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.

Program fees are assessed for each potency in which the approved (non-revoked, non-suspended) product is manufactured in final dosage form. When evaluating the specific strength or potency of a drug in final dosage form for purposes of assessing program fees for liquid parenteral biological products, CDER intends to take into consideration both the total amount of drug substance in mass or units of activity in a product and the concentration of drug substance (mass or units of activity per unit volume of product). Biologic products considered to have a different strength or potency in a final dosage form will be given separate entries in the Biologics List and assessed separate program fees. An auto-injector that has the same strength or potency as a prefilled syringe or vial will generally be assessed a separate prescription drug program fee. In certain circumstances, products which have been discontinued from marketing but are still licensed are not assessed program 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. Product Number is the FDA assigned number to identify the application products. Each strength is a separate product.

The list is updated three times a year. (Latest Update – March 2019)

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

Applicant/License No: **ABBVIE INC / 1889**

Trade Name: HUMIRA

Proper Name: ADALIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125057 / 0	1	12/31/2002	40 MG/0.8 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125057 / 394	2	11/23/2015	40 MG/0.4 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	3	12/31/2002	10 MG/0.2 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: ABBVIE INC / 1889

125057 / 0	4	12/31/2002	20 MG/0.4 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	5	12/31/2002	40 MG/0.8 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
125057 / 0	6	12/31/2002	10 MG/0.1 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	7	12/31/2002	20 MG/0.2 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	8	12/31/2002	40 MG/0.4 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
125057 / 0	9	12/31/2002	80 MG/0.8 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	10	12/31/2002	80 MG/0.8 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Applicant/License No: ABLYNX NV / 2085

Trade Name: CABLIVI

Proper Name: CAPLACIZUMAB-YHDP

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761112 / 0	1	2/6/2019	11 MG/VIAL (11 MG/VIAL) POWDER / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **AEGERION PHARMACEUTICALS INC / 2014**

Trade Name: MYALEPT

Proper Name: METRELEPTIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125390 / 0	1	2/24/2014	11.3 MG (11.3 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **ALEXION PHARMACEUTICALS INC / 1743**

Trade Name: KANUMA

Proper Name: SEBELIPASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125561 / 0	1	12/8/2015	20 MG/10 ML (2 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: SOLIRIS

Proper Name: ECULIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125166 / 0	1	3/16/2007	10 MG/ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: STRENSIQ

Proper Name: ASFOTASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125513 / 0	1	10/23/2015	18 MG/0.45 ML (40 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125513 / 0	2	10/23/2015	80 MG/0.8 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **ALEXION PHARMACEUTICALS INC / 1743**

125513 / 0	3	10/23/2015	28 MG/0.7 ML (40 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125513 / 0	4	10/23/2015	40 MG/ML (40 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: ULTOMIRIS

Proper Name: RAVULIZUMAB-CWVZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761108 / 0	1	12/21/2018	300 MG/30 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **ALLERGAN INC / 1145**

Trade Name: BOTOX

Proper Name: BOTULINUM TOXIN TYPE A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103000 / 0	1	12/9/1991	100 U (100 U/VIAL) POWDER / INTRAMUSCULAR, INTRADERMAL, INTRADETRUSOR / SINGLE-DOSE VIAL
103000 / 5101	3	4/14/2005	50 U (50 U/VIAL) POWDER / INTRAMUSCULAR, INTRADERMAL, INTRADETRUSOR / SINGLE-DOSE VIAL
103000 / 5122	5	11/10/2005	200 U (200 U/VIAL) POWDER / INTRAMUSCULAR, INTRADERMAL, INTRADETRUSOR / SINGLE-DOSE VIAL

Trade Name: BOTOX COSMETIC

Proper Name: BOTULINUM TOXIN TYPE A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103000 / 5000	2	4/12/2002	100 U (100 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **ALLERGAN INC / 1145**

103000 / 5101	4	4/14/2005	50 U (50 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **AMGEN INC / 1080**

Trade Name: AIMOVIG

Proper Name: ERENUMAB-AOOE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761077 / 0	1	5/17/2018	70 MG (70 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761077 / 0	2	5/17/2018	70 MG (70 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
761077 / 1	3	3/11/2019	140 MG (140 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761077 / 1	4	3/11/2019	140 MG (140 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: ARANESP

Proper Name: DARBEPOETIN ALFA IN POLYSORBATE SOLUTION

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103951 / 0	1	9/17/2001	25 MCG/ML (25 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103951 / 0	2	9/17/2001	40 MCG/ML (40 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103951 / 0	3	9/17/2001	60 MCG/ML (60 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: AMGEN INC / 1080

103951 / 0	4	9/17/2001	100 MCG/ML (100 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103951 / 0	5	9/17/2001	150 MCG/0.75 ML (150 MCG/0.75 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103951 / 0	6	9/17/2001	200 MCG/ML (200 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103951 / 0	7	9/17/2001	300 MCG/ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103951 / 0	8	9/17/2001	25 MCG/0.42 ML (25 MCG/0.42 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
103951 / 0	9	9/17/2001	40 MCG/0.4 ML (40 MCG/0.4 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
103951 / 0	10	9/17/2001	60 MCG/0.3 ML (60 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
103951 / 0	11	9/17/2001	100 MCG/0.5 ML (100 MCG/0.5 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
103951 / 0	12	9/17/2001	150 MCG/0.3 ML (150 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
103951 / 0	13	9/17/2001	200 MCG/0.4 ML (200 MCG/0.4 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
103951 / 0	14	9/17/2001	300 MCG/0.6 ML (300 MCG/0.6 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
103951 / 0	15	9/17/2001	500 MCG/ML (500 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **AMGEN INC / 1080**

103951 / 0	31	9/17/2001	10 MCG/0.4 ML (10 MCG/0.4 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: BLINCYTO

Proper Name: BLINATUMOMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125557 / 0	1	12/3/2014	35 MCG (35 MCG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: EPOGEN

Proper Name: EPOETIN ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103234 / 0	6	6/1/1989	10,000 U/ML (10,000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL
103234 / 0	7	6/1/1989	20,000 U/ML (10,000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

Proper Name: EPOETIN ALFA - PRESERVATIVE FREE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103234 / 0	1	6/1/1989	2000 U/ML (2000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103234 / 0	2	6/1/1989	3000 U/ML (3000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103234 / 0	3	6/1/1989	4000 U/ML (4000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103234 / 0	4	6/1/1989	10,000 U/ML (10,000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **AMGEN INC / 1080**

Trade Name: NEULASTA

Proper Name: PEGFILGRASTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125031 / 0	1	1/31/2002	6 MG/0.6 ML (10 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: NEULASTA ONPRO

