

## 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 listed 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 2008)

### \*\*\*\*\* CDER Billable Biologic Product List \*\*\*\*\*

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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
BLA STN:	Approval Date:	Potency:
125057/114	2/21/2008	20 mg/0.4 mL

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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

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

Trade Name: **Botox**

Proper Name: **Botulinum Toxin Type A**

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

Trade Name: **Botox Cosmetic**

Proper Name: **Botulinum 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:	<b>Kepivance</b>		
Proper Name:	Palifermin		
	BLA STN:	Approval Date:	Potency:
	125103/0	12/15/2004	6.25 mg/vial
Trade Name:	<b>Kineret</b>		
Proper Name:	Anakinra		
	BLA STN:	Approval Date:	Potency:
	103950/0	11/14/2001	100 mg/0.67 mL
Trade Name:	<b>Neulasta</b>		
Proper Name:	Pegfilgrastim		
	BLA STN:	Approval Date:	Potency:
	125031/0	1/31/2002	6 mg/0.6 mL
Trade Name:	<b>Neupogen</b>		
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:	<b>Vectibix</b>		
Proper Name:	Panitumumab		
	BLA STN:	Approval Date:	Potency:
	125147/0	9/27/2006	20 mg/mL

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

Trade Name:	<b>Amevive</b>		
Proper Name:	Alefacept		
	BLA STN:	Approval Date:	Potency:
	125036/0	1/30/2003	7.5 mg/vial
			15 mg/vial

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

Trade Name:	<b>Betaseron</b>		
Proper Name:	Interferon beta-1b		
	BLA STN:	Approval Date:	Potency:
	103471/0	7/23/1993	0.3 mg/vial
Trade Name:	<b>Leukine</b>		
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: 103628/0      Approval Date: 5/17/1996      Potency: 30 mcg/0.5 mL syringe  
 30 mcg/vial

Trade Name: **Tysabri**  
 Proper Name: **Natalizumab**  
 BLA STN: 125104/0      Approval Date: 11/23/2004      Potency: 300 mg/15 mL

Trade Name: **Zevalin**  
 Proper Name: **Ibritumomab tiuxetan**  
 BLA STN: 125019/0      Approval Date: 2/19/2002      Potency: 3.2 mg/2 mL

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

Trade Name: **Aldurazyme**  
 Proper Name: **Laronidase**  
 BLA STN: 125058/0      Approval Date: 4/30/2003      Potency: 2.9 mg/5 mL

Trade Name: **Naglazyme**  
 Proper Name: **Galsulfase**  
 BLA STN: 125117/0      Approval Date: 5/31/2005      Potency: 5 mg/5 mL

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

Trade Name: **Verluma**  
 Proper Name: **Nofetumomab**  
 BLA STN: 103769/0      Approval Date: 10/13/1998      Potency: 10 mg/mL

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

Trade Name: **Orencia**  
 Proper Name: **Abatacept**  
 BLA STN: 125118/0      Approval Date: 12/23/2005      Potency: 250 mg/vial

Applicant/License No: Centocor B.V. / License 1178

Trade Name: **ReoPro**  
 Proper Name: **Abciximab**  
 BLA STN: 103575/0      Approval Date: 12/22/1994      Potency: 2 mg/mL

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Applicant/License No: Centocor, Inc. / License 1242

Trade Name: **Remicade**

Proper Name: **Infliximab**

BLA STN:	Approval Date:	Potency:
103772/0	8/24/1998	100 mg/vial

Applicant/License No: Cytogen Corp. / License 1164

Trade Name: **ProstaScint**

Proper Name: **Capromab Pendetide**

BLA STN:	Approval Date:	Potency:
103608/0	10/28/1996	0.5 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: 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: 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: ENZON, Inc. / License 1171

