

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: ENDO GLOBAL AESTHETICS LTD / 2136**Trade Name:** QWO**Proper Name:** COLLAGENASE CLOSTRIDIUM HISTOLYTICUM-AAES

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761146 / 0	1	7/6/2020	0.92 MG (0.92 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
761146 / 0	2	7/6/2020	1.84 MG (1.84 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: EUSA PHARMA UK LIMITED / 2145**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

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 (100 UNITS/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: FERRING PHARMACEUTICALS INC / 2112**Trade Name:** ACTHREL**Proper Name:** CORTICORELIN OVINE TRIFLUTATE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020162 / 0	1	5/23/1996	100 MCG/VIAL (100MCG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: MENOPUR**Proper Name:**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021663 / 0	1	10/29/2004	75 IU/VIAL (75 IU/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: NOVAREL**Proper Name:** GONADOTROPIN, CHORIONIC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
017016 / 0	6	1/15/1974	5000 UNITS/VIAL (5000 UNITS/VIAL) POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL

Trade Name: ZOMACTON**Proper Name:** SOMATROPIN

Applicant/License No: FERRING PHARMACEUTICALS INC / 2112

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
019774 / 0	3	3/7/2012	10 MG/VIAL (10 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-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
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125276 / 0	3	1/8/2010	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
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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-PREFILLED PEN
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Trade Name: ACTIVASE**Proper Name:** ALTEPLASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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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: ENSPRYNG**Proper Name:** SATRALIZUMAB-MWGE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761149 / 0	1	8/14/2020	120 MG/ML (120 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: GAZYVA**Proper Name:** OBINUYUZUMAB

Applicant/License No: GENENTECH INC / 1048

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
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

Applicant/License No: GENENTECH INC / 1048**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
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: NUTROPIN AQ NUSPIN**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: GENENTECH INC / 1048

020522 / 0	3	1/3/2008	5 MG/2ML (2.5 MG/ML)
			SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

020522 / 0	4	1/3/2008	20 MG/2ML (10 MG/ML)
			SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

020522 / 0	5	1/3/2008	10 MG/2ML (5 MG/ML)
			SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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: PHESGO**Proper Name:** PERTUZUMAB, TRASTUZUMAB, AND HYALURONIDASE-ZZXF

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761170 / 0	1	6/29/2020	600 MG, 600 MG, 20000 UNITS/10 ML (60 MG, 60 MG, 2000 UNITS/ML)
			SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: GENENTECH INC / 1048

761170 / 0	2	6/29/2020	1200 MG, 600 MG, 30000 UNITS/15 ML (80 MG, 40 MG, 2000 UNITS/ML)
			SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: POLIVY**Proper Name:** POLATUZUMAB VEDOTIN-PIIQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761121 / 0	1	6/10/2019	140 MG (140 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PULMOZYME**Proper Name:** DORNASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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103532 / 0	1	12/30/1993	2.5 MG/2.5 ML (1 MG/ML)
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SOLUTION / INHALATION / AMPULE

Trade Name: RITUXAN**Proper Name:** RITUXIMAB

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

103705 / 0	2	11/26/1997	500 MG/50 ML (10 MG/ML)
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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
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Applicant/License No: JANSSEN BIOTECH INC / 1864

761036 / 0 2 11/16/2015 400 MG/20 ML (20 MG/ML)

SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: DARZALEX FASPRO**Proper Name:** DARATUMUMAB AND HYALURONIDASE-FIHJ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761145 / 0	1	5/1/2020	1800 MG/30000 UNITS/15 ML (120 MG/2000 UNITS/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: 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)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

125289 / 0	3	4/24/2009	100 MG/ML (100 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: JANSSEN BIOTECH INC / 1864

125289 / 0 4 4/24/2009 100 MG/ML (100 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: SIMPONI ARIA**Proper Name:** GOLIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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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
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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
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761044 / 0 1 9/23/2016 130 MG/26 ML (5 MG/ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: TREMFYA**Proper Name:** GUSELKUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: JANSSEN BIOTECH INC / 1864

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
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125359 / 0 1 11/18/2011 10000 IU (10000 IU/VIAL)

POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: JUBILANT DRAXIMAGE INC / 2186

Trade Name: DRAXIMAGE MAA

Proper Name: TECHNETIUM TC 99M ALBUMIN AGGREGATED KIT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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017881 / 0 1 12/30/1987 2.5 MG/5 MG/0.06 MG/1.2 MG/VIAL (2.5 MG/5 MG/0.06 MG/1.2 MG/VIAL)

POWDER / INTRAVENOUS / MULTI-DOSE VIAL

Applicant/License No: KYOWA KIRIN INC / 2077

Trade Name: CRYSVITA

Proper Name: BUROSUMAB-TWZA

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

Applicant/License No: KYOWA KIRIN INC / 2077

761068 / 0 3 4/17/2018 30 MG/ML (30 MG/ML)

SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: POTELIGEO**Proper Name:** MOGAMULIZUMAB-KPKC

