:
DMP 777

Designated Indication:

Therapeutic management of patients with lung disease attributable to cystic
fibrosis.

Trade Name (if present):

Sponsor Contact Information

DuPont Pharmaceuticals Company
Chestnut Run, Maple Run
Centre Rd.
Wilmington DE 19805

Date Designated 6/4/1996

Date Approved

Generic Name:
Methotrexate with laurocapram

Designated Indication:

Topical treatment of mycosis fungoides.

Trade Name (if present):

Methotrexate/azone

Sponsor Contact Information

Durham Pharmaceuticals LLC
200 Westpark Corporate Center
4364 South Alston Avenue
Durham NC 27713-2280

Date Designated 10/15/1990

Date Approved

Generic Name:
recombinant inhibitor of human plasma
kallikrein

Designated Indication:
Treatment of angioedema

Trade Name (if present):

Sponsor Contact Information

Dyax Corp
300 Technology Square
Cambridge MA 02139

Date Designated 2/4/2003

Date Approved

Generic Name:
recombinant human neutrophil inhibitor (hNE)

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Sponsor Contact Information

Dyax Corporation
300 Technology Square
Cambridge MA 02139

Date Designated 12/9/2003

Date Approved

Generic Name:
Purified extract of *Pseudomonas aeruginosa*

Designated Indication:
Treatment of immune thrombocytopenia purpura where it is required to increase
platelet counts

Trade Name (if present):

ImmuDyn

Sponsor Contact Information

DynaGen, Inc
99 Erie Street
Cambridge MA 02139

Date Designated 9/22/1997

Date Approved

Generic Name:
Patul-end

Designated Indication:
Treatment of patulous eustachian tube

Trade Name (if present):

Sponsor Contact Information

Ear Foundation
2420 Castillo Street, Suite 100
Santa Barbara CA 93105

Date Designated 2/18/1997

Date Approved

Generic Name:
Aminocaproic acid

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

Trade Name (if present):

CaproGel

Sponsor Contact Information

Eastern Virginia Medical School
Department of Ophthalmology
880 Kempsville Road, Suite 2500
Norfolk VA 23502-3990

Date Designated 1/6/1995

Date Approved

Generic Name:
sodium dichloroacetate

Designated Indication:
Use as an antidote in the management of systemic monochloroacetic acid poisoning

Trade Name (if present):

Sponsor Contact Information

EBD Group
6120 Paseo del Norte
Suite J2
Carlsbad CA 92009

Date Designated 7/3/2003
Date Approved

Generic Name:
Phenylbutyrate

Designated Indication:
Treatment of acute promyelocytic leukemia.

Trade Name (if present):

Sponsor Contact Information

Elan Drug Delivery, Inc
1300 Gould Dr
Gainesville GA 30504

Date Designated 1/19/2000
Date Approved

Generic Name:
Phenylacetate

Designated Indication:
For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma

Trade Name (if present):

Sponsor Contact Information

Elan Drug Delivery, Inc.
1300 Gould Dr.
Gainesville GA 30504

Date Designated 3/6/1998
Date Approved

Generic Name:
Sodium phenylbutyrate

Designated Indication:
For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma.

Trade Name (if present):

Sponsor Contact Information

Elan Drug Delivery, Inc
1300 Gould Dr.
Gainesville GA 30504

Date Designated 4/24/1998
Date Approved

Generic Name:
Botulinum toxin type B

Designated Indication:
Treatment of cervical dystonia

Trade Name (if present):
NeuroBloc

Sponsor Contact Information

Elan Pharmaceuticals, Inc
800 Gateway Blvd
South San Francisco CA 94080

Date Designated 1/16/1992
Date Approved 12/8/2000

Generic Name:
Atomoxetine hydrochloride

Designated Indication:
Treatment of Tourette's Syndrome

Trade Name (if present):
STRATTERA

Sponsor Contact Information
ELI LILLY & Company
Lilly Corporate Center
Indianapolis IN 46285

Date Designated 8/26/2003
Date Approved

Generic Name:
pemetrexed disodium

Designated Indication:
Treatment of malignant pleural mesothelioma

Trade Name (if present):
Alimta

Sponsor Contact Information
Eli Lilly and Company
Lilly Corporate Center
Indianapolis IN 46285

Date Designated 8/28/2001
Date Approved 2/4/2004

Generic Name:
Somatropin

Designated Indication:
Treatment of short stature associated with Turner syndrome

Trade Name (if present):
Humatrope

Sponsor Contact Information
Eli Lilly and Company
Lilly Corporate Center
Indianapolis IN 46285

Date Designated 5/8/1990
Date Approved 12/30/1996

Generic Name:
Somatropin for injection

Designated Indication:
For the long-term treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone.

Trade Name (if present):
Humatrope

Sponsor Contact Information
Eli Lilly and Company
Lilly Corporate Center
Indianapolis IN 46285

Date Designated 6/12/1986
Date Approved 3/8/1987

Generic Name:
Morphine sulfate concentrate (preservative free)

Designated Indication:
For use in microinfusion devices for intraspinal administration in the treatment of intractable chronic pain.

Trade Name (if present):
Infumorph

Sponsor Contact Information
Elkins-Sinn, Inc
2 Esterbrook Lane
Cherry Hill NJ 08003

Date Designated 7/12/1990
Date Approved 7/19/1991

Generic Name:
Sodium tetradecyl sulfate

Designated Indication:
Treatment of bleeding esophageal varices

Trade Name (if present):
Sotradecol

Sponsor Contact Information

Elkins-Synn, Inc.
2 Esterbrook Lane
Cherry Hill NJ 08003

Date Designated 6/10/1986
Date Approved

Generic Name:
3,5,3'-triiodothyroacetate

Designated Indication:
Treatment of well-differentiated papillary, follicular or combined
papillary/follicular carcinomas of the thyroid gland

Trade Name (if present):

Sponsor Contact Information

Elliot Danforth, Jr , M.D.
University of Vermont
84 Beartown Road
Underhill VT 05489

Date Designated 9/20/2000
Date Approved

Generic Name:
hydroxocobalamin

Designated Indication:
Treatment of acute cyanide poisoning

Trade Name (if present):
Cyanokit

Sponsor Contact Information

EMD Pharmaceuticals, Inc
P O Box 13319
2311 Shannon Road, Suite 500
Durham NC 27707

Date Designated 11/25/2003
Date Approved

Generic Name:
Technetium Tc 99m pterotetramide

Designated Indication:
For the identification of ovarian carcinomas.

