

Prescription Drug User Fee Act

User Fee Billable Therapeutic Products Approved Under Section 351 of the PHS Act

This list is intended to include all the user fee billable therapeutic biological products and potencies approved under Section 351 of the Public Health Service Act that have been transferred to CDER. The Orange Book includes a section entitled "Drug Products with Approval under Section 505 of the Act Administered by CBER." Included on that list are several products that have been transferred to CDER which would be considered billable also.

Product fees are assessed for each potency in which the approved (non-revoked, non-suspended) product is manufactured in final dosage form. The potency information contained in this list is based on information in our database. Companies are responsible for alerting CDER to any discrepancies regarding potency information.

The list is updated, at least, bi-annually in February and August.

Applicant/ License No.	Tradename(s) / Proper Name	BLA STN	BLA Approval Date	Billable Potencies
Abbott Laboratories License 0043	Humira Adalimumab	125057/0	12/31/2002	40 mg/0.8mL
Advance Biofactures Corp License 0383	Santyl Collagenase	101995/0	6/4/1965	250 u/gram
Allergan, Inc License 1145	Botox Botulinum Toxin Type A	103000/0	12/9/1991	100 u/vial
	Botox Cosmetic Botulinum Toxin Type A	103000/0	4/12/2002	50 u/vial 100 u/vial
Amgen, Inc License 1080	Kineret Anakinra	103950/0	11/14/2001	100 mg/0.67 mL

	Aranesp Darbepoetin alfa (albumin solution)	103951/0	9/17/2001	25 mcg/mL vial 25 mcg/0.42 mL syringe 40 mcg/mL vial 40 mcg/0.4 mL syringe 60 mcg/mL vial 60 mcg/0.3mL syringe 100 mcg/mL vial 100 mcg/0.5mL syringe 150 mcg/0.75mL vial 150 mcg/0.3mL syringe 200 mcg/mL vial 200 mcg/0.4mL syringe 300 mcg/mL vial 300mcg/0.6mL syringe 500 mcg/mL vial
	Aranesp Darbepoetin alfa (polysorbate solution)	103951/0	9/17/2001	25 mcg/mL vial 25 mcg/0.42 mL syringe 40 mcg/mL vial 40 mcg/0.4 mL syringe 60 mcg/mL vial 60 mcg/0.3 mL syringe 100 mcg/mL vial 100 mcg/0.5 mL syringe 150 mcg/0.75 mL vial 150 mcg/0.3mL syringe 200 mcg/0.4 mL syringe 200 mcg/mL vial 300 mcg/0.6 mL syringe 300 mcg/mL vial 500 mcg/mL vial
	Epogen, Procrit Epoetin alfa	103234/0	6/1/1989	2,000 u/mL 3,000 u/mL 4,000 u/mL 10,000 u/mL 40,000 u/mL 10,000 u/mL md 20,000 u/mL md
	Neupogen Filgrastim	103353/0	2/20/1991	300 mcg/mL 300 mcg/0.5mL 480 mcg/0.8mL 480 mcg/1.6mL
	Neulasta Pegfilgrastim	125031/0	1/31/2002	6 mg/0.6mL

Berlex Laboratories, Inc License 1650	Leukine Sargramostim	103362/0	3/5/1991	250 mcg/mL 500 mcg/mL
Biogen Idec, Inc License 1204	Amevive Alefacept	125036/0	1/30/2003	7.5 mg/vial 15 mg/vial
	Avonex Interferon beta-1a	103628/0	5/17/1996	30 mcg/vial 30 mcg/0.5mL syringe
	Zevalin Ibritumomab tiuxetan	125019/0	2/19/2002	3.2 mg/2 mL
Biomarin Pharmaceutical, Inc License 1649	Aldurazyme Laronidase	125058/0	4/30/2003	2.9 mg/5 mL
Boehringer Ingelheim Pharma KG License 1251	Verluma Nofetumomab	103769/0	10/13/1998	
Centocor B.V. License 1178	ReoPro Abciximab	103575/0	12/22/1994	2 mg/mL
Centocor, Inc License 1242	Remicade Infliximab	103772/0	8/24/1998	100 mg/vial
	Retavase Reteplase	103786/0	5/6/1998	18.1 mg/vial
Chiron Corp License 1106	Proleukin Aldesleukin	103293/0	5/5/1992	22 MIU/vial
	Betaseron Interferon beta-1b	103471/0	7/23/1993	0.3 mg/vial
Corixa Corp License 1614	Bexxar Therapeutic Regime Tositumomab and Iodine I-131 Tositumomab	125011/0	6/27/2003	Tositumomab 14 mg/mL I-131 Tositumomab 0.1 mg/mL I -131 Tositumomab 1.1 mg/mL
Cytogen Corp License 1164	ProstaScint Capromab Pendetide	103608/0	10/28/1996	0.5 mg/mL
Elan Pharmaceuticals	MYOBLOC	103846/0	12/8/2000	5,000 IU/mL