Trade Name: **Oncaspar**

Proper Name: **Pegaspargase**

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

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

Trade Name: **Activase, Cathflo Activase**

Proper Name: **Alteplase**

BLA STN:	Approval Date:	Potency:
103172/0	11/13/1987	2 mg/vial 50 mg/vial

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Trade Name:	<b>Activase, Cathflo Activase</b>		
Proper Name:	Alteplase		
	103172/0	11/13/1987	100 mg/vial
Trade Name:	<b>Avastin</b>		
Proper Name:	Bevacizumab		
	BLA STN:	Approval Date:	Potency:
	125085/0	2/26/2004	100 mg/vial
			400 mg/vial
Trade Name:	<b>Herceptin</b>		
Proper Name:	Trastuzumab		
	BLA STN:	Approval Date:	Potency:
	103792/0	9/25/1998	440 mg/vial
Trade Name:	<b>Lucentis</b>		
Proper Name:	Ranibizumab		
	BLA STN:	Approval Date:	Potency:
	125156/0	6/30/2006	0.5 mg/0.05 mL
Trade Name:	<b>Pulmozyme</b>		
Proper Name:	Dornase alfa		
	BLA STN:	Approval Date:	Potency:
	103532/0	12/30/1993	1 mg/mL
Trade Name:	<b>Raptiva</b>		
Proper Name:	Efalizumab		
	BLA STN:	Approval Date:	Potency:
	125075/0	10/27/2003	125 mg/vial
Trade Name:	<b>Rituxan</b>		
Proper Name:	Rituximab		
	BLA STN:	Approval Date:	Potency:
	103705/0	11/26/1997	10 mg/mL
Trade Name:	<b>TNKase</b>		
Proper Name:	Tenecteplase		
	BLA STN:	Approval Date:	Potency:
	103909/0	6/2/2000	50 mg/vial
Trade Name:	<b>Xolair</b>		
Proper Name:	Omalizumab		
	BLA STN:	Approval Date:	Potency:
	103976/0	6/20/2003	75 mg/vial
			150 mg/vial

Applicant/License No: Genzyme Corp. / License 1596

Trade Name:	<b>Campath</b>		
Proper Name:	Alemtuzumab		
	BLA STN:	Approval Date:	Potency:
	103948/0	5/7/2001	10 mg/vial
			30 mg/vial

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Trade Name: **Fabrazyme**  
 Proper Name: **Agalsidase beta**  
 BLA STN: 103979/0      Approval Date: 4/24/2003      Potency: 5 mg/vial  
 37 mg/vial

Trade Name: **Myozyme**  
 Proper Name: **Alglucosidase alfa**  
 BLA STN: 125141/0      Approval Date: 4/28/2006      Potency: 50 mg/vial

Applicant/License No: Hemispherx Biopharma, Inc. / License 1703

Trade Name: **Alferon N Injection**  
 Proper Name: **Interferon alfa-n3 (Human Leukocyte Derived)**  
 BLA STN: 103158/0      Approval Date: 10/10/1989      Potency: 5 MIU/vial

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

Trade Name: **Mircera**  
 Proper Name: **Methoxypolyethylene glycol epoetin beta**  
 BLA STN: 125164/0      Approval Date: 11/14/2007      Potency:  
 50 mcg/0.3 mL  
 50 mcg/mL  
 75 mcg/0.3 mL  
 100 mcg/0.3 mL  
 100 mcg/mL  
 150 mcg/0.3 mL  
 200 mcg/0.3 mL  
 200 mcg/mL  
 250 mcg/0.3 mL  
 300 mcg/mL  
 400 mcg/0.6 mL  
 400 mcg/mL  
 600 mcg/0.6 mL  
 600 mcg/mL  
 800 mcg/0.6 mL  
 1000 mcg/mL

Trade Name: **Pegasys**  
 Proper Name: **Peginterferon alfa-2a**  
 BLA STN: 103964/0      Approval Date: 10/16/2002      Potency:  
 180 mcg/0.5 mL syringe  
 180 mcg/1 mL vial

Trade Name: **Pegasys/ Copegus Combination Pack**  
 Proper Name: **Peginterferon alfa-2a, co-packaged with Ribavirin**  
 BLA STN: 125083/0      Approval Date: 6/4/2004      Potency:  
 180 mcg/0.5 mL + 1000 mg (140 x 200 mg tablets)

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Trade Name: **Pegasys/ Copegus Combination Pack**  
 Proper Name: Peginterferon alfa-2a, co-packaged with Ribavirin  
 125083/0 6/4/2004 180 mcg/0.5 mL + 1200 mg (168 x 200 mg tablets)  
 180 mcg/0.5 mL + 800 mg (112 x 200 mg tablets)

Trade Name: **Roferon A**  
 Proper Name: Interferon alfa-2a  
 BLA STN: Approval Date: Potency:  
 103145/0 6/4/1986 3 MIU/0.5 mL syringe  
 6 MIU/0.5 mL syringe  
 9 MIU/0.5 mL syringe

Trade Name: **Zenapax**  
 Proper Name: Daclizumab  
 BLA STN: Approval Date: Potency:  
 103749/0 12/10/1997 25 mg/5 mL