Proper Name: PEGFILGRASTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125031 / 181	2	9/23/2015	6 MG/0.6 ML (10 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: NEUPOGEN

Proper Name: FILGRASTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103353 / 0	1	2/20/1991	300 MCG/ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103353 / 0	2	2/20/1991	300 MCG/0.5 ML (600 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
103353 / 0	3	2/20/1991	480 MCG/1.6 ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
103353 / 0	4	2/20/1991	480 MCG/0.8 ML (600 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: NPLATE

Proper Name: ROMIPLOSTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **AMGEN INC / 1080**

125268 / 0	1	8/22/2008	250 MCG (250 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
125268 / 0	2	8/22/2008	500 MCG (500 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: PROCRIT

Proper Name: EPOETIN ALFA - PRESERVATIVE FREE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103234 / 0	5	6/1/1989	40,000 U/ML (40,000 U/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: PROLIA

Proper Name: DENOSUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125320 / 0	1	6/1/2010	60 MG/ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: REPATHA

Proper Name: EVOLOCUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125522 / 0	1	8/27/2015	140 MG/ML (140 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125522 / 1	2	7/11/2016	420 MG/3.5 ML (120 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
125522 / 0	3	8/27/2015	140 MG/ML (140 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: VECTIBIX

Applicant/License No: **AMGEN INC / 1080**

Proper Name: PANITUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125147 / 0	1	9/27/2006	100 MG/5 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125147 / 0	3	9/27/2006	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: XGEVA

Proper Name: DENOSUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125320 / 7	2	11/18/2010	120 MG/1.7 ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **ASTRAZENECA AB / 2059**

Trade Name: LUMOXITI

Proper Name: MOXETUMOMAB PASUDOTOX-TDFK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761104 / 0	1	9/13/2018	1 MG/VIAL (1 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **ASTRAZENECA UK LTD / 2043**

Trade Name: FASENRA

Proper Name: BENRALIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761070 / 0	1	11/14/2017	30 MG/ML (30 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **ASTRAZENECA UK LTD / 2043**

Trade Name: IMFINZI

Proper Name: DURVALUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761069 / 0	1	5/1/2017	120 MG/2.4 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761069 / 0	2	5/1/2017	500 MG/10 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **AUXILIUM PHARMACEUTICALS INC / 1816**

Trade Name: XIAFLEX

Proper Name: CLOSTRIDIAL COLLAGENASE HISTOLYTICUM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125338 / 0	1	2/2/2010	0.9 MG (0.9 MG/VIAL) POWDER / INTRALESIONAL / SINGLE-DOSE VIAL

Applicant/License No: **AYTU BIOSCIENCES INC / 2035**

Trade Name: PROSTASCINT

Proper Name: CAPROMAB PENDETIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103608 / 0	1	10/28/1996	0.5 MG/ML (0.5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **BAXALTA US INC / 2020**

Trade Name: ONCASPAR

Proper Name: PEGASPARGASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103411 / 0	1	2/1/1994	3750 IU/5 ML (750 IU/ML) SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **BAYER HEALTHCARE PHARMACEUTICALS INC / 1778**

Trade Name: BETASERON

Proper Name: INTERFERON BETA-1B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103471 / 0	1	7/23/1993	0.3 MG (0.3 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **BIOGEN INC / 1697**

Trade Name: AVONEX

Proper Name: INTERFERON BETA 1A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103628 / 0	1	5/17/1996	30 MCG (30 MCG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
103628 / 0	2	5/17/1996	30 MCG/0.5 ML (30 MCG/0.5 ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
103628 / 0	3	5/17/1996	30 MCG/0.5 ML (30 MCG/0.5 ML) SOLUTION / INTRAMUSCULAR / AUTOINJECTOR

Trade Name: PLEGRIDY

Proper Name: PEGINTERFERON BETA-1A

Applicant/License No: **BIOGEN INC / 1697**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125499 / 0	1	8/15/2014	63 MCG/0.5 ML (126 MCG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125499 / 0	2	8/15/2014	125 MCG/0.5 ML (250 MCG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125499 / 0	3	8/15/2014	63 MCG/0.5 ML (126 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
125499 / 0	4	8/15/2014	94 MCG/0.5 ML (188 MCG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125499 / 0	5	8/15/2014	94 MCG/0.5 ML (188 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
125499 / 0	6	8/15/2014	125 MCG/0.5 ML (250 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: TYSABRI

Proper Name: NATALIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125104 / 0	1	11/23/2004	300 MG/15 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **BIOMARIN PHARMACEUTICAL INC / 1649**

Trade Name: ALDURAZYME

Proper Name: LARONIDASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125058 / 0	1	4/30/2003	2.9 MG/5 ML (0.58 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: BRINEURA

Proper Name: CERLIPONASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761052 / 0	1	4/27/2017	150 MG/5 ML (30 MG/ML) SOLUTION / INTRAVENTRICULAR / SINGLE-DOSE VIAL

Trade Name: NAGLAZYME

Proper Name: GALSULFASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125117 / 0	1	5/31/2005	5 MG/ 5ML (1 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PALYNZIQ

Proper Name: PEGVALIASE-PQPZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761079 / 0	1	5/24/2018	2.5 MG (5 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761079 / 0	2	5/24/2018	10 MG (20 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761079 / 0	3	5/24/2018	20 MG (20 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **BIOMARIN PHARMACEUTICAL INC / 1649**

Trade Name: VIMIZIM

Proper Name: ELOSULFASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125460 / 0	1	2/14/2014	5 MG/5 ML (1 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **BOEHRINGER INGELHEIM PHARMACEUTICALS INC / 2006**

Trade Name: PRAXBIND

Proper Name: IDARUCIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761025 / 0	1	10/16/2015	2500 MG/50 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **BRISTOL MYERS SQUIBB CO / 1713**

Trade Name: EMPLICITI

Proper Name: ELOTUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761035 / 0	1	11/30/2015	300 MG (300 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
761035 / 0	2	11/30/2015	400 MG (400 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: NULOJIX

Proper Name: BELATACEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **BRISTOL MYERS SQUIBB CO / 1713**

125288 / 0	1	6/15/2011	250 MG (250 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: OPDIVO

Proper Name: NIVOLUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125554 / 0	1	12/22/2014	40 MG/4 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125554 / 0	2	12/22/2014	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125554 / 0	3	12/22/2014	240 MG/24 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ORENCIA

Proper Name: ABATACEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125118 / 0	1	12/23/2005	250 MG (250 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125118 / 122	2	7/29/2011	50 MG/0.4 ML (125 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125118 / 122	3	7/29/2011	87.5 MG/0.7 ML (125 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125118 / 122	4	7/29/2011	125 MG/ML (125 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125118 / 122	5	7/29/2011	125 MG/ML (125 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Applicant/License No: **BRISTOL MYERS SQUIBB CO / 1713**