Trade Name (if present):

Sponsor Contact Information

Endocyte, Inc
1205 Kent Ave
West Lafayette IN 47906

Date Designated 2/16/2000
Date Approved

Generic Name:
Liposomal N-Acetylglucosminyl-N-Acetylmuramyl-L-Ala-D-isoGln-L-Ala -
glycerolidpalmitoyl

Designated Indication:
Treatment of Ewing's sarcoma.

Trade Name (if present):
ImmTher

Sponsor Contact Information

Endorex Corp.
900 North Shore Drive
Lake Bluff IL 60044

Date Designated 6/10/1998
Date Approved

Generic Name:
Liposomal N-Acetylglucosminyl-N-Acetylmuramyl-L-Ala-D-isoGln-L-Ala - glycerolidpalmitoyl

Designated Indication:
Treatment of osteosarcoma

Trade Name (if present):
ImmTher

Date Designated 6/10/1998
Date Approved

Sponsor Contact Information
Endorex Corp.
900 North Shore Drive
Lake Bluff IL 60044

Generic Name:
beclomethasone 17,21-dipropionate

Designated Indication:
Prevention of gastrointestinal graft-versus-host disease

Trade Name (if present):

Date Designated 8/28/2001
Date Approved

Sponsor Contact Information
Enteron Pharmaceuticals, Inc.
1680 Michigan Ave
Suite 700
Miami FL 33139

Generic Name:
S(-)-3-[3-amino-phthalimido]-glutaramide

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):

Date Designated 3/14/2002
Date Approved

Sponsor Contact Information
EntreMed Incorporated
9640 Medical Center Dr
Rockville MD 20850

Generic Name:
recombinant human endostatin protein

Designated Indication:
Treatment of metastatic melanoma .

Trade Name (if present):

Date Designated 2/21/2002
Date Approved

Sponsor Contact Information
EntreMed, Inc
9640 Medical Center Drive
Rockville MD 20850

Generic Name:
recombinant human endostatin protein

Designated Indication:
Treatment of neuroendocrine tumors.

Trade Name (if present):

Date Designated 8/13/2001
Date Approved

Sponsor Contact Information
EntreMed, Inc
9640 Medical Center Drive
Rockville MD 20850

Generic Name:
2-methoxyestradiol

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):
Panzem

Sponsor Contact Information

EntreMed, Inc.
9640 Medical Center Drive
Rockville MD 20850

Date Designated 7/10/2001
Date Approved

Generic Name:
Pegaspargase

Designated Indication:
Treatment of acute lymphocytic leukemia

Trade Name (if present):
Oncaspar

Sponsor Contact Information

Enzon, Inc.
20 Kingsbridge Road
Piscataway NJ 08854

Date Designated 10/20/1989
Date Approved 2/1/1994

Generic Name:
Pegademase bovine

Designated Indication:
For enzyme replacement therapy for ADA deficiency in patients with severe combined immunodeficiency.

Trade Name (if present):
Adagen

Sponsor Contact Information

Enzon, Inc.
20 Kingsbridge Road
Piscataway NJ 08854

Date Designated 5/29/1984
Date Approved 3/21/1990

Generic Name:
Sulfadiazine

Designated Indication:
For use in combination with pyrimethamine for the treatment of Toxoplasma gondii encephalitis in patients with and without AIDS.

Trade Name (if present):

Sponsor Contact Information

Eon Labs Manufacturing, Inc.
227-15 North Conduit Avenue
Laurelton NY 11413

Date Designated 3/14/1994
Date Approved 7/29/1994

Generic Name:
Mx-dnG1 or Rexin-G retroviral vector

Designated Indication:
Treatment of pancreatic cancer

Trade Name (if present):
REXIN-G

Sponsor Contact Information

Epeus Biotechnologies Corporation
345 Pioneer Drive, 1803W
Glendale CA 91203

Date Designated 8/15/2003
Date Approved

Generic Name:
Neurotrophin-1

Designated Indication:
Treatment of motor neuron disease/amyotrophic lateral sclerosis

Trade Name (if present):

Sponsor Contact Information

Ericsson, Arthur Dale, M.D.
6560 Fannin, Scurlock Tower, Suite 720
Houston TX 77303

Date Designated 9/13/1994

Date Approved

Generic Name:
Interferon-alfa-1b

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):

Sponsor Contact Information

Ernest C Borden
Center for Cancer Drug Discovery and Development
9500 Euclid Avenue
Cleveland OH 44195

Date Designated 4/17/2001

Date Approved

Generic Name:
Monooctanoïn

Designated Indication:
For dissolution of cholesterol gallstones retained in the common bile duct

Trade Name (if present):

Moctanin

Sponsor Contact Information

Ethitek Pharmaceuticals, Inc.
7855 Gross Point Road, Unit L
Skokie IL 60077

Date Designated 5/30/1984

Date Approved 10/31/1985

Generic Name:
Fluorouracil

Designated Indication:
Treatment of glioblastoma multiforme.