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

SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: LUNDBECK SEATTLE BIOPHARMACEUTICALS INC / 2097**Trade Name:** VYEPTI**Proper Name:** EPTINEZUMAB-JJMR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761119 / 0 1 2/21/2020 100 MG/ML (100 MG/ML)

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: MANKIND CORP / 2190**Trade Name:** AFREZZA**Proper Name:** INSULIN RECOMBINANT HUMAN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
022472 / 0	1	6/27/2014	4 UNITS/INH (4 UNITS/INH) POWDER / INHALATION / CARTRIDGE
022472 / 0	2	6/27/2014	8 UNITS/INH (8 UNITS/INH) POWDER / INHALATION / CARTRIDGE
022472 / 0	3	4/17/2015	12 UNITS/INH (12 UNITS/INH) POWDER / INHALATION / CARTRIDGE

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
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
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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
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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
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Applicant/License No: MERZ PHARMACEUTICALS GMBH / 1830

125360 / 3 3 11/20/2015 200 U (200 U/VIAL)

POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: MORPHOSYS US INC / 2152**Trade Name:** MONJUV**Proper Name:** TAFASITAMAB-CXIX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761163 / 0 1 7/31/2020 200 MG (200 MG/VIAL)

POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: MYLAN PHARMACEUTICALS INC / 2210**Trade Name:** SEMGLEE**Proper Name:** INSULIN GLARGINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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210605 / 0 1 6/11/2020 1000 UNITS/ 10ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

210605 / 0 2 6/11/2020 300 UNITS/3 ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: NOVARTIS PHARMACEUTICALS CORP / 1244**Trade Name:** ADAKVEO**Proper Name:** CRIZANLIZUMAB-TMCA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761128 / 0 1 11/15/2019 100 MG/10 ML (10 MG/ML)

SOLUTION / INTRAVENOUS / 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: BEOVU**Proper Name:** BROLUCIZUMAB-DBLL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761125 / 0	1	10/7/2019	6 MG/0.05 ML (120 MG/ML) SOLUTION / INTRAVITREAL / 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-PREFILLED PEN

Trade Name: EXTAVIA**Proper Name:** INTERFERON BETA-1B

Applicant/License No: NOVARTIS PHARMACEUTICALS CORP / 1244

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

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: KESIMPTA**Proper Name:** OFATUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125326 / 70	3	8/20/2020	20 MG/0.4 ML (20 MG/0.4ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125326 / 70	4	8/20/2020	20 MG/0.4 ML (20 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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: NOVO NORDISK INC / 1261**Trade Name:** FIASP**Proper Name:** INSULIN ASPART

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
208751 / 0	1	9/27/2017	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: FIASP FLEXTOUCH**Proper Name:** INSULIN ASPART

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
208751 / 0	2	9/27/2017	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: FIASP PENFILL**Proper Name:** INSULIN ASPART

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
208751 / 0	3	9/24/2018	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE

Trade Name: LEVEMIR**Proper Name:** INSULIN DETEMIR RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021536 / 0	1	6/16/2005	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: LEVEMIR FLEXTOUCH**Proper Name:** INSULIN DETEMIR RECOMBINANT

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

Applicant/License No: NOVO NORDISK INC / 1261

021536 / 0 5 10/31/2013 300 UNITS/3 ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: NORDITROPIN FLEXPRO**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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021148 / 0 10 3/1/2010 15MG/1.5ML (10MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

021148 / 0 11 1/23/2015 30MG/3ML (10MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: NOVOLOG**Proper Name:** INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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020986 / 0 1 6/7/2000 1000 UNITS/10 ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: NOVOLOG FLEXPEN**Proper Name:** INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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020986 / 0 3 1/19/2001 300 UNITS/3 ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: NOVOLOG MIX 70/30**Proper Name:** INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: NOVO NORDISK INC / 1261

021172 / 0	1	11/1/2001	700 UNITS/10ML; 300 UNITS/10 ML (70 UNITS/ML; 30 UNITS/ML)
SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL			

Trade Name: NOVOLOG MIX 70/30 FLEXPEN**Proper Name:** INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021172 / 0	4	5/3/2002	210 UNITS/3ML; 90 UNITS/3 ML (70 UNITS/ML; 30 UNITS/ML)
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN			

Trade Name: NOVOLOG PENFILL**Proper Name:** INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020986 / 0	2	6/7/2000	300 UNITS/3 ML (100 UNITS/ML)
SOLUTION / SUBCUTANEOUS / CARTRIDGE			

Trade Name: PRALUENT**Proper Name:** ALIROCUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
203313 / 0	4	7/24/2015	150 MG/ML (150 MG/ML)
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN			

Trade Name: SOGROYA**Proper Name:** SOMAPACITAN-BECO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761156 / 0	1	8/28/2020	10 MG/1.5 ML (6.7 MG/ML)
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN			