License 1579	Botulinum Toxin Type B			
Eli Lilly & Company License 1611	Xigris Drotrecogin alfa (Activated)	125029/0	11/21/2001	5 mg/vial 20 mg/vial
Enzon, Inc License 1171	Oncaspar Pegaspargase	103411/0	2/1/1994	750 IU/mL
Genentech, Inc License 1048	Activase, Cathflo Activase Alteplase	103172/0	11/13/1987	2 mg/vial 50 mg/vial 100 mg/vial
	Avastin Bevacizumab	125085/0	2/26/2004	100 mg/vial 400 mg/vial
	Pulmozyme Dornase alfa	103532/0	12/30/1993	1 mg/mL
	Raptiva Efalizumab	125075/0	10/27/2003	125 mg/vial
	Xolair Omalizumab	103976/0	6/20/2003	75 mg/vial 150 mg/vial
	Rituxan Rituximab	103705/0	11/26/1997	10 mg/mL
	TNKase Tenecteplase	103909/0	6/2/2000	50 mg/vial
	Herceptin Trastuzumab	103792/0	9/25/1998	440 mg/vial
Genzyme Corp License 1596	Fabrazyme Agalsidase beta	103979/0	4/24/2003	5 mg/vial 37 mg/vial
Hoffmann-La Roche, Inc License 0136	Zenapax Daclizumab	103749/0	12/10/1997	25 mg/5 mL
	Pegasys Peg-Interferon alfa-2a	103964/0	10/16/2002	180 mcg/1 mL vial 180 mcg/0.5mL syringe
	Roferon A Interferon alfa-2a	103145/0	6/4/1986	3 MIU/0.5mL syringe 6 MIU/0.5mL syringe 9 MIU/0.5mL syringe

	Pegasys Copegus Combination Pack Peginterferon alfa-2a and Ribavirin	103964/0	12/3/2002	180 mcg/0.5mL + 800 mg (112 x 200 mg tablets) 180 mcg/0.5mL + 1000 mg (140 x 200 mg tablets) 180 mcg/0.5mL + 1200 mg (168 x 200 mg tablets)
ILEX Pharmaceuticals L.P. License 1641	Campath Alemtuzumab	103948/0	5/7/2001	10 mg/mL
ImClone Systems, Inc. License 1695	Erbix Cetuximab	125084/0	2/12/2004	100 mg/vial
Immunex Corp License 1132	Enbrel Etanercept	103795/0	11/2/1998	25 mg/vial
Immunomedics, Inc License 1205	CEA-Scan Arcitumomab	103425/0	6/28/1996	1.25 mg/vial
InterMune, Inc License 1626	Infergen Interferon alfacon-1	103663/0	10/6/1997	30 mcg/mL
	Actimmune Interferon gamma-1b	103836/0	2/25/1999	100 mcg/0.5mL
Interferon Sciences, Inc License 0930	Alferon N Injection Interferon alfa-n3 (Human Leukocyte Derived)	103158/0	10/10/1989	5 MIU/vial
MedImmune, Inc License 1252	Synagis Palivizumab	103770/0	6/19/1998	50 mg/vial (powder) 100 mg/vial (powder) 50 mg/0.5 mL 100 mg/mL
Merck & Co., Inc License 0002	Elspar Asparaginase	101063/0	1/10/1978	10,000 IU/vial
Novartis Pharmaceuticals Corp License 1244	Simulect Basiliximab	103764/0	5/12/1998	10 mg/vial 20 mg/vial
OMJ Pharmaceuticals, Inc License 1196	Regranex Becaplermin	103691/0	12/16/1997	100 mcg/gram
Ortho Biologics LLC License 1265	Eporex Epoetin alfa	103839/0	2/25/1999	2,000 u/mL 4,000 u/mL 10,000 u/mL

				20,000 u/mL
Ortho Biotech Products, LP License 1610	Orthoclone OKT3 Muromonab-CD3	103463/0	9/14/1992	1 mg/mL
Palatin Technologies, Inc. License 1588	NeutroSpec Technetium (99m Tc) fanolesomab	103928/0	7/2/2004	250 mcg/vial
Sanofi-Synthelabo, Inc License 1294	Elitek Rasburicase	103946/0	7/12/2002	1.5 mg/vial
Schering Corp License 0994	Intron A Interferon alfa-2b	103132/0	6/4/1986	6 MIU/mL (solution) 10 MIU/mL (solution) 10 MIU/vial (powder) 15 MIU/mL (solution) 18 MIU/vial (powder) 22.5 MIU/1.5mL md pen 25 MIU/mL solution 37.5 MIU/1.5mL md pen 50 MIU/vial (powder) 50 MIU/mL (solution) 75 MIU/1.5mL md pen
	PEG-Intron Peginterferon alfa-2b	103949/0	1/19/2001	74 mcg/vial (50 mcg/0.5mL) 118.4 mcg/vial (80 mcg/0.5mL) 177.6 mcg/vial (120 mcg/0.5mL) 222 mcg/vial (150 mcg/0.5mL)
Seragen, Inc License 1258	Ontak Denileukin diftitox	103767/0	2/5/1999	150 mcg/mL
Serono, Inc License 1574	Rebif Interferon beta-1a	103780/0	3/7/2002	22 mcg/0.5mL 44 mcg/0.5mL
Wyeth Laboratories, Inc License 0003	Neumega Oprelvekin	103694/0	11/25/1997	5 mg/vial
md = multidose				