Trade Name (if present):

Sponsor Contact Information

Ethypharm SA
194 Bureaux de la Colline - Batiment D
92213 Saint-Cloud Cedex

Date Designated 6/29/2000

Date Approved

Generic Name:
Bioartificial liver system utilizing xenogenic
hepatocytes in a hollow fiber bioreactor cartridge
(BAL)

Designated Indication:
Treatment of patients with acute liver failure presenting with encephalopathy
deteriorating beyond Parson's grade 2

Trade Name (if present):

Sponsor Contact Information

Excorp Medical, Inc.
Suite 235
7200 Hudson Blvd.
Oakdale MN 55128

Date Designated 2/11/2002

Date Approved

Generic Name:
hyaluronic acid

Designated Indication:
Treatment of emphysema in patients due to alpha-1 antitrypsin deficiency

Trade Name (if present):

Sponsor Contact Information

Exhale Therapeutics, Inc
1301 Shoreway Road
Suite 320
Belmont CA 94002

Date Designated 3/19/2002

Date Approved

Generic Name:
Benzophenone-3, octylmethoxycinnamate,
avobenzone, titanium dioxide, zinc oxide

Designated Indication:
For the prevention of visible light induced skin photosensitivity as a result of
porfimer sodium photodynamic therapy

Trade Name (if present):

Total Block VL SPF 75

Sponsor Contact Information

Fallien Cosmeceuticals Ltd
677 W Dekalb Pike
King of Prussia PA 19406

Date Designated 8/13/2001

Date Approved

Generic Name:
Ibuprofen i.v. solution

Designated Indication:
Prevention of patent ductus arteriosus

Trade Name (if present):

Salprofen

Sponsor Contact Information

Farmacon-IL, LLC
1720 Post Road East
Suite 213
Westport CT 06880-5643

Date Designated 10/29/1996

Date Approved

Generic Name:
Ibuprofen i.v. solution

Designated Indication:
Treatment of patent ductus arteriosus

Trade Name (if present):

Sponsor Contact Information

Farmacon-IL-LLC
1720 Post Road East
Suite 213
Westport CT 06880-5643

Date Designated 10/29/1996

Date Approved

Generic Name:
NG-29

Designated Indication:
Diagnostic measure of the capacity of the pituitary gland to release growth
hormone

Trade Name (if present):

Somatrel

Sponsor Contact Information

Ferring Laboratories, Inc.
400 Rella Boulevard, Suite 201
Suffern NY 10901

Date Designated 8/8/1989

Date Approved

Generic Name:
Corticotropin ovine tetracetate

Designated Indication:
For use in differentiating pituitary and ectopic production of ACTH in patients with ACTH-dependent Cushing's syndrome.

Trade Name (if present):
Actrel

Sponsor Contact Information
Ferring Laboratories, Inc
400 Rella Boulevard, Suite 201
Suffern NY 10901

Date Designated 11/24/1989
Date Approved 5/23/1996

Generic Name:
Somatostatin

Designated Indication:
Adjunct to the non-operative management of secreting cutaneous fistulas of the stomach, duodenum, small intestine (jejunum and ileum), or pancreas.

Trade Name (if present):
Zinc

Sponsor Contact Information
Ferring Laboratories, Inc
400 Rella Boulevard, Suite 201
Suffern NY 10901

Date Designated 6/20/1988
Date Approved

Generic Name:
Gonadorelin acetate

Designated 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.

Trade Name (if present):
Lutrepulse

Sponsor Contact Information
Ferring Laboratories, Inc
400 Rella Boulevard, Suite 201
Suffern NY 10901

Date Designated 4/22/1987
Date Approved 10/10/1989

Generic Name:
Terlipressin

Designated Indication:
Treatment of bleeding esophageal varices.

Trade Name (if present):
Glypressin

Sponsor Contact Information
Ferring Laboratories, Inc.
400 Rella Boulevard, Suite 201
Suffern NY 10901

Date Designated 3/6/1986
Date Approved

Generic Name:
MTC-DOX for Injection

Designated Indication:
Treatment of hepatocellular carcinoma

Trade Name (if present):

Sponsor Contact Information
FeRx Incorporated
4330 La Jolla Village Drive
Suite #250
San Diego CA 92122

Date Designated 1/3/2001
Date Approved

Generic Name:
Pentamidine isethionate (inhalation)

Designated Indication:
Prevention of Pneumocystis carinii pneumonia in patients at high risk of developing this disease.

Trade Name (if present):
Pneumopent

Sponsor Contact Information
Fisons Corporation
755 Jefferson Rd , P O Box 1710
Rochester NY 14603

Date Designated 10/5/1987
Date Approved

Generic Name:
Cromolyn sodium 4% ophthalmic solution

Designated Indication:
Treatment of vernal keratoconjunctivitis

Trade Name (if present):
Opticrom 4% ophthalmic solution

Sponsor Contact Information
Fisons Corporation
755 Jefferson Rd
P O Box 1710
Rochester NY 14603

Date Designated 7/24/1985
Date Approved 10/3/1984

Generic Name:
Cromolyn sodium

Designated Indication:
Treatment of mastocytosis.

Trade Name (if present):
Gastrocrom

Sponsor Contact Information
Fisons Corporation
755 Jefferson Rd
P O Box 1710
Rochester NY 14603

Date Designated 3/8/1984
Date Approved 12/22/1989

Generic Name:
Nifedipine

Designated Indication:
Treatment of interstitial cystitis

Trade Name (if present):

Sponsor Contact Information
Fleischmann, Jonathan M.D
MetroHealth Medical Center
3395 Scranton Road
Cleveland OH 44109

Date Designated 6/13/1991
Date Approved

Generic Name:
Dipalmitoylphosphatidylcholine
/phosphatidylglycerol

Designated Indication:
Prevention and treatment of neonatal respiratory distress syndrome.

Trade Name (if present):
ALEC

Sponsor Contact Information
Forum Products, Inc.
33 Flying Point Road
Southampton NY 11968

Date Designated 7/28/1988
Date Approved

Generic Name:
L-baclofen

Designated Indication:
Treatment of trigeminal neuralgia

Trade Name (if present):

Sponsor Contact Information

Fromm, Gerhard M.D
University Of Pittsburgh School of Medicine
Pittsburgh PA 15261

Date Designated 7/13/1990

Date Approved

Generic Name:
Lactic acid

Designated Indication:
Treatment of severe aphthous stomatitis in severely, terminally immunocompromised patients

Trade Name (if present):

Aphthaid

Sponsor Contact Information

Frontier Pharmaceutical, Inc.
SUNY Farmingdale
Conklin Hall
Farmingdale NY 11735

Date Designated 6/29/1999

Date Approved

Generic Name:
Tacrolimus

Designated Indication:
Prophylaxis of graft-versus-host-disease

Trade Name (if present):

Prograf

Sponsor Contact Information

Fujisawa USA, Inc.
3 Parkway North Center
Deerfield IL 60015

Date Designated 4/6/1998

Date Approved

Generic Name:
Liposomal amphotericin B

Designated Indication:
Treatment of cryptococcal meningitis

Trade Name (if present):

AmBisome

Sponsor Contact Information

Fujisawa USA, Inc
3 Parkway North Center
Deerfield IL 60015

Date Designated 12/10/1996

Date Approved 8/11/1997

Generic Name:
Liposomal amphotericin B

Designated Indication:
Treatment of visceral leishmaniasis.

