

CDER Therapeutic Biologic Products

This list is intended to include all the Center for Drug Evaluation and Research (CDER) user fee billable therapeutic biological products and potencies approved under Section 351 of the Public Health Service Act. 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. In certain circumstances, products which have been discontinued from marketing but are still licensed are not assessed product fees. Those products are identified on the CDER Discontinued Biologic Product List section.

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. For product approvals after October 1, 2005, the Biologics License Application Submission Tracking Number (BLA STN) approval date reflects the approval date of the product. For product approvals prior to October 1, 2005, the BLA STN approval date reflects the approval date of the original BLA.

The list is updated semi-annually. (Latest Update – MARCH 2012)

CDER Billable Biologic Product List

Applicant/License No: Abbott Laboratories / License 0043

Trade Name: **Humira**

Proper Name: **Adalimumab**

BLA STN:	Approval Date:	Potency:
125057/0	12/31/2002	40 mg/0.8 mL

Applicant/License No: Alexion Pharmaceuticals, Inc. / License 1743

Trade Name: **Soliris**

Proper Name: **Eculizumab**

BLA STN:	Approval Date:	Potency:
125166/0	3/16/2007	10 mg/mL

Applicant/License No: Allergan, Inc. / License 1145

Trade Name: **Botox**

Proper Name: **Onabotulinum Toxin Type A**

BLA STN:	Approval Date:	Potency:
103000/0	12/9/1991	100 u/vial
BLA STN:	Approval Date:	Potency:
103000/5101	4/14/2005	50 u/vial
BLA STN:	Approval Date:	Potency:
103000/5122	11/10/2005	200 u/vial

Trade Name: **Botox Cosmetic**

Proper Name: **Onabotulinum Toxin Type A**

BLA STN:	Approval Date:	Potency:
103000/0	4/12/2002	50 u/vial
		100 u/vial

Applicant/License No: Amgen, Inc. / License 1080

Trade Name: **Aranesp**

Proper Name: **Darbepoetin alfa (albumin solution)**

BLA STN:	Approval Date:	Potency:
103951/0	9/17/2001	25 mcg/0.42 mL syringe
		25 mcg/mL vial
		40 mcg/0.4 mL syringe
		40 mcg/mL vial
		60 mcg/0.3 mL syringe
		60 mcg/mL vial
		100 mcg/0.5 mL syringe
		100 mcg/mL vial
		150 mcg/0.3 mL syringe
		150 mcg/0.75 mL vial
		200 mcg/0.4 mL syringe
		200 mcg/mL vial
		300 mcg/0.6 mL syringe
		300 mcg/mL vial
		500 mcg/mL vial

Proper Name: **Darbepoetin alfa (polysorbate solution)**

BLA STN:	Approval Date:	Potency:
103951/0	9/17/2001	25 mcg/0.42 mL syringe
		25 mcg/mL vial
		40 mcg/0.4 mL syringe
		40 mcg/mL vial
		60 mcg/0.3 mL syringe
		60 mcg/mL vial
		100 mcg/0.5 mL syringe
		100 mcg/mL vial
		150 mcg/0.3 mL syringe
		150 mcg/0.75 mL vial
		200 mcg/0.4 mL syringe
		200 mcg/mL vial
		300 mcg/0.6 mL syringe
		300 mcg/mL vial
		500 mcg/mL vial

Trade Name: **Epogen**

Proper Name: **Epoetin alfa**

BLA STN:	Approval Date:	Potency:
103234/0	6/1/1989	2000 u/mL
		3000 u/mL
		4000 u/mL
		10000 u/mL
		10000 u/mL md
		20000 u/mL md
		40000 u/mL

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Trade Name:	Neulasta		
Proper Name:	Pegfilgrastim		
	BLA STN:	Approval Date:	Potency:
	125031/0	1/31/2002	6 mg/0.6 mL
Trade Name:	Neupogen		
Proper Name:	Filgrastim		
	BLA STN:	Approval Date:	Potency:
	103353/0	2/20/1991	300 mcg/0.5 mL 300 mcg/mL 480 mcg/0.8 mL 480 mcg/1.6 mL
Trade Name:	Nplate		
Proper Name:	Romiplostim		
	BLA STN:	Approval Date:	Potency:
	125268/0	8/22/2008	250 mcg/vial 500 mcg/vial
Trade Name:	Prolia		
Proper Name:	Denosumab		
	BLA STN:	Approval Date:	Potency:
	125320/0	6/1/2010	60 mg/mL
Trade Name:	Vectibix		
Proper Name:	Panitumumab		
	BLA STN:	Approval Date:	Potency:
	125147/0	9/27/2006	20 mg/mL
Trade Name:	Xgeva		
Proper Name:	Denosumab		
	BLA STN:	Approval Date:	Potency:
	125320/7	11/18/2010	120 mg/1.7mL (70mg/mL)

