

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 CDER." 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 – September 2016)

***** CDER Billable Biologic Product List *****

Applicant/License No: AbbVie Inc. / License 1889

Trade Name: **Humira**

Proper Name: **Adalimumab**

BLA STN:	Approval Date:	Potency:
125057	12/31/2002	40 mg/0.8 mL (50 mg/mL)
BLA STN:	Approval Date:	Potency:
125057/394	11/23/2015	40 mg/0.4 mL (100 mg/mL)

Applicant/License No: Aegerion Pharmaceuticals, Inc. / License 2014

Trade Name: **Myalept**

Proper Name: **Metreleptin**

BLA STN:	Approval Date:	Potency:
125390/0	2/24/2014	11.3 mg/vial

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

Trade Name: **Kanuma**

Proper Name: **Sebelipase alfa**

BLA STN:	Approval Date:	Potency:
125561/0	12/8/2015	20 mg/10 mL (2 mg/mL)

Trade Name: **Soliris**

Proper Name: **Eculizumab**

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

Trade Name: **Strensiq**

Proper Name: **Asfotase alfa**

BLA STN:	Approval Date:	Potency:
125513/0	10/23/2015	18 mg/0.45 mL (40 mg/mL)

CDER Billable Biologic Product List

Trade Name: **Strensiq**
 Proper Name: **Asfotase alfa**
 125513/0 10/23/2015 80 mg/0.8 mL (100 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:
 103000/5000 4/12/2002 100 u/vial
 BLA STN: Approval Date: Potency:
 103000/5101 4/14/2005 50 u/vial

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

Trade Name: **Aranesp**
 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: **Blincyto**
 Proper Name: **Blinatumomab**
 BLA STN: Approval Date: Potency:
 125557 12/3/2014 35 mcg/vial

CDER Billable Biologic Product List

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
Trade Name:	Neulasta		
Proper Name:	Pegfilgrastim		
	BLA STN:	Approval Date:	Potency:
	125031/0	1/31/2002	6 mg/0.6 mL
Trade Name:	Neulasta Onpro		
Proper Name:	Pegfilgrastim		
	BLA STN:	Approval Date:	Potency:
	125031/181	9/23/2015	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:	Repatha		
Proper Name:	Evolocumab		
	BLA STN:	Approval Date:	Potency:
	125522/0	8/27/2015	140 mg/mL
	BLA STN:	Approval Date:	Potency:
	125522/1	7/8/2016	420 mg/3.5 mL (120 mg/mL)
Trade Name:	Vectibix		
Proper Name:	Panitumumab		
	BLA STN:	Approval Date:	Potency:
	125147/0	9/27/2006	20 mg/mL

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CDER Billable Biologic Product List

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Trade Name: **Xgeva**
Proper Name: **Denosumab**
BLA STN: 125320/7 Approval Date: 11/18/2010 Potency: 120 mg/1.7mL (70mg/mL)

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

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

Applicant/License No: **Aytu BioScience, Inc. / License 2035**

Trade Name: **ProstaScint**
Proper Name: **Capromab Pendetide**
BLA STN: 103608/0 Approval Date: 10/28/1996 Potency: 0.5 mg/mL

Applicant/License No: **Baxalta US, Inc. / License 1850**

Trade Name: **Oncaspar**
Proper Name: **Pegaspargase**
BLA STN: 103411/0 Approval Date: 2/1/1994 Potency: 750 IU/mL

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

Trade Name: **Betaseron**
Proper Name: **Interferon beta-1b**
BLA STN: 103471/0 Approval Date: 7/23/1993 Potency: 0.3 mg/vial

Applicant/License No: **Biogen 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: **Plegridy**
Proper Name: **Peginterferon beta-1a**
BLA STN: 125499/0 Approval Date: 8/15/2014 Potency: 63 mcg/0.5mL syringe + 94 mcg/0.5mL syringe (starter pack)
125 mcg/0.5 mL syringe

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CDER Billable Biologic Product List

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

Trade Name: **Zinbryta**
Proper Name: **Daclizumab**
BLA STN: 761029/0 Approval Date: 5/27/2016 Potency: 150 mg/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