Trade Name (if present):

AmBisome

Sponsor Contact Information

Fujisawa USA, Inc
3 Parkway North Center
Deerfield IL 60015

Date Designated 12/6/1996

Date Approved 8/11/1997

Generic Name:
Liposomal amphotericin B

Designated Indication:
Treatment of histoplasmosis

Trade Name (if present):
AmBisome

Sponsor Contact Information

Fujisawa USA, Inc.
3 Parkway North Center
Deerfield IL 60015

Date Designated 12/10/1996
Date Approved

Generic Name:
Pentamidine isethionate

Designated Indication:
Prevention of Pneumocystis carinii pneumonia in patients at high risk of developing this disease

Trade Name (if present):
NebuPent

Sponsor Contact Information

Fujisawa USA, Inc.
3 Parkway North Center
Deerfield IL 60015

Date Designated 1/12/1988
Date Approved 6/15/1989

Generic Name:
Pentamidine isethionate

Designated Indication:
Treatment of Pneumocystis carinii pneumonia

Trade Name (if present):
Pentam 300

Sponsor Contact Information

Fujisawa USA, Inc.
3 Parkway North Center
Deerfield IL 60015

Date Designated 2/28/1984
Date Approved 10/16/1984

Generic Name:
Bovine immunoglobulin concentrate,
Cryptosporidium parvum

Designated Indication:
Treatment and symptomatic relief of Cryptosporidium parvum infection of the gastrointestinal tract in immunocompromised patients.

Trade Name (if present):
Sporidm-G

Sponsor Contact Information

GalaGen, Inc
4001 Lexington Avenue North
Arden Hills MN 55126

Date Designated 3/1/1994
Date Approved

Generic Name:
Metronidazole

Designated Indication:
Treatment of perioral dermatitis

Trade Name (if present):
Metrogel

Sponsor Contact Information

Galderma Laboratories, Inc.
P O Box 331329
Fort Worth TX 76163

Date Designated 10/24/1991
Date Approved

Generic Name:
Metronidazole (topical)

Designated Indication:
Treatment of acne rosacea

Trade Name (if present):
Metrogel

Sponsor Contact Information
Galderma Laboratories, Inc
P O Box 331329
Fort Worth TX 76163

Date Designated 10/22/1987

Date Approved 11/22/1988

Generic Name:
N-acetylcysteinate Lysine

Designated Indication:
For the management of cystic fibrosis

Trade Name (if present):
Nacystelyn Dry Powder Inhaler

Sponsor Contact Information
Galephar Pharmaceutical Research, Inc.
Road 198, No. 100 km. 14 7
Juncos Industrial Park
Juncos UN 00777-3873
PUERTO RICO

Date Designated 12/27/2000

Date Approved

Generic Name:
Ubiquinone

Designated Indication:
Treatment of mitochondrial cytopathies.

Trade Name (if present):
Ubr-Q-Gel

Sponsor Contact Information
Gel-Tec, Division of Tishcon Corp
30 New York Ave
PO Box 331
Westbury NY 11590

Date Designated 12/14/1999

Date Approved

Generic Name:
squalamine lactate

Designated Indication:
Treatment of ovarian cancer refractory or resistant to standard chemotherapy

Trade Name (if present):

Sponsor Contact Information
Genaera Corporation
5110 Campus Drive
Plymouth Meeting PA 19462

Date Designated 5/11/2001

Date Approved

Generic Name:
Dehydroepiandrosterone

Designated Indication:
Treatment of systemic lupus erythematosus (SLE) and the reduction in the use of
steroids in steroid-dependent SLE patients

Trade Name (if present):

Sponsor Contact Information
Genelabs Technologies, Inc.
505 Penobscot Drive
Redwood City CA 94063

Date Designated 7/13/1994

Date Approved

Generic Name:
erlotinib Hydrochloride

Designated Indication:
Treatment of malignant gliomas

Trade Name (if present):
Tarceva

Sponsor Contact Information
Genentech, Inc
1 DNA Way
South San Francisco CA 94080-4990

Date Designated 7/18/2003
Date Approved

Generic Name:
rituximab

Designated Indication:
Treatment of immune thrombocytopenic purpura

Trade Name (if present):
Rituxan

Sponsor Contact Information
Genentech, Inc
1 DNA Way
South San Francisco CA 94080-4990

Date Designated 3/12/2002
Date Approved

Generic Name:
Trastuzumab

Designated Indication:
Treatment of patients with pancreatic cancer that overexpress p185HER2.

Trade Name (if present):
Herceptin

Sponsor Contact Information
Genentech, Inc.
1 DNA Way
South San Francisco CA 94080-4990

Date Designated 12/14/1999
Date Approved

Generic Name:
Somatropin (rDNA origin)

Designated Indication:
Long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion

Trade Name (if present):
Nutropin Depot

Sponsor Contact Information
Genentech, Inc
1 DNA Way
South San Francisco CA 94080-4990

Date Designated 10/28/1999
Date Approved

Generic Name:
Recombinant human nerve growth factor

Designated Indication:
Treatment of HIV-associated sensory neuropathy

Trade Name (if present):

Sponsor Contact Information
Genentech, Inc.
1 DNA Way
South San Francisco CA 94080

Date Designated 4/16/1999
Date Approved

Generic Name:
Recombinant human thrombopoietin

Designated Indication:
For use in accelerating platelet recovery in patients undergoing hematopoietic stem cell transplantation.