Applicant/License No: Astellas Pharmaceuticals US, Inc. / License 1748

Trade Name:	Amevive		
Proper Name:	Alefcept		
	BLA STN:	Approval Date:	Potency:
	125036/0	1/30/2003	15 mg/vial

Applicant/License No: Auxilium Pharmaceuticals, Inc. / License 1816

Trade Name:	Xiaflex		
Proper Name:	Collagenase Clostridium Histolyticum		
	BLA STN:	Approval Date:	Potency:
	125338/0	2/2/2010	0.9 mg/vial

CDER Billable Biologic Product List

Applicant/License No: Bayer Healthcare Pharmaceuticals Inc. / License 1778

Trade Name: **Betaseron**

Proper Name: **Interferon beta-1b**

BLA STN:	Approval Date:	Potency:
103471/0	7/23/1993	0.3 mg/vial

Applicant/License No: Bayer Healthcare Pharmaceuticals, LLC / License 1791

Trade Name: **Leukine**

Proper Name: **Sargramostim**

BLA STN:	Approval Date:	Potency:
103362/0	3/5/1991	250 mcg/vial 500 mcg/mL

Applicant/License No: Biogen Idec, Inc. / License 1697

Trade Name: **Avonex**

Proper Name: **Interferon beta-1 a**

BLA STN:	Approval Date:	Potency:
103628/0	5/17/1996	30 mcg/0.5 mL syringe 30 mcg/vial

Trade Name: **Tysabri**

Proper Name: **Natalizumab**

BLA STN:	Approval Date:	Potency:
125104/0	11/23/2004	300 mg/15 mL

Applicant/License No: Biomarin Pharmaceutical, Inc. / License 1649

Trade Name: **Aldurazyme**

Proper Name: **Laronidase**

BLA STN:	Approval Date:	Potency:
125058/0	4/30/2003	2.9 mg/5 mL

Trade Name: **Naglazyme**

Proper Name: **Galsulfase**

BLA STN:	Approval Date:	Potency:
125117/0	5/31/2005	5 mg/5 mL

Applicant/License No: Boehringer Ingelheim Pharma KG / License 1251

Trade Name: **Verluma**

Proper Name: **Nofetumomab**

BLA STN:	Approval Date:	Potency:
103769/0	10/13/1998	10 mg/mL

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Applicant/License No: Bristol-Myers Squibb / License 1713

Trade Name: **Nulojix**
 Proper Name: **Belatacept**
 BLA STN: Approval Date: Potency:
 125288/0 6/15/2011 250 mg/vial

Trade Name: **Orencia**
 Proper Name: **Abatacept**
 BLA STN: Approval Date: Potency:
 125118/0 12/23/2005 250 mg/vial
 BLA STN: Approval Date: Potency:
 125118/122 7/29/2011 125 mg/mL

Trade Name: **Yervoy**
 Proper Name: **Ipilimumab**
 BLA STN: Approval Date: Potency:
 125377 3/25/2011 5 mg/mL

Applicant/License No: BTG International Inc. / License 1861

Trade Name: **Voraxaze**
 Proper Name: **Glucarpidase**
 BLA STN: Approval Date: Potency:
 125327 1/17/2012 1000 u/vial

Applicant/License No: Centocor Ortho Biotech Products LP / License 1824

Trade Name: **Orthoclone OKT3**
 Proper Name: **Muromonab-CD3**
 BLA STN: Approval Date: Potency:
 103463/0 9/14/1992 1 mg/mL

Applicant/License No: DFB Biotech, Inc. / License 1745

Trade Name: **Santyl**
 Proper Name: **Collagenase**
 BLA STN: Approval Date: Potency:
 101995/0 6/4/1965 250 u/gram

Applicant/License No: Dyax Corp. / License 1789

Trade Name: **Kalbitor**
 Proper Name: **Ecallantide**
 BLA STN: Approval Date: Potency:
 125277/0 12/1/2009 10 mg/mL

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Applicant/License No: Eisai Medical Research Inc. / License 1763