Trade Name: TRESIBA

Applicant/License No: NOVO NORDISK INC / 1261**Proper Name:** INSULIN DEGLUDEC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
203314 / 0	1	9/25/2015	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
203314 / 0	2	9/25/2015	600 UNITS/3 ML (200 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
203314 / 0	3	11/21/2018	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: XULTOPHY 100/3.6**Proper Name:** INSULIN DEGLUDEC; LIRAGLUTIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
208583 / 0	1	11/21/2016	300 UNITS/3 ML; 10.8MG/3 ML (100 UNITS/ML; 3.6MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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 / CARTRIDGE
125511 / 1	2	1/23/2015	0.8 MG/CARTRIDGE (50 MCG/DOSE) POWDER / SUBCUTANEOUS / CARTRIDGE

Applicant/License No: NPS PHARMACEUTICALS INC / 1908

125511 / 1	3	1/23/2015	1.21 MG/CARTRIDGE (75 MCG/DOSE)
			POWDER / SUBCUTANEOUS / CARTRIDGE

125511 / 1	4	1/23/2015	1.61 MG/CARTRIDGE (100 MCG/DOSE)
			POWDER / SUBCUTANEOUS / CARTRIDGE

Applicant/License No: ONY INC / 2192**Trade Name:** INFASURF PRESERVATIVE FREE**Proper Name:** CALFACTANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020521 / 0	1	7/1/1998	105 MG/ 3 ML & 210 MG/ 6 ML (35 MG/ML)
			SUSPENSION / INTRATRACHEAL / SINGLE-DOSE VIAL

Applicant/License No: ORGANON USA INC / 2193**Trade Name:** FOLLISTIM AQ**Proper Name:** FOLLITROPIN ALFA/BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021211 / 0	1	3/23/2004	350 IU/0.42 ML (833.33 IU/ML)
			SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
021211 / 0	2	3/23/2004	650 IU/0.78 ML (833.33 IU/ML)
			SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
021211 / 0	4	2/11/2005	975 IU/1.17 ML (833.33 IU/ML)
			SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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: PFIZER INC / 2001**Trade Name:** ELELYSO**Proper Name:** TALIGLUCERASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
022458 / 0	1	5/1/2012	200 UNITS/VIAL (200 UNITS/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: PHARMACIA AND UPJOHN CO / 1216**Trade Name:** GENOTROPIN**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020280 / 0	6	8/24/1995	5.8 MG/VIAL (5.8 MG/VIAL) POWDER / SUBCUTANEOUS / CARTRIDGE
020280 / 0	7	10/23/1996	13.8 MG/VIAL (13.8 MG/VIAL) POWDER / SUBCUTANEOUS / CARTRIDGE

Trade Name: GENOTROPIN PRESERVATIVE FREE**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: PHARMACIA AND UPJOHN CO / 1216

020280 / 0	1	1/27/1998	0.2 MG/VIAL (0.2 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE
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020280 / 0	2	1/27/1998	0.4 MG/VIAL (0.4 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE
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020280 / 0	3	1/27/1998	0.6 MG/VIAL (0.6 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE
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020280 / 0	5	1/27/1998	0.8 MG/VIAL (0.8 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE
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020280 / 0	8	1/27/1998	1 MG/VIAL (1 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE
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020280 / 0	9	1/27/1998	1.2 MG/VIAL (1.2 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE
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020280 / 0	10	1/27/1998	1.4 MG/VIAL (1.4 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE
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020280 / 0	11	1/27/1998	1.6 MG/VIAL (1.6 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE
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020280 / 0	12	1/27/1998	1.8 MG/VIAL (1.8 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE
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020280 / 0	13	1/27/1998	2 MG/VIAL (2 MG/VIAL)
			POWDER / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: SOMAVERT**Proper Name:** PEGVISOMANT

Applicant/License No: PHARMACIA AND UPJOHN CO / 1216

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021106 / 0	1	3/25/2003	10MG/VIAL (10MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
021106 / 0	2	3/25/2003	15MG/VIAL (15MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
021106 / 0	3	3/25/2003	20MG/VIAL (20MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
021106 / 0	4	7/31/2014	25MG/VIAL (25MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
021106 / 0	5	7/31/2014	30MG/VIAL (30MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: QOL MEDICAL LLC / 2195**Trade Name:** SUCRAID**Proper Name:**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020772 / 0	1	4/9/1998	1003000 IU/118 ML (8500 IU/ML) SOLUTION / ORAL /

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
761055 / 7	2	10/19/2018	200 MG/1.14 ML (175 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761055 / 0	3	6/18/2020	300 MG/2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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 & PREFILLED SYRINGE

Trade Name: LIBTAYO**Proper Name:** CEMIPILIMAB-RWLC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: REGENERON PHARMACEUTICALS INC / 1760

761097 / 0 1 9/28/2018 350 MG/7 ML (50 MG/ML)

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PRALUENT**Proper Name:** ALIROCUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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125559 / 0 3 7/24/2015 75 MG/ML (75 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: SANDOZ INC / 2003**Trade Name:** OMNITROPE**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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021426 / 0 1 5/30/2006 5.8 MG/VIAL (5.8 MG/VIAL)

POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

021426 / 0 2 5/30/2006 1.5 MG/VIAL (1.5 MG/VIAL)

POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: SANOFI AVENTIS US LLC / 1752**Trade Name:** ADLYXIN**Proper Name:** LIXISENATIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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208471 / 0 1 7/27/2016 0.15MG/3ML (0.05MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: SANOFI AVENTIS US LLC / 1752

208471 / 0	2	7/27/2016	0.3MG/3ML (0.1MG/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: ADMELOG**Proper Name:** INSULIN LISPRO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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209196 / 0	1	12/11/2017	1000 UNITS/10 ML (100 UNITS/ML)
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SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

209196 / 0	3	10/19/2018	300 UNITS/3 ML (100 UNITS/ML)
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SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: ADMELOG SOLOSTAR**Proper Name:** INSULIN LISPRO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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209196 / 0	2	12/11/2017	300 UNITS/3 ML (100 UNITS/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: APIDRA**Proper Name:** INSULIN GLULISINE RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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021629 / 0	1	4/16/2004	1000 UNITS/10 ML (100 UNITS/ML)
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SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: APIDRA SOLOSTAR**Proper Name:** INSULIN GLULISINE RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: SANOFI AVENTIS US LLC / 1752

021629 / 0 3 2/24/2009 300 UNITS/3 ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: ELITEK**Proper Name:** RASBURICASE

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

761037 / 1 4 4/13/2018 200 MG/1.14 ML (175.44 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: LANTUS**Proper Name:** INSULIN GLARGINE RECOMBINANT

Applicant/License No: SANOFI AVENTIS US LLC / 1752

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021081 / 0	1	4/20/2000	1000 UNITS/10 ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: LANTUS SOLOSTAR**Proper Name:** INSULIN GLARGINE RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021081 / 0	2	4/27/2007	300 UNITS/3 ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: SARCLISA**Proper Name:** ISATUXIMAB-IRFC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761113 / 0	1	3/2/2020	100 MG/5 ML (20 MG/ML)

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

761113 / 0	2	3/2/2020	500 MG/25 ML (20 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: SOLIQUA 100/33**Proper Name:** INSULIN GLARGINE; LIXISENATIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
208673 / 0	1	11/21/2016	300 UNITS/3 ML; 99MCG/3 ML (100 UNITS/ML; 33MCG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: TOUJEO MAX SOLOSTAR**Proper Name:** INSULIN GLARGINE RECOMBINANT

Applicant/License No: SANOFI AVENTIS US LLC / 1752

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
206538 / 0	2	3/26/2018	900 UNITS/3 ML (300 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: TOUJEO SOLOSTAR**Proper Name:** INSULIN GLARGINE RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
206538 / 0	1	2/25/2015	450 UNITS/1.5 ML (300 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

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: 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

Trade Name: VPRIV**Proper Name:** VELAGLUCERASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
022575 / 0	1	2/26/2010	400 UNITS/VIAL (400 UNITS/VIAL) POWDER / 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: 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 / 1859**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
761107 / 0	3	6/26/2020	100 MG/20 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: KINERET**Proper Name:** ANAKINRA

Applicant/License No: SWEDISH ORPHAN BIOVITRUM AB / 1859

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
761089 / 2	2	1/27/2020	225MG/1.5 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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
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761033 / 0	1	3/23/2016	100 MG/10 ML (10 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: THERATECHNOLOGIES INC / 2091**Trade Name:** EGRIFTA**Proper Name:** TESAMORELIN ACETATE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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022505 / 0	2	11/10/2010	2MG BASE/VIAL (2MG BASE/VIAL)
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: TROGARZO**Proper Name:** IBALIZUMAB-UIYK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761065 / 0	1	3/6/2018	200 MG/1.33 ML (150 MG/ML)
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SOLUTION / INTRAVENOUS / 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
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125160 / 0	1	4/22/2008	200 MG (200 MG/VIAL)
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: UCB INC / 1736

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: MEPSEVII

Proper Name: VESTRONIDASE ALFA-VJBK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761047 / 0	1	11/15/2017	10 MG/5 ML (2 MG/ML)
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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
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125516 / 0	1	3/10/2015	17.5 MG/5 ML (3.5 MG/ML)
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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
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761032 / 0	1	2/15/2017	210 MG/1.5 ML (140 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: VIELA BIO / 2129**Trade Name:** UPLIZNA**Proper Name:** INEBILIZUMAB-CDON

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761142 / 0	1	6/11/2020	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