Trade Name: YERVOY

Proper Name: IPILIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125377 / 0	1	3/25/2011	50 MG/10 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125377 / 0	2	3/25/2011	200 MG/40 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **BTG INTERNATIONAL INC / 1861**

Trade Name: VORAXAZE

Proper Name: GLUCARPIDASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125327 / 0	1	1/17/2012	1,000 U (1,000 U/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **DOMPE FARMACEUTICI SPA / 2074**

Trade Name: OXERVATE

Proper Name: CENEGERMIN-BKBJ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761094 / 0	1	8/22/2018	20 MCG/ML (0.002%) SOLUTION / OPHTHALMIC / MULTI-DOSE VIAL

Applicant/License No: **DYAX CORPORATION / 1789**

Trade Name: KALBITOR

Proper Name: ECALLANTIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125277 / 0	1	12/1/2009	10 MG/ML (10 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: TAKHZYRO

Proper Name: LANADELUMAB-FLYO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761090 / 0	1	8/23/2018	300 MG/2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **EKR THERAPEUTICS INC / 1814**

Trade Name: RETAVASE

Proper Name: RETEPLASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103786 / 0	1	5/6/1998	10 U (10 U/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **ELI LILLY AND CO / 1891**

Trade Name: CYRAMZA

Proper Name: RAMUCIRUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125477 / 0	1	4/21/2014	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **ELI LILLY AND CO / 1891**

125477 / 0	2	4/21/2014	500 MG/50 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: EMGALITY

Proper Name: GALCANEZUMAB-GNLM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761063 / 0	1	9/27/2018	120 MG/ML (120 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761063 / 0	2	9/27/2018	120 MG/ML (120 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: LARTRUVO

Proper Name: OLARATUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761038 / 0	1	10/19/2016	500 MG/50 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761038 / 0	2	10/19/2016	190 MG/19 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PORTRAZZA

Proper Name: NECITUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125547 / 0	1	11/24/2015	800 MG/50 ML (16 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: TALTZ

Proper Name: IXEKIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **ELI LILLY AND CO / 1891**

125521 / 0	1	3/22/2016	80 MG/ML (80 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125521 / 0	2	3/22/2016	80 MG/ML (80 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: TRULICITY

Proper Name: DULAGLUTIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125469 / 0	3	9/18/2014	0.75 MG/0.5 ML (0.75 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
125469 / 0	4	9/18/2014	1.5 MG/0.5 ML (1.5 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Applicant/License No: **ELUSYS THERAPEUTICS INC / 1907**

Trade Name: ANTHIM

Proper Name: OBILTOXAXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125509 / 1	1	3/18/2016	600 MG/6 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **EMD SERONO INC / 1773**

Trade Name: BAVENCIO

Proper Name: AVELUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761049 / 0	1	3/23/2017	200 MG/10 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: REBIF

Applicant/License No: **EMD SERONO INC / 1773**

Proper Name: INTERFERON BETA 1A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103780 / 0	1	3/7/2002	8.8 MCG/0.2 ML (44 MCG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103780 / 0	2	3/7/2002	8.8 MCG/0.2 ML (44 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
103780 / 0	3	3/7/2002	22 MCG/0.5 ML (44 MCG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103780 / 0	4	3/7/2002	22 MCG/0.5 ML (44 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
103780 / 0	5	3/7/2002	44 MCG/0.5 ML (88 MCG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103780 / 0	6	3/7/2002	44 MCG/0.5 ML (88 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Applicant/License No: **EMERGENT MANUFACTURING OPERATIONS BALTIMORE LLC / 2083**

Trade Name: RAXIBACUMAB

Proper Name: RAXIBACUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125349 / 0	1	12/14/2012	1700 MG/34 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **EVOLUS INC / 2070**

Trade Name: JEUVEAU

Proper Name: PRABOTULINUMTOXINA-XVFS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761085 / 0	1	2/1/2019	100 UNITS/VIAL (100 UNITS/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **GENENTECH INC / 1048**

Trade Name: ACTEMRA

Proper Name: TOCILIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125276 / 0	1	1/8/2010	80 MG/4 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125276 / 0	2	1/8/2010	200 MG/10 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125276 / 0	3	1/8/2010	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125472 / 1	1	10/21/2013	162 MG/0.9 ML (179 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125472 / 29	2	11/19/2018	162 MG/0.9 ML (179 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: ACTIVASE

Proper Name: ALTEPLASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **GENENTECH INC / 1048**

103172 / 0	2	11/13/1987	50 MG (50 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103172 / 0	3	3/2/1992	100 MG (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: AVASTIN

Proper Name: BEVACIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125085 / 0	1	2/26/2004	100 MG/4 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125085 / 0	2	2/26/2004	400 MG/16 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: CATHFLO ACTIVASE

Proper Name: ALTEPLASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103172 / 0	1	9/4/2001	2 MG (2 MG/VIAL) POWDER / INTRACATHETER / SINGLE-DOSE VIAL

Trade Name: GAZYVA

Proper Name: OBINUYUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125486 / 0	1	11/1/2013	1000 MG/40 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: HEMLIBRA

Proper Name: EMICIZUMAB-KXWH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **GENENTECH INC / 1048**

761083 / 0	1	11/16/2017	30 MG/ML (30 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761083 / 0	2	11/16/2017	60 MG/0.4 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761083 / 0	3	11/16/2017	105 MG/0.7 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761083 / 0	4	11/16/2017	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: HERCEPTIN

Proper Name: TRASTUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103792 / 0	1	9/25/1998	420 MG (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL
103792 / 5336	2	2/10/2017	150 MG (150 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: HERCEPTIN HYLECTA

Proper Name: TRASTUZUMAB AND HYALURONIDASE-OYSK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761106 / 0	1	2/28/2019	600 MG/10000 UNITS/5ML (120 MG/2000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: KADCYLA

Proper Name: ADO-TRASIUZUMAB EMTANSINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **GENENTECH INC / 1048**

125427 / 0	1	2/22/2013	100 MG (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125427 / 0	2	2/22/2013	160 MG (160 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: LUCENTIS

Proper Name: RANIBIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125156 / 0	1	6/30/2006	0.5 MG/0.05 ML (10 MG/ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125156 / 076	2	8/10/2012	0.3 MG/0.05 ML (6 MG/ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: OCREVUS

Proper Name: OCRELIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761053 / 0	1	3/28/2017	300 MG/10 ML (30 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PERJETA

Proper Name: PERTUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125409 / 0	1	6/8/2012	420 MG/14 ML (30 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PULMOZYME