Trade Name (if present):

Sponsor Contact Information
Genentech, Inc
1 DNA Way
South San Francisco CA 94080-4990

Date Designated 9/29/1997
Date Approved

Generic Name:
Somatropin for injection

Designated Indication:
As replacement therapy for growth hormone deficiency in adults after epiphyseal closure

Trade Name (if present):
Nutropin

Sponsor Contact Information
Genentech, Inc.
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 11/18/1996
Date Approved 12/15/1997

Generic Name:
Interferon gamma-1b

Designated Indication:
Treatment of renal cell carcinoma

Trade Name (if present):
Actimmune

Sponsor Contact Information
Genentech, Inc.
1 DNA Way
South San Francisco CA 94080-4990

Date Designated 12/4/1995
Date Approved

Generic Name:
Mecasermin

Designated Indication:
Treatment of growth hormone insufficiency syndrome

Trade Name (if present):

Sponsor Contact Information
Genentech, Inc.
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 12/12/1995
Date Approved

Generic Name:
Dornase alfa

Designated Indication:
To reduce mucous viscosity and enable the clearance of airway secretions in patients with cystic fibrosis

Trade Name (if present):
Pulmozyme

Sponsor Contact Information
Genentech, Inc.
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 1/16/1991
Date Approved 12/30/1993

Generic Name:
Recombinant human CD4 immunoglobulin G

Designated Indication:
Treatment of AIDS resulting from infection with HIV-1

Trade Name (if present):

Sponsor Contact Information

Genentech, Inc
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 8/30/1990

Date Approved

Generic Name:
Recombinant soluble human CD4 (rCD4)

Designated Indication:
Treatment of AIDS in patients infected with HIV virus

Trade Name (if present):

Sponsor Contact Information

Genentech, Inc.
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 3/23/1989

Date Approved

Generic Name:
Somatropin for injection

Designated Indication:
Treatment of growth retardation associated with chronic renal failure.

Trade Name (if present):

Nutropin

Sponsor Contact Information

Genentech, Inc.
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 8/4/1989

Date Approved 11/17/1993

Generic Name:
Somatropin

Designated Indication:
For use in the long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion

Trade Name (if present):

Nutropin

Sponsor Contact Information

Genentech, Inc
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 3/6/1987

Date Approved 10/17/1985

Generic Name:
Somatropin for injection

Designated Indication:
Treatment of short stature associated with Turner's syndrome

Trade Name (if present):

Nutropin

Sponsor Contact Information

Genentech, Inc.
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 3/23/1989

Date Approved 12/30/1996

Generic Name:
Somatrem for injection

Designated Indication:
For long-term treatment of children who have growth failure due to a lack of adequate endogenous growth hormone secretion

Trade Name (if present):
Protropin

Sponsor Contact Information
Genentech, Inc
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 12/9/1985
Date Approved 10/17/1985

Generic Name:
Somatrem for injection

Designated Indication:
Treatment of short stature associated with Turner's syndrome.

Trade Name (if present):
Protropin

Sponsor Contact Information
Genentech, Inc.
460 Point San Bruno Boulevard
South San Francisco CA 94080

Date Designated 12/9/1985
Date Approved

Generic Name:
rhuMAb VEGF[bevacizumab])

Designated Indication:
Treatment of renal cell carcinoma

Trade Name (if present):
Avastin

Sponsor Contact Information
Genentech, Inc.
1 DNA Way
South San Francisco CA 94080-4990

Date Designated 11/6/2003
Date Approved

Generic Name:
Recombinant retroviral vector -
glucocerebrosidase

Designated Indication:
For use as enzyme replacement therapy for patients with types I, II, or III Gaucher disease.

Trade Name (if present):

Sponsor Contact Information
Genetic Therapy, Inc.
938 Clopper Road
Gaithersburg MD 20878

Date Designated 11/15/1993
Date Approved

Generic Name:
Cystic fibrosis transmembrane conductance
regulator gene

Designated Indication:
Treatment of cystic fibrosis.

Trade Name (if present):

Sponsor Contact Information
Genetic Therapy, Inc.
938 Clopper Road
Gaithersburg MD 20878

Date Designated 1/8/1993
Date Approved

Generic Name:
Herpes simplex virus gene

Designated Indication:
Treatment of primary and metastatic brain tumors.

Trade Name (if present):

Sponsor Contact Information
Genetic Therapy, Inc
938 Clopper Road
Gaithersburg MD 20878

Date Designated 10/16/1992
Date Approved

Generic Name:
Recombinant human interleukin-12

Designated Indication:
Treatment of renal cell carcinoma.

Trade Name (if present):

Sponsor Contact Information
Genetics Institute, Inc.
87 CambridgePark Drive
Cambridge MA 02140

Date Designated 10/20/1997
Date Approved

Generic Name:
Oprelvekin

Designated Indication:
Prevention of severe chemotherapy-induced thrombocytopenia.

Trade Name (if present):
Neumega

Sponsor Contact Information
Genetics Institute, Inc.
87 Cambridge Park Drive
Cambridge MA 02140

Date Designated 12/17/1996
Date Approved 11/25/1997

Generic Name:
Antihemophilic factor (recombinant)

Designated 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).

Trade Name (if present):
ReFacto

Sponsor Contact Information
Genetics Institute, Inc
87 CambridgePark Drive
Cambridge MA 02140

Date Designated 2/8/1996
Date Approved

Generic Name:
Coagulation Factor IX (recombinant)

Designated Indication:
Treatment of hemophilia B.

Trade Name (if present):
BeneFix

Sponsor Contact Information
Genetics Institute, Inc.
87 Cambridge Park Drive
Cambridge MA 02140

Date Designated 10/3/1994
Date Approved 2/11/1997

Generic Name:
Bleomycin

Designated Indication:
Treatment of pancreatic cancer

Trade Name (if present):
Blenoxane

Sponsor Contact Information
Genetronics, Inc
11199 Sorrento Valley Rd.
San Diego CA 92121-1334

Date Designated 2/9/1999

Date Approved

Generic Name:
MaxAdFVIII

Designated Indication:
Treatment of Hemophilia A

Trade Name (if present):

Sponsor Contact Information
GenStar Therapeutics Corporation
10865 Altman Row
Suite 200
San Diego CA 92121-1113

Date Designated 3/3/2003

Date Approved

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

Designated Indication:
Treatment of hemophilia A.

