

List of Orphan Products Designated January thru February 2007

Total Number of Active Designations 17 **Effective:** 2/26/2007

Generic Name

17 a-Hydroxyprogesterone caproate

Approved Orphan Indication:

Trade Name:

Gestiva

Orphan Designation:

Prevention of preterm birth in singleton pregnancies

Designation

1/25/2007

Marketing Exclusivity

Sponsor and Address

Adeza Biomedical
1240 Elko Drive
Sunnyvale CA 94089

Generic Name

cAC10-vcMMAE (4)

Approved Orphan Indication:

Trade Name:

Orphan Designation:

Treatment of Hodgkin's lymphoma.

Designation

1/30/2007

Marketing Exclusivity

Sponsor and Address

Seattle Genetics, Inc.
21823 30th Drive Southeast
Bothell WA 98021

Generic Name

chenodeoxycholic acid

Approved Orphan Indication:

Trade Name:

Orphan Designation:

Treatment of cerebrotendinous xanthomatosis.

Designation

2/12/2007

Marketing Exclusivity

Sponsor and Address

Sigma-Tau Pharmaceuticals, Inc.
800 South Frederick Avenue
Gaithersburg MD 20877

Generic Name
cytarabine liposome

Approved Orphan Indication:

Trade Name:
DepoCyt

Orphan Designation:
Treatment of gliomas

Designation
1/30/2007
Marketing Exclusivity

Sponsor and Address
Bruce Frankel, MD
Medical University of South Carolina
96 Jonathan Lucas Street, Suite 428 CSB
Charleston SC 29425

Generic Name
Droxidopa

Approved Orphan Indication:

Trade Name:

Orphan Designation:
Treatment of neurogenic symptomatic orthostatic hypotension in patients with primary autonomic failure, dopamine-beta-hydroxylase deficiency, and nondiabetic autonomic neuropathy.

Designation
1/17/2007
Marketing Exclusivity

Sponsor and Address
Chelsea Therapeutics, Inc.
13950 Ballantyne Corporate Place
Charlotte NC 28277

Generic Name
fenretinide

Approved Orphan Indication:

Trade Name:

Orphan Designation:
Treatment of Ewing's sarcoma family of tumors.

Designation
2/1/2007
Marketing Exclusivity

Sponsor and Address
Cancer Research UK
61 Lincoln's Inn Fields
London WC2A 3PX

UNITED KINGDOM

Generic Name

idebenone

Trade Name:

Designation

2/16/2007

Marketing Exclusivity

Approved Orphan Indication:

Orphan Designation:

Treatment of Duchenne muscular dystrophy

Sponsor and Address

Santhera Pharmaceuticals Limited

Hammerstrasse 47

SWITZERLAND

Generic Name

lenalidomide

Trade Name:

Revlimid

Designation

1/17/2007

Marketing Exclusivity

Approved Orphan Indication:

Orphan Designation:

Treatment of chronic lymphocytic leukemia.

Sponsor and Address

Celgene Corporation

86 Morris Avenue

Summit NJ 07901

Generic Name

lintuzumab

Trade Name:

Designation

1/30/2007

Marketing Exclusivity

Approved Orphan Indication:

Orphan Designation:

Treatment of acute myeloid leukemia.

Sponsor and Address

Seattle Genetics, Inc.

21823 30th Drive Southeast

Bothell WA 98021

Generic Name

maribavir

Approved Orphan Indication:

Trade Name:

Orphan Designation:

Prevention of cytomegalovirus viremia and disease in the populations at risk.

Designation

2/1/2007

Marketing Exclusivity

Sponsor and Address

ViroPharma Inc.
397 Eagleview Blvd.
Exton PA 19341

Generic Name

microvesiculated modified glycosylated tissue factor

Approved Orphan Indication:

Trade Name:

Orphan Designation:

Treatment of non-life threatening, mild to severe bleeding episodes due to cutaneous injuries or dental procedures in hemophiliac patients

Designation

1/25/2007

Marketing Exclusivity

Sponsor and Address

Thrombotargets Corp.
210 South Biscayne Blvd.
Miami FL 33131

Generic Name

Ranprinase

Approved Orphan Indication:

Trade Name:

Onconase

Orphan Designation:

Treatment for malignant mesothelioma

Designation

1/25/2007

Marketing Exclusivity

Sponsor and Address

Alfacell Corporation
225 Belleville Ave.
Bloomfield NJ 07003

Generic Name

Recombinant human platelet derived growth factor BB

Approved Orphan Indication:**Trade Name:****Orphan Designation:**

treatment of osteonecrosis of the jaws.

Designation

2/1/2007

Marketing Exclusivity**Sponsor and Address**BioMimetic Therapeutics, Inc.
389-A Nichol Hill Road
Franklin TN 37067

Generic Name

Sodium nitrite

Approved Orphan Indication:**Trade Name:****Orphan Designation:**

Prevention of vasospasm associated with subarachnoid hemorrhage

Designation

1/17/2007

Marketing Exclusivity**Sponsor and Address**Hope Pharmaceuticals
8260 E. Gelding Drive
Scottsdale AZ 85260

Generic Name

Sodium phenylbutyrate

Approved Orphan Indication:**Trade Name:**

Buphenyl

Orphan Designation:

Treatment of spinal muscular atrophy

Designation

1/25/2007

Marketing Exclusivity**Sponsor and Address**Ucyclyd Pharma, Inc.
8125 N. Hayden Road
Scottsdale AZ 85258

Generic Name

TGp1PTH1-34

Trade Name:

Designation

2/1/2007

Marketing Exclusivity

Approved Orphan Indication:

Orphan Designation:

Treatment of solitary (unicameral) bone cysts.

Sponsor and Address

Kuros Biosurgery AG
Technoparkstrasse 1
Zurich

SWITZERLAND

Generic Name

Tissue repair cells obtained from autologous bone marrow expanded ex vivo with a cell production system

Trade Name:

Approved Orphan Indication:

Orphan Designation:

Treatment of dilated cardiomyopathy

Designation

1/25/2007

Marketing Exclusivity

Sponsor and Address

Aastrom Biosciences, Inc.
Domino's Farms, Lobby L
Ann Arbor MI 48105