Proper Name: DORNASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **GENENTECH INC / 1048**

103532 / 0	1	12/30/1993	2.5 MG/2.5 ML (1 MG/ML) SOLUTION / INHALATION / AMPULE

Trade Name: RITUXAN

Proper Name: RITUXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103705 / 0	1	11/26/1997	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
103705 / 0	2	11/26/1997	500 MG/50 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: RITUXAN HYCELA

Proper Name: RITUXIMAB AND HYALURONIDASE HUMAN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761064 / 0	1	6/22/2017	1400 MG AND 23400 U/11.7 ML (120 MG AND 2000 U/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761064 / 0	2	6/22/2017	1600 MG AND 26800 U/13.4 ML (120 MG AND 2000 U/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: TECENTRIQ

Proper Name: ATEZOLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761034 / 0	1	5/8/2016	1200 MG/20 ML (60 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761034 / 18	2	3/8/2019	840 MG/14 ML (60 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: TNKASE

Applicant/License No: **GENENTECH INC / 1048**

Proper Name: TENECTEPLASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103909 / 0	1	6/2/2000	50 MG (50 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: XOLAIR

Proper Name: OMALIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103976 / 0	1	6/20/2003	150 MG/VIAL (150 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
103976 / 5231	3	9/28/2018	75 MG/0.5 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103976 / 5231	4	9/28/2018	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **GENZYME CORP / 1596**

Trade Name: CAMPATH

Proper Name: ALEMTUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103948 / 0	1	5/7/2001	30 MG/ML (30 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: FABRAZYME

Proper Name: AGALSIDASE BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **GENZYME CORP / 1596**

103979 / 0	1	4/24/2003	5 MG (5 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103979 / 0	2	4/24/2003	35 MG (35 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: LEMTRADA

Proper Name: ALEMTUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103948 / 5139	2	11/14/2014	12 MG/1.2 ML (10MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: LUMIZYME

Proper Name: ALGLUCOSIDASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125291 / 0	1	5/24/2010	50 MG (50 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **GLAXOSMITHKLINE LLC / 1727**

Trade Name: NUCALA

Proper Name: MEPOLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125526 / 0	1	11/14/2015	100 MG (100 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: TANZEUM

Proper Name: ALBIGLUTIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **GLAXOSMITHKLINE LLC / 1727**

125431 / 0	1	4/15/2014	30 MG (30 MG/AUTOINJECTOR) POWDER / SUBCUTANEOUS / AUTOINJECTOR
125431 / 0	2	4/15/2014	50 MG (50 MG/AUTOINJECTOR) POWDER / SUBCUTANEOUS / AUTOINJECTOR

Applicant/License No: **HOFFMANN LA ROCHE INC / 0136**

Trade Name: PEGASYS

Proper Name: PEGINTERFERON ALFA 2A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103964 / 5204	4	9/29/2011	180 MCG/0.5 ML (360 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Proper Name: PEG-INTERFERON ALFA-2A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103964 / 0	1	10/16/2002	180 MCG/ML (180 MCG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
103964 / 0	2	10/16/2002	180 MCG/0.5 ML (360 MCG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103964 / 5204	3	9/29/2011	135 MCG/0.5 ML (270 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Applicant/License No: **HORIZON PHARMA IRELAND LTD / 2022**

Trade Name: ACTIMMUNE

Proper Name: INTERFERON GAMMA-1B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103836 / 0	1	2/25/1999	100 MCG/0.5 ML (200 MCG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **HORIZON PHARMA RHEUMATOLOGY LLC / 1998**

Trade Name: KRYSTEXXA

Proper Name: PEGLOTICASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125293 / 0	1	9/14/2010	8MG/ML (8MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **HUMAN GENOME SCIENCES INC / 1820**

Trade Name: BENLYSTA

Proper Name: BELIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125370 / 0	1	3/9/2011	120 MG (120 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125370 / 0	2	3/9/2011	400 MG (400 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125370 / 0	3	3/9/2011	200 MG/ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125370 / 0	4	3/9/2011	200 MG/ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Applicant/License No: **HUMAN GENOME SCIENCES INC / 1820**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761043 / 0	1	7/20/2017	200 MG/ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **IMCLONE LLC / 1827**

Trade Name: ERBITUX

Proper Name: CETUXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125084 / 0	1	2/12/2004	100 MG/50 ML (2 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125084 / 0	2	2/12/2004	200 MG/100 ML (2 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **IMMUNEX CORP / 1132**

Trade Name: ENBREL

Proper Name: ETANERCEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103795 / 0	1	11/2/1998	25 MG (25 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL
103795 / 5184	2	9/27/2004	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103795 / 0	3	9/27/2004	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
103795 / 5184	4	9/27/2004	25 MG/0.5 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **IMMUNEX CORP / 1132**

103795 / 5556	5	9/14/2017	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Applicant/License No: **IPSEN BIOPHARM LIMITED / 1787**

Trade Name: DYSPORT

Proper Name: ABOBOTULINUMTOXINA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125274 / 0	1	4/29/2009	300 UNITS (300 UNITS/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
125274 / 0	2	4/29/2009	500 UNITS (500 UNITS/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **JANSSEN BIOTECH INC / 1864**

Trade Name: DARZALEX

Proper Name: DARATUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761036 / 0	1	11/16/2015	100 MG/5 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761036 / 0	2	11/16/2015	400 MG/20 ML (20 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: REMICADE

Proper Name: INFLIXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103772 / 0	1	8/24/1998	100 MG (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: REOPRO

Applicant/License No: **JANSSEN BIOTECH INC / 1864**

Proper Name: ABCIXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103575 / 0	1	12/22/1994	10 MG/5 ML (2 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: SIMPONI

Proper Name: GOLIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125289 / 0	1	4/24/2009	50 MG/0.5 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125289 / 0	2	4/24/2009	50 MG/0.5 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
125289 / 0	3	4/24/2009	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125289 / 0	4	4/24/2009	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: SIMPONI ARIA

Proper Name: GOLIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125433 / 0	1	7/18/2013	50 MG/4 ML (12.5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: STELARA

Proper Name: USTEKINUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **JANSSEN BIOTECH INC / 1864**

125261 / 0	1	9/25/2009	90 MG/ML (90 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125261 / 0	2	9/25/2009	45 MG/0.5 ML (90 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125261 / 0	3	9/25/2009	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761044 / 0	1	9/23/2016	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: SYLVANT

Proper Name: SILTUXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125496 / 0	1	4/23/2014	100 MG (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125496 / 0	2	4/23/2014	400 MG (400 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: TREMFYA