Trade Name: **Vimizim**
Proper Name: **Elosulfase alfa**
BLA STN: 125460/0 Approval Date: 2/14/2014 Potency: 5 mg/5 mL

Applicant/License No: **Boehringer Ingelheim Pharmaceuticals, Inc. / License 2006**

Trade Name: **Praxbind**
Proper Name: **Idarucizumab**
BLA STN: 761025/0 Approval Date: 10/16/2015 Potency: 2.5 g/50 mL (50 mg/mL)

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

Trade Name: **Empliciti**
Proper Name: **Elotuzumab**
BLA STN: 761035/0 Approval Date: 11/30/2015 Potency: 300 mg/vial
400 mg/vial

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

Trade Name: **Opdivo**
Proper Name: **Nivolumab**
BLA STN: 125554 Approval Date: 12/22/2014 Potency: 40 mg/4mL (10mg/mL)

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CDER Billable Biologic Product List

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

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

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

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

Applicant/License No: **Dyax Corp. / License 1789**

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

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

Trade Name: **Retavase**
Proper Name: **Reteplase**
BLA STN: 103786/0 Approval Date: 5/6/1998 Potency: 18.1 mg/vial

Applicant/License No: **Eli Lilly and Company / License 1891**

Trade Name: **CYRAMZA**
Proper Name: **Ramucirumab**
BLA STN: 125477/0 Approval Date: 4/21/2014 Potency: 500 mg/50mL (10 mg/mL)

Trade Name: **Portrazza**
Proper Name: **Necitumumab**
BLA STN: 125547/0 Approval Date: 11/24/2015 Potency: 800 mg/50 mL (16 mg/mL)

Trade Name: **Taltz**
Proper Name: **Ixekizumab**
BLA STN: 125521/0 Approval Date: 3/22/2016 Potency: 80 mg/mL

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Trade Name: **Trulicity**
Proper Name: **Dulaglutide**
BLA STN: 125469/0 Approval Date: 9/18/2014 Potency: 0.75 mg/0.5mL
1.5 mg/0.5mL

Applicant/License No: Elusys Therapeutics, Inc. / License 1907

Trade Name: **Anthim**
Proper Name: **Obiltoxaximab**
BLA STN: 125509 Approval Date: 3/18/2016 Potency: 600 mg/6 mL (100 mg/mL)

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

Trade Name: **Rebif**
Proper Name: **Interferon beta-1a**
BLA STN: 103780/0 Approval Date: 3/7/2002 Potency: 8.8 mcg/0.2 mL
22 mcg/0.5 mL
44 mcg/0.5 mL

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

Trade Name: **Actemra**
Proper Name: **Tocilizumab**
BLA STN: 125276/0 Approval Date: 1/8/2010 Potency: 80 mg/4 mL (20 mg/mL)
BLA STN: 125472/0 Approval Date: 10/21/2013 Potency: 162 mg/0.9 mL

Trade Name: **Activase**
Proper Name: **Alteplase**
BLA STN: 103172/0 Approval Date: 11/13/1987 Potency: 50 mg/vial
100 mg/vial

Trade Name: **Avastin**
Proper Name: **Bevacizumab**
BLA STN: 125085/0 Approval Date: 2/26/2004 Potency: 25 mg/mL

Trade Name: **Cathflo Activase**
Proper Name: **Alteplase**
BLA STN: 103172/0 Approval Date: 11/13/1987 Potency: 2 mg/vial

Trade Name: **Gazyva**
Proper Name: **Obinutuzumab**
BLA STN: 125486/0 Approval Date: 11/1/2013 Potency: 1000 mg/40 mL (25 mg/mL)