Trade Name (if present):
MimAdFVIII

Sponsor Contact Information
GenStar Therapeutics Corporation
10835 Altman Row
Suite 150
San Diego CA 92121

Date Designated 12/15/1999

Date Approved

Generic Name:
augmerosen

Designated Indication:
Treatment of chronic lymphocytic leukemia

Trade Name (if present):
Genasense

Sponsor Contact Information
Genta Incorporated
Two Oak Way
Berkeley Heights NJ 07922

Date Designated 8/28/2001

Date Approved

Generic Name:
augmerosen

Designated Indication:
Treatment of multiple myeloma

Trade Name (if present):
Genasense

Sponsor Contact Information
Genta Incorporated
Two Oak Way
Berkeley Heights NJ 07922

Date Designated 8/28/2001

Date Approved

Generic Name:
augmerosen

Designated Indication:
Treatment of acute myelocytic leukemia

Trade Name (if present):
Genasense

Sponsor Contact Information
Genta Incorporated
Two Oak Way
Berkeley Heights NJ 07922

Date Designated 8/28/2001
Date Approved

Generic Name:
oblimersen

Designated Indication:
Treatment of advanced malignant melanoma (Stages II,III, IV)

Trade Name (if present):
Genasense

Sponsor Contact Information
Genta, Inc
99 Hayden Ave., Suite 200
Lexington MA 02421-7966

Date Designated 7/31/2000
Date Approved

Generic Name:
Defibrotide

Designated Indication:
For the treatment of hepatic veno-occlusive disease

Trade Name (if present):

Sponsor Contact Information
Gentium SpA
Piazza XX Settembre, 2
22079 Villa Guardia (CO)

Date Designated 5/21/2003
Date Approved

ITALY

Generic Name:
Cystic fibrosis Tr gene therapy (recombinant adenovirus)

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):
AdGVCFTFTR.10

Sponsor Contact Information
GenVec, Inc.
12111 Parklawn Drive
Rockville MD 20852

Date Designated 3/9/1995
Date Approved

Generic Name:
human anti-transforming growth factor beta 1 monoclonal antibody

Designated Indication:
Treatment of systemic sclerosis

Trade Name (if present):

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139

Date Designated 1/11/2002
Date Approved

Generic Name:
Thyrotropin alfa

Designated Indication:
Treatment of well-differentiated papillary, follicular or combined papillary/follicular carcinomas of the thyroid

Trade Name (if present):
Thyrogen

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139-1562

Date Designated 8/3/2001
Date Approved

Generic Name: Anti-thymocyte Globulin (Rabbitt) **Designated Indication:** Treatment of myelodysplastic syndrome (MDS)

Trade Name (if present):
Thymoglobulin

Sponsor Contact Information
Genzyme Corporation
500 Kendall Street
Cambridge MA 02142

Date Designated 9/6/2000
Date Approved

Generic Name: Acid sphingomyelinase **Designated Indication:** Treatment of Niemann-Pick disease type B

Trade Name (if present):

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139

Date Designated 8/3/2000
Date Approved

Generic Name: Recombinant human acid alpha-glucosidase **Designated Indication:** Treatment of glycogen storage disease type II.

Trade Name (if present):

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139

Date Designated 8/19/1997
Date Approved

Generic Name: Gp100 adenoviral gene therapy **Designated Indication:** Treatment of metastatic melanoma.

Trade Name (if present):

Sponsor Contact Information
Genzyme Corporation
One Mountain Rd.
P.O. Box 9322
Framingham MA 01701-9322

Date Designated 3/25/1997
Date Approved

Generic Name:
MART-1 adenoviral gene therapy for malignant melanoma

Designated Indication:
Treatment of metastatic melanoma.

Trade Name (if present):

Sponsor Contact Information
Genzyme Corporation
One Mountain Road
P O. Box 9322
Framingham MA 01701-9322

Date Designated 3/28/1997
Date Approved

Generic Name:
Retroviral vector, R-GC and GC gene 1750

Designated Indication:
Treatment of Gaucher disease

Trade Name (if present):

Sponsor Contact Information
Genzyme Corporation
One Mountain Road
P.O. Box 9322
Framingham MA 01701-9322

Date Designated 5/6/1997
Date Approved

Generic Name:
Aglucerase injection

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

Trade Name (if present):
Ceredase

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139-1562

Date Designated 7/21/1995
Date Approved

Generic Name:
Lipid/DNA human cystic fibrosis gene

Designated Indication:
Treatment of cystic fibrosis

Trade Name (if present):

Sponsor Contact Information
Genzyme Corporation
One Mountain Road
P O Box 9322
Framungham MA 01701-9322

Date Designated 4/8/1996
Date Approved

Generic Name:
Cystic fibrosis gene therapy

Designated Indication:
Treatment of cystic fibrosis.

Trade Name (if present):

Sponsor Contact Information
Genzyme Corporation
One Mountain Rd.
P O. Box 9322
Framingham MA 01701-9322

Date Designated 6/30/1992
Date Approved

Generic Name:
Ananain, comosain

Designated Indication:
For the enzymatic debridement of severe burns

Trade Name (if present):
Vianain

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139

Date Designated 1/21/1992
Date Approved

Generic Name:
Thyrotropin alpha

Designated Indication:
As an adjunct in the diagnosis of thyroid cancer

Trade Name (if present):
Thyrogen

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139

Date Designated 2/24/1992
Date Approved 11/30/1998

Generic Name:
Imiglucerase

Designated Indication:
Replacement therapy in patients with types I, II, and III Gaucher's disease.

Trade Name (if present):
Cerezyme

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139-1562

Date Designated 11/5/1991
Date Approved 5/23/1994

Generic Name:
Ceramide trihexosidase/alpha-galactosidase A

Designated Indication:
Treatment of Fabry's disease.

Trade Name (if present):
Fabrazyme

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139-1562

Date Designated 1/19/1988
Date Approved 4/24/2003

Generic Name:
Alglucerase injection

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

Trade Name (if present):
Ceredase

Sponsor Contact Information
Genzyme Corporation
One Kendall Square
Cambridge MA 02139-1562

Date Designated 3/11/1985
Date Approved 4/5/1991

Generic Name:
Beclomethasone dipropionate

Designated Indication:
For oral administration in the treatment of intestinal graft-versus-host disease.