Proper Name: GUSELKUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761061 / 0	1	7/13/2017	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **JAZZ PHARMACEUTICALS INC / 1901**

Trade Name: ERWINAZE

Proper Name: ASPARAGINASE ERWINIA CHRYSANTHEMI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
105359 / 0	1	11/18/2011	10000 IU (10000 IU/VIAL) POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **KYOWA KIRIN INC / 2077**

Trade Name: POTELIGEO

Proper Name: MOGAMULIZUMAB-KPKC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761051 / 0	1	8/8/2018	20 MG/5 ML (4 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **LEADIANT BIOSCIENCES INC / 2073**

Trade Name: REVCOVI

Proper Name: ELAPEGADEMASE-LVLR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761092 / 0	1	10/5/2018	2.4 MG/1.5 ML (1.6 MG/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **MEDIMMUNE LLC / 1799**

Trade Name: SYNAGIS

Proper Name: PALIVIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103770 / 0	1	6/19/1998	50 MG/0.5 ML (100 MG/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **MEDIMMUNE LLC / 1799**

103770 / 0	2	6/19/1998	100 MG/ML (100 MG/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002**

Trade Name: INTRON A

Proper Name: INTERFERON ALFA-2B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103132 / 0	1	6/4/1986	10 MIU (10 MIU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS, INTRALESIONAL, INTRAVENOUS / SINGLE-DOSE VIAL
103132 / 0	2	6/4/1986	18 MIU (18 MIU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS / SINGLE-DOSE VIAL
103132 / 0	3	6/4/1986	50 MIU (50 MIU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS / SINGLE-DOSE VIAL
103132 / 0	4	6/4/1986	22.8 MIU/3.8 ML (6 MIU/ML) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL
103132 / 0	5	6/4/1986	32 MIU/3.2 ML (10 MIU/ML) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS, INTRALESIONAL / MULTI-DOSE VIAL

Trade Name: KEYTRUDA

Proper Name: PEMBROLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125514 / 1	2	1/15/2015	100 MG/4 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PEGINTRON

Proper Name: PEGINTERFERON ALFA-2B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation

Applicant/License No: **MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002**

103949 / 0	1	1/19/2001	74 MCG (74 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: SYLATRON

Proper Name: PEGINTERFERON ALFA-2B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103949 / 5153	2	3/29/2011	296 MCG (296 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
103949 / 5153	3	3/29/2011	444 MCG (444 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
103949 / 5153	4	3/29/2011	888 MCG (888 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: ZINPLAVA

Proper Name: BEZLOTOXUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761046 / 0	1	10/21/2016	1000 MG/40 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **MERZ PHARMACEUTICALS GMBH / 1830**

Trade Name: XEOMIN

Proper Name: INCOBOTULINUMTOXINA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125360 / 0	1	7/30/2010	50 U (50 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
125360 / 0	2	7/30/2010	100 U (100 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **MERZ PHARMACEUTICALS GMBH / 1830**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125360 / 3	3	11/20/2015	200 U (200 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **NOVARTIS PHARMACEUTICALS CORP / 1244**

Trade Name: ARZERRA

Proper Name: OFATUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125326 / 0	1	10/26/2009	100 MG/5 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125326 / 0	2	10/26/2009	1000 MG/50 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: COSENTYX

Proper Name: SECUKINUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125504 / 0	1	1/21/2015	150 MG (150 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
125504 / 0	2	1/21/2015	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125504 / 0	3	1/21/2015	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: EXTAVIA

Proper Name: INTERFERON BETA-1B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125290 / 0	1	8/14/2009	0.3 MG (0.3 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **NOVARTIS PHARMACEUTICALS CORP / 1244**

Trade Name: ILARIS

Proper Name: CANAKINUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125319 / 0	3	12/22/2016	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: SIMULECT

Proper Name: BASILIXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103764 / 0	1	5/12/1998	10 MG (10 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103764 / 0	2	5/12/1998	20 MG (20 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **NOVIMMUNE SA / 2082**

Trade Name: GAMIFANT

Proper Name: EMAPALUMAB-LZSG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761107 / 0	1	11/20/2018	10 MG/2 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761107 / 0	2	11/20/2018	50 MG/10 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **NPS PHARMACEUTICALS INC / 1908**

Trade Name: NATPARA

Proper Name: PARATHYROID HORMONE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125511 / 1	1	1/23/2015	0.4 MG/CARTRIDGE (25 MCG/DOSE) POWDER / SUBCUTANEOUS / AUTOINJECTOR
125511 / 1	2	1/23/2015	0.8 MG/CARTRIDGE (50 MCG/DOSE) POWDER / SUBCUTANEOUS / AUTOINJECTOR
125511 / 1	3	1/23/2015	1.21 MG/CARTRIDGE (75 MCG/DOSE) POWDER / SUBCUTANEOUS / AUTOINJECTOR
125511 / 1	4	1/23/2015	1.61 MG/CARTRIDGE (100 MCG/DOSE) POWDER / SUBCUTANEOUS / AUTOINJECTOR

Applicant/License No: **PARTNER THERAPEUTICS INC / 2087**

Trade Name: LEUKINE

Proper Name: SARGRAMOSTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103362 / 0	1	3/5/1991	250 MCG (250 MCG/VIAL) POWDER / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **PROMETHEUS LABORATORIES INC / 1848**

Trade Name: PROLEUKIN

Proper Name: ALDESLEUKIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103293 / 0	1	5/5/1992	22 MIU (22 MIU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **REGENERON PHARMACEUTICALS INC / 1760**

Trade Name: ARCALYST

Proper Name: RILONACEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125249 / 0	1	2/27/2008	220MG (220MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: DUPIXENT

Proper Name: DUPILUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761055 / 0	1	3/28/2017	300 MG/2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: EYLEA

Proper Name: AFLIBERCEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125387 / 0	1	11/18/2011	2 MG/0.05 ML (40 MG/ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL

Trade Name: LIBTAYO

Proper Name: CEMIPLIMAB-RWLC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761097 / 0	1	9/28/2018	350 MG/7 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **SANOFI AVENTIS US LLC / 1752**

Trade Name: ELITEK

Proper Name: RASBURICASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103946 / 0	1	7/12/2002	1.5 MG (1.5 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103946 / 5020	2	1/6/2006	7.5 MG (7.5 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: KEVZARA

Proper Name: SARILUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761037 / 0	1	5/22/2017	150 MG/1.14 ML (131.58 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761037 / 0	2	5/22/2017	200 MG/1.14 ML (175.44 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761037 / 1	3	4/13/2018	150 MG/1.14 ML (131.58 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
761037 / 1	4	4/13/2018	200 MG/1.14 ML (175.44 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: PRALUENT