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Trade Name:	Herceptin		
Proper Name:	Trastuzumab		
	BLA STN:	Approval Date:	Potency:
	103792/0	9/25/1998	440 mg/vial
Trade Name:	Kadcyla		
Proper Name:	ado-trastuzumab emtansine		
	BLA STN:	Approval Date:	Potency:
	125427/0	2/22/2013	100 mg/vial
			160 mg/vial
Trade Name:	Lucentis		
Proper Name:	Ranibizumab		
	BLA STN:	Approval Date:	Potency:
	125156/0	6/30/2006	0.5 mg/0.05 mL
	BLA STN:	Approval Date:	Potency:
	125156/076	8/10/2012	0.3 mg/0.05 mL
Trade Name:	Perjeta		
Proper Name:	Pertuzumab		
	BLA STN:	Approval Date:	Potency:
	125409/0	6/8/2012	420 mg/14 mL (30 mg/mL)
Trade Name:	Pulmozyme		
Proper Name:	Dornase alfa		
	BLA STN:	Approval Date:	Potency:
	103532/0	12/30/1993	1 mg/mL
Trade Name:	Rituxan		
Proper Name:	Rituximab		
	BLA STN:	Approval Date:	Potency:
	103705/0	11/26/1997	100 mg/10 mL (10 mg/mL)
Trade Name:	Tecentriq		
Proper Name:	Atezolizumab		
	BLA STN:	Approval Date:	Potency:
	761034	5/18/2016	1200 mg/20 mL (60 mg/mL)
Trade Name:	TNKase		
Proper Name:	Tenecteplase		
	BLA STN:	Approval Date:	Potency:
	103909/0	6/2/2000	50 mg/vial
Trade Name:	Xolair		
Proper Name:	Omalizumab		
	BLA STN:	Approval Date:	Potency:
	103976/0	6/20/2003	150 mg/vial

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Applicant/License No: Genzyme Corp. / License 1596Trade Name: **Campath**Proper Name: **Alemtuzumab**

BLA STN:	Approval Date:	Potency:
103948/0	5/7/2001	30 mg/mL

Trade Name: **Fabrazyme**Proper Name: **Agalsidase beta**

BLA STN:	Approval Date:	Potency:
103979/0	4/24/2003	5 mg/vial 35 mg/vial

Trade Name: **Lemtrada**Proper Name: **Alemtuzumab**

BLA STN:	Approval Date:	Potency:
103948/5139	11/14/2014	12 mg/1.2mL (10mg/mL)

Trade Name: **Lumizyme**Proper Name: **Alglucosidase alfa**

BLA STN:	Approval Date:	Potency:
125291/0	5/24/2010	50 mg/vial

Trade Name: **Myozyme**Proper Name: **Alglucosidase alfa**

BLA STN:	Approval Date:	Potency:
125141/0	4/28/2006	50 mg/vial

Applicant/License No: GlaxoSmithKline LLC / License 1727Trade Name: **Nucala**Proper Name: **Mepolizumab**

BLA STN:	Approval Date:	Potency:
125526/0	11/4/2015	100 mg/vial

Trade Name: **Tanzeum**Proper Name: **Albiglutide**

BLA STN:	Approval Date:	Potency:
125431/0	4/15/2014	30 mg/pen 50 mg/pen

Applicant/License No: Hoffmann-La Roche, Inc. / License 0136Trade Name: **Pegasys**Proper Name: **Peginterferon alfa-2a**

BLA STN:	Approval Date:	Potency:
103964/0	10/16/2002	180 mcg/0.5 mL syringe 180 mcg/mL

BLA STN:	Approval Date:	Potency:
103964/5204	9/29/2011	135 mcg/0.5 mL syringe

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Applicant/License No: Horizon Pharma Ireland Limited / License 2022Trade 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: Horizon Pharma Rheumatology LLC / License 1998Trade Name: **Krystexxa**Proper Name: **Pegloticase**

BLA STN:

Approval Date:

Potency:

125293

9/14/2010

8 mg/mL

Applicant/License No: Human Genome Sciences, Inc / License 1820Trade Name: **Benlysta**Proper Name: **Belimumab**

BLA STN:

Approval Date:

Potency:

125370

3/9/2011

120 mg/vial

400 mg/vial

Trade Name: **Raxibacumab**Proper Name: **Raxibacumab**

BLA STN:

Approval Date:

Potency:

125349/0

12/14/2012

1700 mg/34 mL (50 mg/mL)

Applicant/License No: ImClone Systems, Inc. / License 1695Trade Name: **Erbitux**Proper Name: **Cetuximab**

BLA STN:

Approval Date:

Potency:

125084/0

2/12/2004

100 mg/50 mL (2mg/mL)

Applicant/License No: Immunex Corp. / License 1132Trade 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: Ipsen Biopharm Limited / License 1787Trade Name: **Dysport**Proper Name: **Abobotulinum Toxin Type A**

BLA STN:

Approval Date:

Potency:

125274/0

4/29/2009

300 U/vial

500 U/vial

CDER Billable Biologic Product List

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

Trade Name:	Darzalex		
Proper Name:	Daratumumab		
	BLA STN:	Approval Date:	Potency:
	761036/0	11/16/2015	100 mg/5 mL (20 mg/mL)
Trade Name:	Remicade		
Proper Name:	Infliximab		
	BLA STN:	Approval Date:	Potency:
	103772/0	8/24/1998	100 mg/vial
Trade Name:	ReoPro		
Proper Name:	Abciximab		
	BLA STN:	Approval Date:	Potency:
	103575/0	12/22/1994	2 mg/mL (10 mg/5 mL)
Trade Name:	Simponi		
Proper Name:	Golimumab		
	BLA STN:	Approval Date:	Potency:
	125289/0	4/24/2009	50 mg/0.5 mL
Trade Name:	Simponi Aria		
Proper Name:	Golimumab		
	BLA STN:	Approval Date:	Potency:
	125433/0	7/18/2013	50 mg/4mL
Trade Name:	Stelara		
Proper Name:	Ustekinumab		
	BLA STN:	Approval Date:	Potency:
	125261/0	9/25/2009	90 mg/mL
	BLA STN:	Approval Date:	Potency:
	761044/0	9/23/2016	130 mg/26 mL (5 mg/mL)
Trade Name:	Sylvant		
Proper Name:	Siltuximab		
	BLA STN:	Approval Date:	Potency:
	125496/0	4/23/2014	100 mg/vial
			400 mg/vial

Applicant/License No: Jazz Pharmaceuticals, Inc. / License 1901

Trade Name:	Erwinaze		
Proper Name:	asparaginase Erwinia chrysanthemi		
	BLA STN:	Approval Date:	Potency:
	125359	11/18/2011	10000 IU/vial

CDER Billable Biologic Product List

Applicant/License No: MedImmune, LLC / License 1799Trade Name: **Synagis**Proper Name: **Palivizumab**

BLA STN:

Approval Date:

Potency:

103770/0

6/19/1998

50 mg/0.5 mL

100 mg/mL

Applicant/License No: Merck Sharp & Dohme Corp. / License 0002Trade Name: **Intron A**Proper Name: **Interferon alfa-2b**

BLA STN:

Approval Date:

Potency:

103132/0

6/4/1986

10 MIU/vial (powder)

18 MIU/vial (powder)

22.8 MIU/3.8 mL (3 MIU/0.5mL) (md vials)

32 MIU/3.2 mL (5 MIU/0.5mL) (md vials)

50 MIU/vial (powder)

Trade Name: **Keytruda**Proper Name: **Pembrolizumab**

BLA STN:

Approval Date:

Potency:

125514/0

9/4/2014

50 mg/vial

BLA STN:

Approval Date:

Potency:

125514/1

1/15/2015

100 mg/4 mL (25mg/mL)

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

BLA STN:

Approval Date:

Potency:

103949/5153

3/29/2011

296 mcg/vial

444 mcg/vial

888 mcg/vial

Applicant/License No: Merz Pharmaceuticals / License 1830Trade Name: **Xeomin**Proper Name: **IncobotulinumtoxinA**

BLA STN:

Approval Date:

Potency:

125360/0

7/30/2010

50 u/vial

100 u/vial

BLA STN:

Approval Date:

Potency:

125360/066

11/20/2015

200 u/vial

Applicant/License No: Novartis Pharmaceuticals Corporation / License 1244Trade Name: **Arzerra**Proper Name: **Ofatumumab**

BLA STN:

Approval Date:

Potency:

125326/0

10/26/2009

100 mg/5 mL (20 mg/mL)