Applicant/License No: VIFOR INTERNATIONAL AG / 2039

125164 / 073	7	4/28/2016	30 MCG/0.3 ML (100 MCG/ML)
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
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: VIOKACE LLC / 2196**Trade Name:** VIOKACE**Proper Name:** PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
022542 / 0	1	3/1/2012	39,150USP UNITS; 10,440USP UNITS; 39,150USP UNITS (39,150USP UNITS; 10,440USP UNITS; 39,150USP UNITS) TABLET / ORAL /
022542 / 0	2	3/1/2012	78,300USP UNITS; 20,880USP UNITS; 78,300USP UNITS (78,300USP UNITS; 20,880USP UNITS; 78,300USP UNITS) TABLET / ORAL /

Applicant/License No: VIVUS INC / 2197**Trade Name:** PANCREAZE**Proper Name:** PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
022523 / 0	1	4/12/2010	24,600USP UNITS; 4,200USP UNITS; 14,200USP UNITS (24,600USP UNITS; 4,200USP UNITS; 14,200USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
022523 / 0	2	4/12/2010	61,500USP UNITS; 10,500USP UNITS; 35,500USP UNITS (61,500USP UNITS; 10,500USP UNITS; 35,500USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /

Applicant/License No: VIVUS INC / 2197

022523 / 0	3	4/12/2010	98,400USP UNITS; 16,800USP UNITS; 56,800USP UNITS (98,400USP UNITS; 16,800USP UNITS; 56,800USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
022523 / 0	4	4/12/2010	83,900USP UNITS; 21,000USP UNITS; 54,700USP UNITS (83,900USP UNITS; 21,000USP UNITS; 54,700USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
022523 / 0	5	3/7/2014	10,850USP UNITS; 2,600USP UNITS; 6,200USP UNITS (10,850USP UNITS; 2,600USP UNITS; 6,200USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /

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: ZENPEP LLC / 2198**Trade Name:** ZENPEP**Proper Name:** PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
022210 / 0	1	8/27/2009	24,000USP UNITS; 5,000USP UNITS; 17,000USP UNITS (24,000USP UNITS; 5,000USP UNITS; 17,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
022210 / 0	2	8/27/2009	42,000USP UNITS; 10,000USP UNITS; 32,000USP UNITS (42,000USP UNITS; 10,000USP UNITS; 32,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
022210 / 0	3	8/27/2009	63,000USP UNITS; 15,000USP UNITS; 47,000USP UNITS (63,000USP UNITS; 15,000USP UNITS; 47,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
022210 / 0	4	8/27/2009	84,000USP UNITS; 20,000USP UNITS; 63,000USP UNITS (84,000USP UNITS; 20,000USP UNITS; 63,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
022210 / 0	5	6/15/2011	14,000USP UNITS; 3,000USP UNITS; 10,000USP UNITS (14,000USP UNITS; 3,000USP UNITS; 10,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
022210 / 0	6	7/13/2011	105,000USP UNITS; 25,000USP UNITS; 79,000USP UNITS (105,000USP UNITS; 25,000USP UNITS; 79,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
022210 / 0	7	3/25/2014	168,000USP UNITS; 40,000USP UNITS; 126,000USP UNITS (168,000USP UNITS; 40,000USP UNITS; 126,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /

Applicant/License No: AKORN INC / 2173

Trade Name: HYDASE

Proper Name: HYALURONIDASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021716 / 0	1	10/25/2005	150 UNITS/ML (150 UNITS/ML) SOLUTION / INTERSTITIAL, INTRAOCULAR, RETROBULBAR, SOFT TISSUE, SUBCUTANEOUS / SINGLE-DOSE VIAL	5/5/2020

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	9/27/2012
103951 / 0	17	9/17/2001	25 MCG/0.42 ML (60 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	9/27/2012
103951 / 0	18	9/17/2001	40 MCG/ML (40 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/27/2012
103951 / 0	19	9/17/2001	40 MCG/0.4 ML (100 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	9/27/2012
103951 / 0	20	9/17/2001	60 MCG/ML (60 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/27/2012
103951 / 0	21	9/17/2001	60 MCG/0.3 ML (200 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	9/27/2012
103951 / 0	22	9/17/2001	100 MCG/ML (100 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/27/2012

Applicant/License No: AMGEN INC / 1080

Trade Name: ARANESP

103951 / 0	23	9/17/2001	100 MCG/0.5 ML (200 MCG/ML)	9/27/2012
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE				
103951 / 0	24	9/17/2001	150 MCG/0.75 ML (200 MCG/ML)	9/27/2012
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				
103951 / 0	25	9/17/2001	150 MCG/0.3 ML (500 MCG/ML)	9/27/2012
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE				
103951 / 0	26	9/17/2001	200 MCG/ML (200 MCG/ML)	9/27/2012
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				
103951 / 0	27	9/17/2001	200 MCG/0.4 ML (500 MCG/ML)	9/27/2012
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE				
103951 / 0	28	9/17/2001	300 MCG/ML (300 MCG/ML)	9/27/2012
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				
103951 / 0	29	9/17/2001	300 MCG/0.6 ML (500 MCG/ML)	9/27/2012
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE				
103951 / 0	30	9/17/2001	500 MCG/ML (500 MCG/ML)	9/27/2012
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				