Trade Name: **Ontak**

Proper Name: **Denileukin diftitox**

BLA STN: Approval Date: Potency:
103767/0 2/5/1999 150 mcg/mL

Applicant/License No: EKR Therapeutics, Inc. / License 1814

Trade Name: **Retavase**

Proper Name: **Reteplase**

BLA STN: Approval Date: Potency:
103786/0 5/6/1998 18.1 mg/vial

Applicant/License No: Eli Lilly & Company / License 1611

Trade Name: **Xigris**

Proper Name: **Drotrecogin alfa (Activated)**

BLA STN: Approval Date: Potency:
125029/0 11/21/2001 5 mg/vial
20 mg/vial

Applicant/License No: EMD Serono Inc. / License 1773

Trade Name: **Rebif**

Proper Name: **Interferon beta-1a**

BLA STN: Approval Date: Potency:
103780/0 3/7/2002 8.8 mcg/0.2 mL
22 mcg/0.5 mL
44 mcg/0.5 mL

Applicant/License No: EUSA Pharma (USA) Inc. / License 1829

Trade Name: **Erwinaze**

Proper Name: **Asparaginase Erwinia chrysanthemi**

BLA STN: Approval Date: Potency:
125359 11/18/2011 10000 IU/vial

Trade Name: **ProstaScint**

Proper Name: **Capromab Pendetide**

BLA STN: Approval Date: Potency:
103608/0 10/28/1996 0.5 mg/mL

Applicant/License No: Genentech, Inc. / License 1048

Trade Name: **Actemra**

Proper Name: **Tocilizumab**

BLA STN: Approval Date: Potency:
125276/0 1/8/2010 20 mg/mL

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Applicant/License No: Human Genome Sciences, Inc / License 1820

Trade Name: **Benlysta**

Proper Name: **Belimumab**

BLA STN:	Approval Date:	Potency:
125370	3/9/2011	120 mg/vial
		400 mg/vial

Applicant/License No: ImClone Systems, Inc. / License 1695

Trade Name: **Erbix**

Proper Name: **Cetuximab**

BLA STN:	Approval Date:	Potency:
125084/0	2/12/2004	2 mg/mL

Applicant/License No: Immunex Corp. / License 1132

Trade Name: **Enbrel**

Proper Name: **Etanercept**

BLA STN:	Approval Date:	Potency:
103795/0	11/2/1998	25 mg/vial
BLA STN:	Approval Date:	Potency:
103795/5184	9/27/2004	50 mg/mL syringe

Applicant/License No: InterMune, Inc. / License 1626

Trade Name: **Actimmune**

Proper Name: **Interferon gamma-1b**

BLA STN:	Approval Date:	Potency:
103836/0	2/25/1999	100 mcg/0.5 mL

Applicant/License No: Ipsen Biopharm Limited / License 1787

Trade Name: **Dysport**

Proper Name: **Abobotulinum Toxin Type A**

BLA STN:	Approval Date:	Potency:
125274/0	4/29/2009	300 U/vial
		500 U/vial

Applicant/License No: Janssen Biologics B.V. / License 1865

Trade Name: **ReoPro**

Proper Name: **Abciximab**

BLA STN:	Approval Date:	Potency:
103575/0	12/22/1994	2 mg/mL

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Applicant/License No: Janssen Biotech, Inc. / License 1864

Trade Name:	Remicade		
Proper Name:	Infliximab		
	BLA STN:	Approval Date:	Potency:
	103772/0	8/24/1998	100 mg/vial
Trade Name:	Simponi		
Proper Name:	Golimumab		
	BLA STN:	Approval Date:	Potency:
	125289/0	4/24/2009	50 mg/0.5 mL
Trade Name:	Stelara		
Proper Name:	Ustekinumab		
	BLA STN:	Approval Date:	Potency:
	125261/0	9/25/2009	90 mg/mL

Applicant/License No: Kadmon Pharmaceuticals, LLC / License 1867

Trade Name:	Infergen		
Proper Name:	Interferon alfacon-1		
	BLA STN:	Approval Date:	Potency:
	103663/0	10/6/1997	30 mcg/mL

Applicant/License No: Lundbeck, Inc. / License 1822

Trade Name:	Elspar		
Proper Name:	Asparaginase		
	BLA STN:	Approval Date:	Potency:
	101063/0	1/10/1978	10000 IU/vial

Applicant/License No: MedImmune, LLC / License 1799

Trade Name:	Synagis (Liquid)		
Proper Name:	Palivizumab		
	BLA STN:	Approval Date:	Potency:
	103770/0	6/19/1998	50 mg/0.5 mL 100 mg/mL

Applicant/License No: Merz Pharmaceuticals / License 1830

Trade Name:	Xeomin		
Proper Name:	IncobotulinumtoxinA		
	BLA STN:	Approval Date:	Potency:
	125360/0	7/30/2010	50 u/vial 100 u/vial