CDER Billable Biologic Product List

Trade Name: **Cosentyx**
Proper Name: **Secukinumab**
BLA STN: 125504 Approval Date: 1/21/2015 Potency: 150 mg/mL syringe
150 mg/vial

Trade Name: **Extavia**
Proper Name: **Interferon Beta-1b**
BLA STN: 125290/0 Approval Date: 8/14/2009 Potency: 0.3 mg/vial

Trade Name: **Ilaris**
Proper Name: **Canakinumab**
BLA STN: 125319/0 Approval Date: 6/17/2009 Potency: 180 mg/vial

Trade Name: **Simulect**
Proper Name: **Basiliximab**
BLA STN: 103764/0 Approval Date: 5/12/1998 Potency: 10 mg/vial
20 mg/vial

Applicant/License No: **NPS Pharmaceuticals Inc. / License 125511**

Trade Name: **Natpara**
Proper Name: **Parathyroid hormone**
BLA STN: 125511 Approval Date: 1/23/2015 Potency: 0.4 mg/syringe (25 mcg/dose)
0.8 mg/syringe (50 mcg/dose)
1.21 mg/syringe (75 mcg/dose)
1.61 mg/syringe (100 mcg/dose)

Applicant/License No: **Prometheus Laboratories Inc. / License 1848**

Trade Name: **Proleukin**
Proper Name: **Aldesleukin**
BLA STN: 103293/0 Approval Date: 5/5/1992 Potency: 22 MIU/vial

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

Trade Name: **Arcalyst**
Proper Name: **Rilonacept**
BLA STN: 125249/0 Approval Date: 2/27/2008 Potency: 220 mg/vial

Trade Name: **Eylea**
Proper Name: **Aflibercept**
BLA STN: 125387 Approval Date: 11/18/2011 Potency: 2 mg/0.05 mL (40 mg/mL)

CDER Billable Biologic Product List

Applicant/License No: Sanofi-Aventis U.S. LLC / License 1752Trade Name: **Elitek**Proper Name: **Rasburicase**

BLA STN:	Approval Date:	Potency:
103946/0	7/12/2002	1.5 mg/vial
BLA STN:	Approval Date:	Potency:
103946/5020	1/6/2006	7.5 mg/vial

Trade Name: **Leukine**Proper Name: **Sargramostim**

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

Trade Name: **Praluent**Proper Name: **Alirocumab**

BLA STN:	Approval Date:	Potency:
125559/0	7/24/2015	75 mg/mL
		150 mg/mL

Trade Name: **Zaltrap**Proper Name: **ziv-aflibercept**

BLA STN:	Approval Date:	Potency:
125418/0	8/3/2012	25 mg/mL

Applicant/License No: Seattle Genetics, Inc. / License 1853Trade 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 1593Trade Name: **Elaprase**Proper Name: **Idursulfase**

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

Applicant/License No: Sicor Biotech, UAB / License 1803Trade Name: **Granix**Proper Name: **tbo-filgrastim**

BLA STN:	Approval Date:	Potency:
125294/0	8/29/2012	300 mcg/0.5mL (600 mcg/mL)

CDER Billable Biologic Product List

Applicant/License No: Smith & Nephew, Inc. / License 2004Trade Name: **Regranex**Proper Name: **Becaplermin**

BLA STN:

Approval Date:

Potency:

103691/0

12/16/1997

100 mcg/gram

Trade Name: **Santyl**Proper Name: **Collagenase**

BLA STN:

Approval Date:

Potency:

101995/0

6/4/1965

250 u/gram

Applicant/License No: Solstice NeuroSciences, LLC / License 1718Trade 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 1832Trade 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 (publ) / License 1828Trade Name: **Kepivance**Proper Name: **Palifermin**

BLA STN:

Approval Date:

Potency:

125103

12/15/2004

6.25 mg/vial

Trade Name: **Kineret**Proper Name: **Anakinra**

BLA STN:

Approval Date:

Potency:

103950/0

11/14/2001

100 mg/0.67 mL

Applicant/License No: Takeda Pharmaceuticals U.S.A., Inc. / License 1898Trade Name: **Entyvio**Proper Name: **Vedolizumab**

BLA STN:

Approval Date:

Potency:

125476/0

5/20/2014

300 mg/vial

Applicant/License No: Teva Respiratory, LLC / License 2047Trade Name: **Cinqair**Proper Name: **Reslizumab**

BLA STN:

Approval Date:

Potency:

761033

3/23/2016

100 mg/10 mL (10 mg/mL)

CDER Billable Biologic Product List

Applicant/License No: ThromboGenics Inc. / License 1866Trade Name: **Jetrea**Proper Name: **Ocriplasmin**

BLA STN:

Approval Date:

Potency:

125422/0

10/17/2012

0.5 mg/0.2 mL (2.5 mg/mL)

Applicant/License No: UCB, Inc. / License 1736Trade Name: **Cimzia**Proper Name: **Certolizumab pegol**

BLA STN:

Approval Date:

Potency:

125160/0

4/22/2008

200 mg/vial

BLA STN:

Approval Date:

Potency:

125160/080

5/13/2009

200 mg/mL

Applicant/License No: United Therapeutics Corp. / License 1993Trade Name: **Unituxin**Proper Name: **Dinutuximab**

BLA STN:

Approval Date:

Potency:

125516

3/10/2015

17.5 mg/5.0 mL

Applicant/License No: Vifor (International) Inc. / License 2039Trade Name: **Mircera**Proper Name: **Methoxypolyethylene glycol epoetin beta**

BLA STN:

Approval Date:

Potency:

125164/0

11/14/2007

50 mcg/0.3 mL

75 mcg/0.3 mL

100 mcg/0.3 mL

150 mcg/0.3 mL

200 mcg/0.3 mL

250 mcg/0.3 mL

BLA STN:

Approval Date:

Potency:

125164/073

4/28/2016

30 mcg/0.3 mL

120 mcg/0.3 mL

360 mcg/0.6 mL

Applicant/License No: Wyeth Pharmaceuticals, Inc. / License 0003Trade 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: Amgen, Inc. / License 1080Trade Name: **Aranesp**Proper Name: **Darbepoetin alfa (albumin solution)**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103951/0	9/17/2001	9/27/2012	25 mcg/0.42 mL syringe
		9/27/2012	25 mcg/mL vial
		9/27/2012	40 mcg/0.4 mL syringe
		9/27/2012	40 mcg/mL vial
		9/27/2012	60 mcg/0.3 mL syringe
		9/27/2012	60 mcg/mL vial
		9/27/2012	100 mcg/0.5 mL syringe
		9/27/2012	100 mcg/mL vial
		9/27/2012	150 mcg/0.3 mL syringe
		9/27/2012	150 mcg/0.75 mL vial
		9/27/2012	200 mcg/0.4 mL syringe
		9/27/2012	200 mcg/mL vial
		9/27/2012	300 mcg/0.6 mL syringe
		9/27/2012	300 mcg/mL vial
		9/27/2012	500 mcg/mL vial

Applicant/License No: Astellas Pharmaceuticals US, Inc. / License 1748Trade Name: **Amevive**Proper Name: **Alefacept**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
125036/0	1/30/2003	9/24/2008	7.5 mg/vial
		9/28/2012	15 mg/vial

Applicant/License No: Boehringer Ingelheim Pharma KG / License 1251Trade Name: **Verluma**Proper Name: **Nofetumomab**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103769/0	10/13/1998	8/13/2013	10 mg/mL

Applicant/License No: Centocor Ortho Biotech Products LP / License 1824Trade Name: **Orthoclone OKT3**Proper Name: **Muromonab-CD3**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103463/0	9/14/1992	1/11/2012	1 mg/mL

Applicant/License No: Eisai, Incorporated / License 1862Trade Name: **Ontak**Proper Name: **Denileukin diftitox**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103767/0	2/5/1999	1/30/2014	150 mcg/mL

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CDER Discontinued Biologic Product List

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Applicant/License No: Eli Lilly & Company / License 1611Trade Name: **Xigris**Proper Name: **Drotrecogin alfa (Activated)**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
125029/0	11/21/2001	10/26/2011	5 mg/vial
		10/10/2011	20 mg/vial