Proper Name: DARBEPOETIN ALFA IN POLYSORBATE SOLUTION

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103951 / 0	5	9/17/2001	150 MCG/0.75 ML (150 MCG/0.75 ML)	12/20/2018
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				

Trade Name: VECTIBIX

Proper Name: PANITUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
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Applicant/License No: AMGEN INC / 1080

Trade Name: VECTIBIX

125147 / 0	2	9/27/2006	200 MG/10 ML (20 MG/ML)	6/29/2017
SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL				

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 (7.5 MG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	9/24/2008
125036 / 0	2	1/30/2003	15 MG (15 MG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	9/28/2012

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	Date added to Discontinued List
103608 / 0	1	10/28/1996	0.5 MG/ML (0.5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	5/16/2019

Applicant/License No: BAUSCH AND LOMB INC / 2180

Trade Name: VITRASE

Proper Name: HYALURONIDASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021640 / 0	1	5/5/2004	6200 UNITS/ML (6200 UNITS/ML) SOLUTION / INTERSTITIAL, INTRAMUSCULAR, INTRAOCULAR, PERIBULBAR, RETROBULBAR, SOFT TISSUE, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/23/2009

Applicant/License No: BAUSCH HEALTH US LLC / 2181

Trade Name: IPRIVASK

Proper Name: DESIRUDIN RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021271 / 0	1	4/4/2003	15 MG/VIAL (15 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	9/27/2018

Applicant/License No: BAYER HEALTHCARE PHARMACEUTICALS INC / 1778

Trade Name: TRASYLOL

Proper Name: APROTININ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020304 / 0	1	12/29/1993	1,000,000 KIU/100 ML (10000 KIU/ ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	5/25/2012
020304 / 0	2	12/29/1993	2,000,000 KIU/200 ML (10000 KIU/ ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	5/25/2012

Applicant/License No: BEL MAR LABORATORIES INC / 2182

Trade Name: CHORIONIC GONADOTROPIN

Proper Name: GONADOTROPIN, CHORIONIC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017054 / 0	1	3/26/1974	5000 UNITS/VIAL (5000 UNITS/VIAL) / /	1/1/1990
017054 / 0	2	3/26/1974	10000 UNITS/VIAL (10000 UNITS/VIAL) / /	1/1/1990

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	Date added to Discontinued List
103628 / 0	1	5/17/1996	30 MCG (30 MCG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/30/2018

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 /	8/13/2013

Applicant/License No: BRACCO DIAGNOSTICS INC / 2183

Trade Name: MACROTEC

Proper Name: TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017833 / 0	1	2/23/1976	1.5 MG/10 MG/0.07 MG/0.19 MG/1.8 MG/VIAL (1.5 MG/10 MG/0.07 MG/0.19 MG/1.8 MG/VIAL) POWDER / INTRAVENOUS /	2/5/2018

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	1/11/2012

Applicant/License No: DISCURE MEDICAL LLC / 2185

Trade Name: CHYMODIACTIN

Proper Name: CHYMOPAPAIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
018663 / 0	1	11/10/1982	10000 UNITS/VIAL (10000 UNITS/VIAL) POWDER / INTRADISCAL / MULTI-DOSE VIAL	1/1/1900
018663 / 0	2	8/21/1984	4000 UNITS/VIAL (4000 UNITS/VIAL) POWDER / INTRADISCAL / MULTI-DOSE VIAL	7/16/2002

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	1/30/2014

Applicant/License No: ELI LILLY AND CO / 1891

Trade Name: HUMALOG MIX 50/50 PEN

Proper Name: INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021018 / 0	3	12/22/1999	150 UNITS/3 ML; 150 UNITS/3 ML (50 UNITS/ML; 50 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	6/22/2012

Trade Name: HUMALOG MIX 75/25 PEN

Proper Name: INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021017 / 0	3	12/22/1999	226 UNITS/3 ML; 75 UNITS/3 ML (75 UNITS/ML; 25 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	6/22/2012

Trade Name: HUMALOG PEN

Applicant/License No: ELI LILLY AND CO / 1891

Trade Name: HUMALOG PEN

Proper Name: INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020563 / 0	2	8/6/1998	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE	6/22/2012

Trade Name: HUMATROPE

Proper Name: SOMATROPIN RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
019640 / 0	1	6/23/1987	2 MG/VIAL (2 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	1/1/1900

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	6/28/2018
125469 / 0	2	9/18/2014	1.5 MG/0.5 ML (1.5 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	6/28/2018

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 (5 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	10/26/2011
125029 / 0	2	11/21/2001	20 MG (20 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	10/10/2011

Applicant/License No: EMD SERONO INC / 1773

Trade Name: GONAL-F

Proper Name: FOLLITROPIN ALFA/BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020378 / 0	1	9/29/1997	75 IU/VIAL (NF) / /	7/8/2004
020378 / 0	2	9/29/1997	150 IU/VIAL (NF) / /	7/8/2004
020378 / 0	3	9/29/1997	37.5 IU/VIAL (NF) / /	6/25/2002
BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021765 / 0	1	3/25/2004	37.5 IU/VIAL (NF) / /	6/7/2004
021765 / 0	3	3/25/2004	150 IU/VIAL (NF) / /	6/7/2004