Trade Name (if present):

Sponsor Contact Information

George B. McDonald, M.D.
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North (SC-113), PO Box 19024
Seattle WA 98109

Date Designated 3/27/1998
Date Approved

Generic Name:
Monolaurin

Designated Indication:
Treatment of congenital primary ichthyosis

Trade Name (if present):
Glylorin

Sponsor Contact Information

Glaxo Wellcome Inc.
5 Moore Drive
PO Box 13398
Research Triangle Park NC 27709

Date Designated 4/29/1993
Date Approved

Generic Name:
Atovaquone

Designated Indication:
Treatment and suppression of Toxoplasma gondii encephalitis

Trade Name (if present):
Mepron

Sponsor Contact Information

Glaxo Wellcome Inc.
5 Moore Drive
PO Box 13398
Research Triangle Park NC 27709-3398

Date Designated 3/16/1993
Date Approved

Generic Name:
Atovaquone

Designated Indication:
Primary prophylaxis of HIV-infected persons at high risk for developing Toxoplasma gondii encephalitis.

Trade Name (if present):
Mepron

Sponsor Contact Information

Glaxo Wellcome Inc.
5 Moore Drive
PO Box 13398
Research Triangle Park NC 27709

Date Designated 3/16/1993
Date Approved

Generic Name:
Melfalan

Designated Indication:
Treatment of patients with multiple myeloma for whom oral therapy is inappropriate.

Trade Name (if present):
Alkeran For Injection

Sponsor Contact Information

Glaxo Wellcome Inc.
5 Moore Drive
Research Triangle Park NC 27709

Date Designated 2/24/1992
Date Approved 11/18/1992

Generic Name:
Atovaquone

Designated Indication:
Treatment of AIDS associated Pneumocystis Carinii Pneumonia

Trade Name (if present):
Mepron

Sponsor Contact Information
Glaxo Wellcome Inc.
5 Moore Drive
Research Triangle Park NC 27709

Date Designated 9/10/1990
Date Approved 11/25/1992

Generic Name:
Colfosceril palmitate, cetyl alcohol, tyloxapol

Designated Indication:
Prevention of hyaline membrane disease, also known as respiratory distress syndrome, in infants born at 32 weeks gestation or less.

Trade Name (if present):
Exosurf Neonatal for Intratracheal

Sponsor Contact Information
Glaxo Wellcome Inc
5 Moore Drive
Research Triangle Park NC 27709

Date Designated 10/20/1989
Date Approved 8/2/1990

Generic Name:
Colfosceril palmitate, cetyl alcohol, tyloxapol

Designated Indication:
Treatment of established hyaline membrane disease at all gestational ages.

Trade Name (if present):
Exosurf Neonatal for Intratracheal

Sponsor Contact Information
Glaxo Wellcome Inc.
5 Moore Drive
Research Triangle Park NC 27709

Date Designated 10/20/1989
Date Approved 8/2/1990

Generic Name:
Zidovudine

Designated Indication:
Treatment of AIDS related complex.

Trade Name (if present):
Retrovir

Sponsor Contact Information
Glaxo Wellcome Inc.
5 Moore Drive
Research Triangle Park NC 27709

Date Designated 5/12/1987
Date Approved 3/19/1987

Generic Name:
Zidovudine

Designated Indication:
Treatment of AIDS.

Trade Name (if present):
Retrovir

Sponsor Contact Information
Glaxo Wellcome Inc
5 Moore Drive
Research Triangle Park NC 27709

Date Designated 7/17/1985
Date Approved 3/19/1987

Generic Name:
Epoprostenol

Designated Indication:
Treatment of primary pulmonary hypertension.

Trade Name (if present):
Flolan

Sponsor Contact Information
Glaxo Wellcome Inc
5 Moore Drive
Research Triangle Park NC 27709

Date Designated 9/25/1985
Date Approved 9/20/1995

Generic Name:
Digoxin immune FAB (Ovine)

Designated Indication:
Treatment of potentially life threatening digitalis intoxication in patients who are refractory to management by conventional therapy

Trade Name (if present):
Digibind

Sponsor Contact Information
Glaxo Wellcome Inc
5 Moore Drive
Research Triangle Park NC 27709

Date Designated 11/1/1984
Date Approved 4/22/1986

Generic Name:
Lamotrigine

Designated Indication:
Treatment of Lennox-Gastaut syndrome

Trade Name (if present):
Lamictal

Sponsor Contact Information
Glaxo Wellcome Research and Development
5 Moore Drive
P.O. Box 13398
Research Triangle Park NC 27709

Date Designated 8/23/1995
Date Approved 8/24/1998

Generic Name:
Atovaquone

Designated Indication:
Prevention of Pneumocystis carinii pneumonia (PCP) in high-risk, HIV-infected patients defined by a history of one or more episodes of PCP and/or a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to 200/mm3

Trade Name (if present):
Mepron

Sponsor Contact Information
Glaxo Wellcome Research and Development
5 Moore Drive
PO Box 13398
Research Triangle Park NC 27709

Date Designated 8/14/1991
Date Approved 1/5/1999

Generic Name:
506U78

Designated Indication:
Treatment of chronic lymphocytic leukemia.

Trade Name (if present):

Sponsor Contact Information
GlaxoSmithKline
Five Moore Dr.
P.O. Box 13398
Research Triangle Park NC 27709-3398

Date Designated 9/2/1999
Date Approved

Generic Name:
Epoprostenol

Designated Indication:
Treatment of secondary pulmonary hypertension due to intrinsic precapillary pulmonary vascular disease.

Trade Name (if present):
Flolan

Sponsor Contact Information
GlaxoSmithKline
Five Moore Dr.
PO Box 13398
Research Triangle Park NC 27709-3398

Date Designated 3/22/1999
Date Approved 4/14/2000

Generic Name:
Colfosceril palmitate, cetyl alcohol, tyloxapol

Designated Indication:
Treatment of adult respiratory distress syndrome.