Proper Name: ALIROCUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125559 / 0	1	7/24/2015	75 MG/ML (75 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **SANOFI AVENTIS US LLC / 1752**

125559 / 0	2	7/24/2015	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125559 / 0	3	7/24/2015	75 MG/ML (75 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR
125559 / 0	4	7/24/2015	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR

Trade Name: ZALTRAP

Proper Name: ZIV-AFLIBERCEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125418 / 0	1	8/3/2012	100 MG/4 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125418 / 0	2	8/3/2012	200 MG/8 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **SEATTLE GENETICS INC / 1853**

Trade Name: ADCETRIS

Proper Name: BRENTUXIMAB VEDOTIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125388 / 1	1	8/19/2011	50 MG (50 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **SERVIER PHARMACEUTICALS LLC / 2125**

Trade Name: ASPARLAS

Proper Name: CALASPARGASE PEGOL-MKNL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761102 / 0	1	12/20/2018	3750 UNITS/5 ML (750 UNITS/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **SHIRE HUMAN GENETIC THERAPIES INC / 1593**

Trade Name: ELAPRASE

Proper Name: IDURSULFASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125151 / 0	1	7/24/2006	6 MG/3 ML (2 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **SICOR BIOTECH UAB / 1803**

Trade Name: GRANIX

Proper Name: TBO-FILGRASTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125294 / 0	1	8/29/2012	300 MCG/0. 5 ML (600 MCG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125294 / 0	2	8/29/2012	480 MCG/0.8 ML (600 MCG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125294 / 45	3	7/31/2018	300 MCG/ML (300 MCG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125294 / 45	4	7/31/2018	480MCG/1.6 ML (300 MCG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **SMITH AND NEPHEW INC / 2004**

Trade Name: REGRANEX

Proper Name: BECAPLERMIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103691 / 0	1	12/16/1997	15 GM TUBE (100 UG/GM) GEL / TOPICAL /

Trade Name: SANTYL

Proper Name: COLLAGENASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101995 / 0	1	6/4/1965	30 GM & 90 GM TUBE (250 U/GM) OINTMENT / TOPICAL /

Applicant/License No: **SOLSTICE NEUROSCIENCES LLC / 1718**

Trade Name: MYOBLOC

Proper Name: RIMABOTULINUM TOXIN B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103846 / 0	1	12/8/2002	2500 IU/0.5 ML (5000 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
103846 / 0	3	12/8/2002	10,000 IU/2 ML (5000 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Proper Name: RIMABOTULINUMTOXINB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103846 / 0	2	12/8/2002	5000 IU/ML (5000 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: **SPECTRUM PHARMACEUTICALS INC / 1832**

Trade Name: ZEVALIN

Proper Name: IBRITUMOMAB TIUXETAN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125019 / 0	1	2/19/2002	3.2 MG/2 ML (1.6 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **STEMLINE THERAPEUTICS INC / 2088**

Trade Name: ELZONRIS

Proper Name: TAGRAXOFUSP-ERZS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761116 / 0	1	12/21/2018	1000 MCG/ML (1000 MCG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **SUN PHARMA GLOBAL FZE / 2092**

Trade Name: ILUMYA

Proper Name: TILDRAKIZUMAB-ASMN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761067 / 0	1	3/20/2018	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **SWEDISH ORPHAN BIOVITRUM AB / 1828**

Trade Name: KEPIVANCE

Proper Name: PALIFERMIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125103 / 0	1	12/15/2004	6.25 MG (6.25 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **SWEDISH ORPHAN BIOVITRUM AB / 1828**

Trade Name: KINERET

Proper Name: ANAKINRA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103950 / 0	1	11/14/2001	100 MG/0.67 ML (100 MG/0.67 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **TAKEDA PHARMACEUTICALS USA INC / 1898**

Trade Name: ENTYVIO

Proper Name: VEDOLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125476 / 0	1	5/20/2014	300 MG (300 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **TEVA PHARMACEUTICALS USA INC / 2016**

Trade Name: AJOVY

Proper Name: FREMANEZUMAB-VFRM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761089 / 0	1	9/14/2018	225 MG/1.5 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **TEVA RESPIRATORY LLC / 2047**

Trade Name: CINQAIR

Proper Name: RESLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761033 / 0	1	3/23/2016	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **THERATECHNOLOGIES INC / 2091**

Trade Name: TROGARZO

Proper Name: IBALIZUMAB-UIYK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761065 / 0	1	3/6/2018	200 MG/1.33 ML (150 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **THROMBOGENICS INC / 1866**

Trade Name: JETREA

Proper Name: OCRIPLASMIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125422 / 038	1	2/22/2017	0.375 MG/0.3 ML (1.25 MG/ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL

Applicant/License No: **UCB INC / 1736**

Trade Name: CIMZIA

Proper Name: CERTOLIZUMAB PEGOL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125160 / 0	1	4/22/2008	200 MG (200 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
125160 / 080	2	5/13/2009	200 MG/ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **ULTRAGENYX PHARMACEUTICAL INC / 2040**

Trade Name: CRYSVITA

Proper Name: BUROSUMAB-TWZA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761068 / 0	1	4/17/2018	10 MG/ML (10 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761068 / 0	2	4/17/2018	20 MG/ML (20 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761068 / 0	3	4/17/2018	30 MG/ML (30 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: MEPSEVII

Proper Name: VESTRONIDASE ALFA-VJBK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761047 / 0	1	11/15/2017	10 MG/5 ML (2 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **UNITED THERAPEUTICS CORP / 1993**

Trade Name: UNITUXIN

Proper Name: DINUTUXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125516 / 0	1	3/10/2015	17.5 MG/5 ML (3.5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **VALEANT PHARMACEUTICALS LUXEMBOURG SARL / 2053**

Trade Name: SILIQ

Proper Name: BRODALUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761032 / 0	1	2/15/2017	210 MG/1.5 ML (140 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **VIFOR INTERNATIONAL AG / 2039**

Trade Name: MIRCERA

Proper Name: METHOXYPOLYETHYLENE GLYCOL EPOETIN BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125164 / 0	1	11/14/2007	50 MCG/0.3 ML (166.66 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	2	11/14/2007	75 MCG/0.3 ML (250 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	3	11/14/2007	100 MCG/0.3 ML (333.33 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	4	11/14/2007	150 MCG/0.3 ML (500 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	5	11/14/2007	200 MCG/0.3 ML (666.66 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	6	11/14/2007	250 MCG/0.3 ML (833.33 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 073	7	4/28/2016	30 MCG/0.3 ML (100 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **VIFOR INTERNATIONAL AG / 2039**