Trade Name: GONAL-F RFF REDI-JECT

Proper Name: FOLLITROPIN ALFA/BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021684 / 0	4	11/25/2019	150 IU/0.25 ML (600 IU/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	2/27/2020

Trade Name: OVIDREL

Proper Name: CHORIOGONADOTROPIN ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021149 / 0	1	9/20/2000	0.25 MG/VIAL (0.25 MG/VIAL) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL	6/7/2004

Trade Name: PERGONAL

Applicant/License No: EMD SERONO INC / 1773

Trade Name: PERGONAL

Proper Name: MENOTROPINS (FSH;LH)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017646 / 0	1	8/22/1975	75 IU/VIAL (75 IU/VIAL) POWDER / /	2/1/2002
017646 / 0	2	8/22/1975	150 IU/VIAL (150 IU/VIAL) POWDER / /	6/7/2004

Trade Name: SAIZEN

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
019764 / 0	1	10/8/1996	6 MG/VIAL (6 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	6/7/2004
019764 / 0	5	1/16/2007	4 MG/VIAL (4 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	6/7/2004

Trade Name: SEROSTIM

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020604 / 0	4	9/6/2001	8.8 MG/VIAL (8.8 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	5/14/2008

Trade Name: SEROSTIM LQ

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020604 / 0	5	2/11/2005	6 MG/0.5 ML (12 MG/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE	5/14/2008

Trade Name: ZORBITIVE

Applicant/License No: EMD SERONO INC / 1773

Trade Name: ZORBTIVE

Proper Name: SOMATROPIN RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021597 / 0	1	12/1/2003	4 MG/VIAL (4 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL	6/7/2004
021597 / 0	2	12/1/2003	5 MG/VIAL (5 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL	6/7/2004
021597 / 0	3	12/1/2003	6 MG/VIAL (6 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL	6/7/2004

Applicant/License No: EMERGENT BIOSOLUTIONS CANADA INC / 2084

Trade Name: ACCRETROPIN

Proper Name: SOMATROPIN RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021538 / 0	1	1/23/2008	5 MG/ML (5 MG/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL	7/31/2009

Applicant/License No: FERRING PHARMACEUTICALS INC / 2112

Trade Name: A.P.L.

Proper Name: GONADOTROPIN, CHORIONIC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017055 / 0	1	12/13/1974	5000 UNITS/VIAL (5000 UNITS/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	6/23/2003
017055 / 0	2	12/13/1974	10000 UNITS/VIAL (10000 UNITS/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	6/23/2003

Applicant/License No: FERRING PHARMACEUTICALS INC / 2112

Trade Name: A.P.L.

017055 / 0	3	12/13/1974	20000 UNITS/VIAL (20000 UNITS/VIAL)	6/20/2002
POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL				

Trade Name: BIO-TROPIN

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
019774 / 0	1	5/25/1995	4.8 MG/VIAL (4.8 MG/VIAL)	3/20/2003
POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL				

Trade Name: BRAVELLE

Proper Name: UROFOLLITROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021289 / 0	1	5/6/2002	82.5 IU/VIAL (82.5 IU/VIAL)	6/30/2003
POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL				

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021484 / 0	1		82.5 IU/VIAL (82.5 IU/VIAL)	6/5/2018
POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL				

Trade Name: NOVAREL

Proper Name: GONADOTROPIN, CHORIONIC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017016 / 0	4	1/15/1974	20000 UNITS/VIAL (20000 UNITS/VIAL)	10/12/1994
POWDER / /				

017016 / 0	9	12/27/1984	2000 UNITS/VIAL (2000 UNITS/VIAL)	1/1/1900
POWDER / /				

017016 / 0	10	1/15/1974	15000 UNITS/VIAL (15000 UNITS/VIAL)	10/12/1994
POWDER / /				

Applicant/License No: FERRING PHARMACEUTICALS INC / 2112

Trade Name: NOVAREL

017016 / 0	11	2/16/1990	2000 UNITS/VIAL (2000 UNITS/VIAL)	6/28/2002
POWDER / /				

Trade Name: REPRONEX

Proper Name: MENOTROPINS (FSH;LH)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021047 / 0	1	8/27/1999	75 IU/VIAL (75 IU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	2/1/2002
021047 / 0	2	5/20/1985	150 IU/VIAL (150 IU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	5/6/2003

Applicant/License No: FRESENIUS KABI USA LLC / 2146

Trade Name: CHORIONIC GONADOTROPIN

Proper Name: GONADOTROPIN, CHORIONIC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017067 / 0	1	3/5/1973	5000 UNITS/VIAL (5000 UNITS/VIAL) POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL	6/23/1994
017067 / 0	3	3/5/1973	15000 UNITS/VIAL (15000 UNITS/VIAL) POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL	1/1/1900
017067 / 0	4	3/5/1973	20000 UNITS/VIAL (20000 UNITS/VIAL) POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL	6/23/1994