CDER Billable Biologic Product List

Applicant/License No: Seattle Genetics, Inc. / License 1853

Trade Name: **Adcetris**

Proper Name: **Brentuximab vedotin**

BLA STN:	Approval Date:	Potency:
125388/0	8/19/2011	50 mg/vial

Applicant/License No: Shire Human Genetic Therapies, Inc. / License 1593

Trade Name: **Elaprase**

Proper Name: **Idursulfase**

BLA STN:	Approval Date:	Potency:
125151/0	7/24/2006	6 mg/3 mL

Applicant/License No: Sigma Tau Pharmaceuticals Inc. / License 1850

Trade Name: **Oncaspar**

Proper Name: **Pegaspargase**

BLA STN:	Approval Date:	Potency:
103411/0	2/1/1994	750 IU/mL

Applicant/License No: SmithKline Beecham Corp. dba GlaxoSmithKline / License 1727

Trade Name: **Bexxar Therapeutic Regime**

Proper Name: **Tositumomab and Iodine I-131 Tositumomab**

BLA STN:	Approval Date:	Potency:
125011/0	6/27/2003	0.1 mg/mL I-131 Tositumomab 1.1 mg/mL I-131 Tositumomab 14 mg/mL Tositumomab

Applicant/License No: Solstice NeuroSciences, LLC / License 1718

Trade Name: **MYOBLOC**

Proper Name: **RimabotulinumToxinB**

BLA STN:	Approval Date:	Potency:
103846/0	12/8/2000	5000 IU/mL

Applicant/License No: Spectrum Pharmaceuticals, Inc. / License 1832

Trade Name: **Zevalin**

Proper Name: **Ibritumomab tiuxetan**

BLA STN:	Approval Date:	Potency:
125019/0	2/19/2002	3.2 mg/2 mL

Applicant/License No: Swedish Orphan Biovitrum AB / License 1859

Trade Name: **Kepivance**

Proper Name: **Palifermin**

BLA STN:	Approval Date:	Potency:
125103/0	12/15/2004	6.25 mg/vial

CDER Billable Biologic Product List

Trade Name: **Kineret**
Proper Name: **Anakinra**
BLA STN: 103950/0 Approval Date: 11/14/2001 Potency: 100 mg/0.67 mL

Applicant/License No: UCB, Inc. / License 1736

Trade Name: **Cimzia**
Proper Name: **Certolizumab pegol**
BLA STN: 125160/080 Approval Date: 4/22/2008 Potency: 200 mg/vial
5/13/2009 200 mg/mL

Applicant/License No: Wyeth Pharmaceuticals, Inc. / License 0003

Trade Name: **Neumega**
Proper Name: **Oprelvekin**
BLA STN: 103694/0 Approval Date: 11/25/1997 Potency: 5 mg/vial

CDER Discontinued Biologic Product List

Applicant/License No: Astellas Pharmaceuticals US, Inc. / License 1748

Trade Name: **Amevive**

Proper Name: **Alefacept**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
125036/0	1/30/2003	9/24/2008	7.5 mg/vial

Applicant/License No: Genentech, Inc. / License 1048

Trade Name: **Raptiva**

Proper Name: **Efalizumab**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
125075/0	10/27/2003	9/1/2009	125 mg/vial

Applicant/License No: Genzyme Corp. / License 1596

Trade Name: **Campath**

Proper Name: **Alemtuzumab**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103948/0	5/7/2001	7/6/2011	10 mg/vial

Applicant/License No: Hoffmann-La Roche, Inc. / License 0136

Trade Name: **Mircera**

Proper Name: **Methoxypolyethylene glycol epoetin beta**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
125164/0	11/14/2007	9/24/2008	50 mcg/0.3 mL
		9/24/2008	50 mcg/mL
		9/24/2008	75 mcg/0.3 mL
		9/24/2008	100 mcg/0.3 mL
		9/24/2008	100 mcg/mL
		9/24/2008	150 mcg/0.3 mL
		9/24/2008	200 mcg/0.3 mL
		9/24/2008	200 mcg/mL
		9/24/2008	250 mcg/0.3 mL
		9/24/2008	300 mcg/mL
		9/24/2008	400 mcg/0.6 mL
		9/24/2008	400 mcg/mL
		9/24/2008	600 mcg/0.6 mL
		9/24/2008	600 mcg/mL
		9/24/2008	800 mcg/0.6 mL
		9/24/2008	1000 mcg/mL

Trade Name: **Roferon A**

Proper Name: **Interferon alfa-2a**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103145/0	6/4/1986	6/1/2009	3 MIU/0.5 mL syringe
		6/1/2009	6 MIU/0.5 mL syringe
		6/1/2009	9 MIU/0.5 mL syringe