125164 / 073	8	4/28/2016	120 MCG/0.3 ML (400 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 073	9	4/28/2016	360 MCG/0.6 ML (600 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **WYETH PHARMACEUTICALS INC / 0003**

Trade Name: BESPONSA

Proper Name: INOTUZUMAB OZOGAMICIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761040 / 0	1	8/17/2017	0.9 MG (0.9 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: MYLOTARG

Proper Name: GEMTUZUMAB OZOGAMICIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761060 / 0	1	9/1/2017	4.5 MG (4.5 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **AMGEN INC / 1080**

Trade Name: ARANESP

Proper Name: DARBEPOETIN ALFA (ALBUMIN SOLUTION)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103951 / 0	16	9/17/2001	25 MCG/ML (25 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/27/2012
103951 / 0	17	9/17/2001	25 MCG/0.42 ML (60 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/27/2012
103951 / 0	18	9/17/2001	40 MCG/ML (40 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/27/2012
103951 / 0	19	9/17/2001	40 MCG/0.4 ML (100 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/27/2012
103951 / 0	20	9/17/2001	60 MCG/ML (60 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/27/2012
103951 / 0	21	9/17/2001	60 MCG/0.3 ML (200 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/27/2012
103951 / 0	22	9/17/2001	100 MCG/ML (100 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/27/2012
103951 / 0	23	9/17/2001	100 MCG/0.5 ML (200 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/27/2012
103951 / 0	24	9/17/2001	150 MCG/0.75 ML (200 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/27/2012
103951 / 0	25	9/17/2001	150 MCG/0.3 ML (500 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/27/2012

Applicant/License No: **AMGEN INC / 1080**

Trade Name: ARANESP

103951 / 0	26	9/17/2001	200 MCG/ML (200 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/27/2012
103951 / 0	27	9/17/2001	200 MCG/0.4 ML (500 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/27/2012
103951 / 0	28	9/17/2001	300 MCG/ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/27/2012
103951 / 0	29	9/17/2001	300 MCG/0.6 ML (500 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/27/2012
103951 / 0	30	9/17/2001	500 MCG/ML (500 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/27/2012

Trade Name: VECTIBIX

Proper Name: PANITUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125147 / 0	2	9/27/2006	200 MG/10 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	06/29/2017

Applicant/License No: **ASTELLAS PHARMACEUTICALS US INC / 1748**

Trade Name: AMEVIVE

Proper Name: ALEFACEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125036 / 0	1	1/30/2003	7.5 MG/VIAL (7.5 MG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	09/24/2008
125036 / 0	2	1/30/2003	15 MG/VIAL (15 MG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	09/28/2012

Applicant/License No: **BOEHRINGER INGELHEIM PHARMA KG / 1251**

Trade Name: VERLUMA

Proper Name: NOFETUMOMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103769 / 0	1	10/13/1998	10 MG/ML (10 MG/ML) / INTRAVENOUS /	08/13/2013

Applicant/License No: **CENTOCOR ORTHO BIOTECH PRODUCTS LP / 1824**

Trade Name: ORTHOCLONE OKT3

Proper Name: MUROMONAB-CD3

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103463 / 0	1	9/14/1992	1 MG/ML (1 MG/ML) SOLUTION / INTRAVENOUS / AMPULE	01/11/2012

Applicant/License No: **EISAI INCORPORATED / 1862**

Trade Name: ONTAK

Proper Name: DENILEUKIN DIFTITOX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103767 / 0	1	2/5/1999	300 MCG/2 ML (150 MCG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	01/30/2014

Applicant/License No: **ELI LILLY AND CO / 1891**

Trade Name: TRULICITY

Proper Name: DULAGLUTIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125469 / 0	1	9/18/2014	0.75 MG/0.5 ML (0.75 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	06/28/2018

Applicant/License No: **ELI LILLY AND CO / 1891**

Trade Name: TRULICITY

125469 / 0	2	9/18/2014	1.5 MG/0.5 ML (1.5 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	06/28/2018

Trade Name: XIGRIS

Proper Name: DROTRECOGIN ALFA (ACTIVATED)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125029 / 0	1	11/21/2001	5 MG/VIAL (5 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	10/26/2011
125029 / 0	2	11/21/2001	20 MG/VIAL (20 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	10/10/2011

Applicant/License No: **GENENTECH INC / 1048**

Trade Name: RAPTIVA

Proper Name: EFALIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125075 / 0	1	10/27/2003	125 MG/VIAL (125 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	09/01/2009

Trade Name: XOLAIR

Proper Name: OMALIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103976 / 0	2	6/20/2003	125 MG/VIAL (125 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	08/25/2016

Applicant/License No: **GENZYME CORP / 1596**

Trade Name: CAMPATH

Proper Name: ALEMTUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103948 / 0	3	5/7/2001	10 MG/VIAL (10 MG/VIAL) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	07/06/2011

Trade Name: MYOZYME

Proper Name: ALGLUCOSIDASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125141 / 0	1	4/28/2006	50 MG/VIAL (50 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	10/17/2014

Applicant/License No: **GLAXOSMITHKLINE LLC / 1727**

Trade Name: BEXXAR THERAPEUTIC REGIME

Proper Name: TOSITUMOMAB AND IODINE I-131 TOSITUMOMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125011 / 0	1	6/27/2003	0.1 MG/ML I-131 TOSITUMOMAB (0.1 MG/ML I-131 TOSITUMOMAB) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	03/10/2014
125011 / 0	2	6/27/2003	1.1 MG/ML I-131 TOSITUMOMAB (1.1 MG/ML I-131 TOSITUMOMAB) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	03/10/2014
125011 / 0	3	6/27/2003	14 MG/ML TOSITUMOMAB (14 MG/ML TOSITUMOMAB) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	03/10/2014

Applicant/License No: **HEMISPHERX BIOPHARMA INC / 1703**

Trade Name: ALFERON N INJECTION

Proper Name: INTERFERON ALFA-N3 (HUMAN LEUKOCYTE DERIVED)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103158 / 0	1	10/10/1989	5 MIU/VIAL (5 MIU/VIAL) SOLUTION / INTRALESIONAL / MULTI-DOSE VIAL	06/27/2013

Applicant/License No: **HOFFMANN LA ROCHE INC / 0136**

Trade Name: ROFERON A

Proper Name: INTERFERON ALFA-2A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103145 / 0	1	6/4/1986	3 MIU/0.5 ML (3 MIU/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	06/01/2009

Trade Name: ZENAPAX

Proper Name: DACLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103749 / 0	1	12/10/1997	25 MG/5 ML (25 MG/5 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	07/07/2011

Applicant/License No: **KADMON PHARMACEUTICALS LLC / 1867**

Trade Name: INFERGEN

Proper Name: INTERFERON ALFACON-1

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103663 / 0	1	10/6/1997	9 MCG/0.3 ML (30 MCG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL	07/25/2013