Applicant/License No: Genentech, Inc. / License 1048Trade Name: **Raptiva**Proper Name: **Efalizumab**

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

Trade Name: **Xolair**Proper Name: **Omalizumab**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103976/0	6/20/2003	8/25/2016	75 mg/vial

Applicant/License No: Genzyme Corp. / License 1596Trade 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: GlaxoSmithKline LLC / License 1727Trade Name: **Bexxar Therapeutic Regime**Proper Name: **Tositumomab and Iodine I-131 Tositumomab**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
125011/0	6/27/2003	3/10/2014	0.1 mg/mL I-131 Tositumomab
		3/10/2014	1.1 mg/mL I-131 Tositumomab
		3/10/2014	14 mg/mL Tositumomab

Applicant/License No: Hemispherx Biopharma, Inc. / License 1703Trade Name: **Alferon N Injection**Proper Name: **Interferon alfa-n3 (Human Leukocyte Derived)**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103158/0	10/10/1989	6/27/2013	5 MIU/vial

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

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CDER Discontinued Biologic Product List

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Trade Name: **Zenapax**Proper Name: **Daclizumab**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103749/0	12/10/1997	7/7/2011	25 mg/5 mL

Applicant/License No: **Kadmon Pharmaceuticals, LLC / License 1867**Trade Name: **Infergen**Proper Name: **Interferon alfacon-1**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103663/0	10/6/1997	7/25/2013	30 mcg/mL

Applicant/License No: **MedImmune, LLC / License 1799**Trade Name: **Synagis**Proper Name: **Palivizumab**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103770/0	6/19/1998	2/28/2007	50 mg/vial (powder)
		2/28/2007	100 mg/vial (powder)

Applicant/License No: **Merck Sharp & Dohme Corp. / License 0002**Trade Name: **Intron A**Proper Name: **Interferon alfa-2b**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103132/0	6/4/1986	9/23/2013	10 MIU/mL (solution)
		9/23/2013	22.5 MIU/1.5 mL md pen
		9/23/2013	37.5 MIU/1.5 mL md pen
		9/23/2013	75 MIU/1.5 mL md pen

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

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103949/0	1/19/2001	10/14/2016	67.5 mcg/pen (powder)
		10/14/2016	74 mcg/vial (powder)
		10/14/2016	108 mcg/pen (powder)
		10/1/2016	118.4 mcg/vial (powder)
		10/14/2016	162 mcg/pen (powder)
		10/1/2016	177.6 mcg/vial (powder)
		10/14/2016	202.5 mcg/pen (powder)
		10/1/2016	222 mcg/vial (powder)

Applicant/License No: **Palatin Technologies, Inc. / License 1588**Trade Name: **NeutroSpec Technetium (99m Tc)**Proper Name: **Fanolesomab**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
103928/0	7/2/2004	9/22/2008	0.25 mg/vial

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CDER Discontinued Biologic Product List

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Applicant/License No: Recordati Rare Diseases, Inc / License 1899Trade Name: **Elspar**Proper Name: **Asparaginase**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
101063/0	1/10/1978	4/9/2014	10000 IU/vial

Applicant/License No: Schering Corp. / License 0994Trade Name: **PegIntron/ReBETOL Combo Pack**Proper Name: **Peginterferon alfa-2b and Ribavirin**

BLA STN:	Approval Date:	Discontinued Date:	Potency:
125196/0	6/13/2008	6/25/2009	4 (120 mcg/0.5mL) Redipen & 140 (200 mg) capsules Ribavirin
		6/25/2009	4 (150 mcg/0.5mL) Redipen & 168 (200 mg) capsules Ribavirin
		6/25/2009	4 (150 mcg/0.5mL) Redipen & 196 (200 mg) capsules Ribavirin
		6/25/2009	4 (50 mcg/0.5mL) Redipen & 112 (200 mg) capsules Ribavirin
		6/25/2009	4 (80 mcg/0.5mL) Redipen & 112 (200 mg) capsules Ribavirin

Applicant/License No: Vifor (International) Inc. / License 2039Trade 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/mL
		9/24/2008	100 mcg/mL
		9/24/2008	200 mcg/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