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: MedImmune, Inc. / License 1252

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: Novartis Pharmaceuticals Corp. / License 1244

Trade Name: **Simulect**

Proper Name: **Basiliximab**

BLA STN:	Approval Date:	Potency:
103764/0	5/12/1998	10 mg/vial 20 mg/vial

Applicant/License No: Novartis Vaccines and Diagnostics, Inc. / License 1751

Trade Name: **Proleukin**

Proper Name: **Aldesleukin**

BLA STN:	Approval Date:	Potency:
103293/0	5/5/1992	22 MIU/vial

Applicant/License No: OMJ Pharmaceuticals, Inc. / License 1196

Trade Name: **Regranex**

Proper Name: **Becaplermin**

BLA STN:	Approval Date:	Potency:
103691/0	12/16/1997	100 mcg/gram

Applicant/License No: Ortho Biotech Products, LP / License 1610

Trade Name: **Orthoclone OKT3**

Proper Name: **Muromonab-CD3**

BLA STN:	Approval Date:	Potency:
103463/0	9/14/1992	1 mg/mL

Applicant/License No: Ovation Pharmaceuticals, Inc. / License 1688

Trade Name: **Elspar**

Proper Name: **Asparaginase**

BLA STN:	Approval Date:	Potency:
101063/0	1/10/1978	10000 IU/vial

Applicant/License No: Palatin Technologies, Inc. / License 1588

Trade Name: **NeuroSpec Technetium (99m Tc)**

Proper Name: **Fanolesomab**

BLA STN:	Approval Date:	Potency:
103928/0	7/2/2004	0.25 mg/vial

Applicant/License No: PDL BioPharma, Inc. / License 1722

Trade Name: **Retavase**

Proper Name: **Reteplase**

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

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Applicant/License No: Regeneron Pharmaceuticals, Inc. / License 1760

Trade Name: **Arcalyst**

Proper Name: **Riloncept**

BLA STN:	Approval Date:	Potency:
125249/0	2/27/2008	80 mg/mL

Applicant/License No: Sanofi-Synthelabo, Inc. / License 1294

Trade Name: **Elitek**

Proper Name: **Rasburicase**

BLA STN:	Approval Date:	Potency:
103946/0	7/12/2002	1.5 mg/vial
BLA STN:	Approval Date:	Potency:
105020/0	1/6/2006	7.5 mg/vial

Applicant/License No: Schering Corp. / License 0994

Trade Name: **Intron A**

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

BLA STN:	Approval Date:	Potency:
103132/0	6/4/1986	10 MIU/vial (powder)
		18 MIU/mL (solution)
		18 MIU/vial (powder)
		22.5 MIU/1.5 mL md pen
		25 MIU/mL (solution)
		37.5 MIU/1.5 mL md pen
		50 MIU/vial (powder)
		75 MIU/1.5 mL md pen

Trade Name: **PegIntron**

Proper Name: **Peginterferon alfa-2b**

BLA STN:	Approval Date:	Potency:
103949/0	1/19/2001	50 mcg/vial
		74 mcg/vial (50 mcg/0.5 mL)
		80 mcg/vial
		118.4 mcg/vial (80 mcg/0.5mL)
		120 mcg/vial
		150 mcg/vial
		177.6 mcg/vial (120 mcg/0.5mL)
		222 mcg/vial (150 mcg/0.5mL)

Applicant/License No: Serono, Inc. / License 1574

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

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CDER Billable Biologic Product List

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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: 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: **Botulinum Toxin Type B**

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

Applicant/License No: Valeant Pharmaceuticals International / License 1735

Trade Name: **Infergen**

Proper Name: **Interferon alfacon-1**

BLA STN:	Approval Date:	Potency:
103663/0	10/6/1997	30 mcg/mL

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

Trade Name: **Neumega**

Proper Name: **Oprelvekin**

BLA STN:	Approval Date:	Potency:
103694/0	11/25/1997	5 mg/vial

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CDER Discontinued Biologic Product List

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Applicant/License No: MedImmune, Inc. / License 1252

Trade Name: **Synagis**

Proper Name: **Palivizumab**

BLA STN:  
103770/0

Approval Date:  
6/19/1998

Potency:  
50 mg/vial (powder)  
100 mg/vial (powder)

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Applicant/License No: Schering Corp. / License 0994

Trade Name: **Intron A**

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

BLA STN:  
103132/0

Approval Date:  
6/4/1986

Potency:  
10 MIU/mL (solution)