Trade Name (if present):
Exosurf

Sponsor Contact Information
GlaxoSmithKline
5 Moore Drive
P O. Box 13398
Research Triangle Park NC 27709

Date Designated 1/11/1993
Date Approved

Generic Name:
Matrix metalloproteinase inhibitor

Designated Indication:
Treatment of corneal ulcers

Trade Name (if present):
Galarin

Sponsor Contact Information
Glycomed, Inc
860 Atlantic Avenue
Alameda CA 94501

Date Designated 12/5/1991
Date Approved

Generic Name:
bryostatin-1

Designated Indication:
For use in combination with paclitaxel in the treatment of esophageal cancer

Trade Name (if present):

Sponsor Contact Information
GPC Biotech, Inc.
610 Lincoln Street
Waltham MA 02451

Date Designated 12/3/2001
Date Approved

Generic Name:
2'-deoxycytidine

Designated Indication:
As a host-protective agent in the treatment of acute myelogenous leukemia.

Trade Name (if present):

Sponsor Contact Information
Grant, Steven M.D.
Massey Cancer Center, VCU
P.O. Box 980230
Richmond VA 23298-0230

Date Designated 9/9/1996
Date Approved

Generic Name:
Recombinant human insulin-like growth factor-I

Designated 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.

Trade Name (if present):
PV802

Sponsor Contact Information
GroPep Pty Ltd.
Gate 11, Victoria Dr
Adelaide SA 5000

Date Designated 2/16/2000
Date Approved

AUSTRALIA

Generic Name:
Polifeprosan 20 with carmustine

Designated Indication:
Treatment of malignant glioma.

Trade Name (if present):
Gliadel

Sponsor Contact Information
Guilford Pharmaceuticals, Inc
6611 Tributary Street
Baltimore MD 21224

Date Designated 12/13/1989
Date Approved 9/23/1996

Generic Name:
vapeotide

Designated Indication:
For the treatment of acromegaly

Trade Name (if present):
Sanvar

Sponsor Contact Information
H3 Pharma, Inc.
666 Sherbrooke Street West, Suite 1400
Montreal, Quebec

Date Designated 11/4/2003
Date Approved

Generic Name:
SC-1 monoclonal antibody

Designated Indication:
Treatment of patients with CD55 (sc-1) positive gastric tumors

Trade Name (if present):

Sponsor Contact Information
H3 Pharma, Inc
666 Sherbrooke Street West, Suite 1400
Montreal, Quebec

Date Designated 11/12/2003
Date Approved

Generic Name:
Tretinoin

Designated Indication:
Treatment of squamous metaplasia of the ocular surface epithelia (conjunctiva and/or cornea) with mucous deficiency and keratinization.

Trade Name (if present):

Sponsor Contact Information
Hannan Ophthalmic Marketing Services, Inc
34 Sherrill Rd.
Marshfield MA 02050

Date Designated 4/15/1985
Date Approved

Generic Name:
Bovine colostrum

Designated Indication:
Treatment of AIDS-related diarrhea.

Trade Name (if present):

Sponsor Contact Information

Hastings, Donald DVM
1030 North Parkview Drive
Bismarck ND 58501

Date Designated 11/19/1990

Date Approved

Generic Name:
recombinant human porphobilinogen deaminase

Designated Indication:
Treatment of acute intermittent porphyria attacks

Trade Name (if present):

Porphozyme

Sponsor Contact Information

HemeBiotech A/S
Roskildevej 12C
3400 Hillerod

Date Designated 9/9/2002

Date Approved

DENMARK

Generic Name:
recombinant human porphobilinogen deaminase,
erythropoietic form

Designated Indication:
Treatment of acute intermittent porphyria preventing attacks

Trade Name (if present):

Sponsor Contact Information

HemeBiotech A/S
Roskildevej 12C
3400 Hillerod

Date Designated 7/11/2002

Date Approved

DENMARK

Generic Name:
Poly I: poly C12U

Designated Indication:
Treatment of invasive metastatic melanoma (stage IIb, III, IV).

Trade Name (if present):

Ampligen

Sponsor Contact Information

Hemispherx Biopharma, Inc.
One Penn Center
1617 JFK Boulevard
Philadelphia PA 19103

Date Designated 12/9/1993

Date Approved

Generic Name:
Poly I: poly C12U

Designated Indication:
Treatment of chronic fatigue syndrome.

Trade Name (if present):

Ampligen

Sponsor Contact Information

Hemispherx Biopharma, Inc.
One Penn Center
1617 JFK Boulevard
Philadelphia PA 19103

Date Designated 12/9/1993

Date Approved

Generic Name:
Poly I: poly C12U

Designated Indication:
Treatment of renal cell carcinoma

Trade Name (if present):
Amphigen

Date Designated 5/20/1991
Date Approved

Sponsor Contact Information
Hemispherx Biopharma, Inc
One Penn Center
1617 JFK Boulevard
Philadelphia PA 19103

Generic Name:
Poly I: poly C12U

Designated Indication:
Treatment of AIDS.

Trade Name (if present):
Amphigen

Date Designated 7/19/1988
Date Approved

Sponsor Contact Information
Hemispherx Biopharma, Inc.
One Penn Center
1617 JFK Boulevard
Philadelphia PA 19103

Generic Name:
Trisodium citrate concentration

Designated Indication:
For use in leukapheresis procedures.

Trade Name (if present):
Hemocitrate

Date Designated 6/15/1995
Date Approved

Sponsor Contact Information
Hemotec Medical Products, Inc.
Box 19255
Johnston RI 02919

Generic Name:
Teriparatide

Designated Indication:
Treatment of idiopathic osteoporosis.

Trade Name (if present):
Parathar

Date Designated 10/28/1999
Date Approved

Sponsor Contact Information
Henri Beaufour Institute USA, Inc.
27 Maple St.
Milford MA 01757

Generic Name:
iron(III)-hexacyanoferrate(II)

Designated Indication:
Treatment of patients with known or suspected internal contamination with radioactive or non-radioactive cesium or thallium

Trade Name (if present):
Radiogardase

Date Designated 5/1/2003
Date Approved 10/2/2003

Sponsor Contact Information
Heyl Chemisch-Pharmzeutische Fabrik GMBH & Co, KG
Goerzallee 253
D-14167 Berlin, Federal Republic of Germany