Applicant/License No: **MEDIMMUNE LLC / 1799**

Trade Name: SYNAGIS

Proper Name: PALIVIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103770 / 0	3	6/19/1998	50 MG/VIAL (50 MG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	02/28/2007
103770 / 0	4	6/19/1998	100 MG/VIAL (100 MG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	02/28/2007

Applicant/License No: **MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002**

Trade Name: INTRON A

Proper Name: INTERFERON ALFA-2B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103132 / 0	6	6/4/1986	10 MIU/ML (10 MIU/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/23/2013
103132 / 0	7	6/4/1986	22.5 MIU/1.5 ML (22.5 MIU/1.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED PEN	09/23/2013
103132 / 0	8	6/4/1986	37.5 MIU/1.5 ML (37.5 MIU/1.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED PEN	09/23/2013
103132 / 0	9	6/4/1986	75 MIU/1.5 ML (75 MIU/1.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED PEN	09/23/2013

Trade Name: KEYTRUDA

Proper Name: PEMBROLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125514 / 0	1	9/4/2014	50 MG (50 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	06/13/2018

Trade Name: PEGINTRON

Applicant/License No: **MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002**

Trade Name: PEGINTRON

Proper Name: PEGINTERFERON ALFA-2B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103949 / 0	5	1/19/2001	67.5 MCG/PEN (67.5 MCG/PEN) POWDER / SUBCUTANEOUS / PREFILLED PEN	10/14/2016
103949 / 0	6	1/19/2001	108 MCG/PEN (108 MCG/PEN) POWDER / SUBCUTANEOUS / PREFILLED PEN	10/14/2016
103949 / 0	7	1/19/2001	118.4 MCG/VIAL (118.4 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	10/01/2016
103949 / 0	8	1/19/2001	162 MCG/PEN (162 MCG/PEN) POWDER / SUBCUTANEOUS / PREFILLED PEN	10/14/2016
103949 / 0	9	1/19/2001	177.6 MCG/VIAL (177.6 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	10/01/2016
103949 / 0	10	1/19/2001	202.5 MCG/PEN (202.5 MCG/PEN) POWDER / SUBCUTANEOUS / PREFILLED PEN	10/14/2016
103949 / 0	11	1/19/2001	222 MCG/VIAL (222 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	10/01/2016

Applicant/License No: **NOVARTIS PHARMACEUTICALS CORP / 1244**

Trade Name: ILARIS

Proper Name: CANAKINUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125319 / 0	1	6/17/2009	180 MG/VIAL (180 MG/VIAL) / /	05/25/2018

Applicant/License No: **NOVARTIS PHARMACEUTICALS CORP / 1244**

Trade Name: ILARIS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125319 / 88	2	12/22/2016	150 MG (150 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	05/25/2018

Applicant/License No: **PALATIN TECHNOLOGIES INC / 1588**

Trade Name: NEUTROSPEC TECHNETIUM (99M TC)

Proper Name: FANOLESOMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103928 / 0	1	7/2/2004	0.25 MG/VIAL (0.25 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	09/22/2008

Applicant/License No: **PARTNER THERAPEUTICS INC / 2087**

Trade Name: LEUKINE

Proper Name: SARGRAMOSTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103362 / 0	2	3/5/1991	500 MCG/ML (500 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL	06/15/2018

Applicant/License No: **RECORDATI RARE DISEASES INC / 1899**

Trade Name: ELSPAR

Proper Name: ASPARAGINASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
101063 / 0	1	1/10/1978	10000 IU (10000 IU/VIAL) POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	04/09/2014

Applicant/License No: **SCHERING CORP / 0994**

Trade Name: PEGINTRON/REBETOL COMBO PACK

Proper Name: PEGINTERFERON ALFA-2B AND RIBAVIRIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125196 / 0	1	6/13/2008	(4 (120 MCG/0.5ML) REDIPEN & 140 (200 MG) CAPSULES RIBAVIRIN) POWDER & CAPSULE (COMBO KIT) / SUBCUTANEOUS, ORAL /	06/25/2009
125196 / 0	2	6/13/2008	(4 (150 MCG/0.5ML) REDIPEN & 168 (200 MG) CAPSULES RIBAVIRIN) POWDER & CAPSULE (COMBO KIT) / SUBCUTANEOUS, ORAL /	06/25/2009
125196 / 0	3	6/13/2008	(4 (150 MCG/0.5ML) REDIPEN & 196 (200 MG) CAPSULES RIBAVIRIN) POWDER & CAPSULE (COMBO KIT) / SUBCUTANEOUS, ORAL /	06/25/2009
125196 / 0	4	6/13/2008	(4 (50 MCG/0.5ML) REDIPEN & 112 (200 MG) CAPSULES RIBAVIRIN) POWDER & CAPSULE (COMBO KIT) / SUBCUTANEOUS, ORAL /	06/25/2009
125196 / 0	5	6/13/2008	(4 (80 MCG/0.5ML) REDIPEN & 112 (200 MG) CAPSULES RIBAVIRIN) POWDER & CAPSULE (COMBO KIT) / SUBCUTANEOUS, ORAL /	06/25/2009

Applicant/License No: **THROMBOGENICS INC / 1866**

Trade Name: JETREA

Proper Name: OCRIPLASMIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125422 / 0	2	10/17/2012	0.5 MG (2.5 MG/ML) SOLUTION / INTRAVETREAL / SINGLE-DOSE VIAL	08/08/2017

Applicant/License No: **VIFOR INTERNATIONAL AG / 2039**

Trade Name: MIRCERA

Proper Name: METHOXYPOLYETHYLENE GLYCOL EPOETIN BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125164 / 0	10	11/14/2007	50 MCG/ML (50 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/24/2008
125164 / 0	11	11/14/2007	100 MCG/ML (100 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/24/2008
125164 / 0	12	11/14/2007	200 MCG/ML (200 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/24/2008
125164 / 0	13	11/14/2007	300 MCG/ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/24/2008
125164 / 0	14	11/14/2007	400 MCG/ML (400 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/24/2008
125164 / 0	15	11/14/2007	400 MCG/0.6 ML (400 MCG/0.6 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/24/2008
125164 / 0	16	11/14/2007	600 MCG/ML (600 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/24/2008
125164 / 0	17	11/14/2007	600 MCG/0.6 ML (600 MCG/0.6 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/24/2008
125164 / 0	18	11/14/2007	800 MCG/0.6 ML (800 MCG/0.6 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	09/24/2008
125164 / 0	19	11/14/2007	1000 MCG/ML (1000 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	09/24/2008