Applicant/License No: GENENTECH INC / 1048

Trade Name: NUTROPIN

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
019676 / 0	1	3/9/1994	5 MG/VIAL (5 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/1/2015
019676 / 0	2	3/9/1994	10 MG/VIAL (10 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/2/2015
020168 / 0	1	11/17/1993	5 MG/VIAL (5 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/2/2015
020168 / 0	2	11/17/1993	10 MG/VIAL (10 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/2/2015
020656 / 0	1	12/30/1996	5 MG/VIAL (5 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/1/2015
020656 / 0	2	12/30/1996	10 MG/VIAL (10 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/8/2015

Trade Name: NUTROPIN AQ NUSPIN

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020522 / 0	1	12/29/1995	10 MG/2ML (5 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/8/2015

Trade Name: NUTROPIN AQ PEN

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
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Applicant/License No: GENENTECH INC / 1048

Trade Name: NUTROPIN AQ PEN

020522 / 0	2	4/22/2002	10 MG/2ML (5 MG/ML)	6/28/2018
SOLUTION / SUBCUTANEOUS / CARTRIDGE				

020522 / 0	6	1/3/2008	20 MG/2ML (10 MG/ML)	6/26/2018
SOLUTION / SUBCUTANEOUS / CARTRIDGE				

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 (125 MG/VIAL)	9/1/2009
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

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 (125 MG/VIAL)	8/25/2016
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

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)	7/6/2011
SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL				

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

Applicant/License No: GENZYME CORP / 1596

Trade Name: MYOZYME

125141 / 0	1	4/28/2006	50 MG (50 MG/VIAL)	10/17/2014
POWDER / INTRAVENOUS / SINGLE-DOSE VIAL				

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	3/10/2014
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	3/10/2014
125011 / 0	3	6/27/2003	14 MG/ML TOSITUMOMAB (14 MG/ML TOSITUMOMAB) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	3/10/2014

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	6/27/2013

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	Date added to Discontinued List
103964 / 5204	4	9/29/2011	180 MCG/0.5 ML (360 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/28/2020

Proper Name: PEG-INTERFERON ALFA-2A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103964 / 5204	3	9/29/2011	135 MCG/0.5 ML (270 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/28/2020

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	6/1/2009

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	7/7/2011

Applicant/License No: INSMED INC / 2188

Trade Name: IPLEX

Proper Name: MECASERMIN RINFABATE RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021884 / 0	1	12/12/2005	36 MG/0.6 ML (60 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL	12/19/2001

Applicant/License No: ISO TEX DIAGNOSTICS INC / 2189

Trade Name: CHROMALBIN

Proper Name: ALBUMIN CHROMATED CR-51 SERUM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017835 / 0	1	2/23/1976	100 uCi/VIAL (100 uCi/VIAL) / /	7/1/1979
017835 / 0	2	2/24/1976	250 uCi/VIAL (250 uCi/VIAL) / /	7/1/1979
017835 / 0	3	2/25/1976	500 uCi/VIAL (500 uCi/VIAL) / /	7/1/1979

Trade Name: MEGATOPE

Proper Name: ALBUMIN IODINATED I-131 SERUM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017837 / 0	3	2/23/1976	2mCi/VIAL (2mCi/VIAL) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL	1/1/1900
017837 / 0	4	2/23/1976	5uCi/AMP (5uCi/AMP) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL	1/1/1900
017837 / 0	5	2/23/1976	20uCi/AMP (20uCi/AMP) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL	6/7/2002

Applicant/License No: JANSSEN BIOTECH INC / 1864

Trade Name: REOPRO

Proper Name: ABCIXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103575 / 0	1	12/22/1994	10 MG/5 ML (2 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	8/15/2019

Applicant/License No: JUBILANT DRAXIMAGE INC / 2186

Trade Name: PULMOLITE

Proper Name: TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017776 / 0	1	11/16/1976	1 MG/10 MG/0.24 MG/0.7 MG0.13 MG/10 MG/VIAL (1 MG/10 MG/0.24 MG/0.7 MG0.13 POWDER / INTRAVENOUS /	6/25/2002

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	7/25/2013

Applicant/License No: LEADIANT BIOSCIENCES INC / 2073

Trade Name: ADAGEN

Proper Name: PEGADEMASE BOVINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
019818 / 0	1	3/21/1990	375 UNITS/1.5 ML (250 UNITS/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/31/2019

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 (50 MG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	2/28/2007

Applicant/License No: MEDIMMUNE LLC / 1799

Trade Name: SYNAGIS

103770 / 0	4	6/19/1998	100 MG (100 MG/VIAL)	2/28/2007
POWDER / 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	Date added to Discontinued List
103132 / 0	6	6/4/1986	10 MIU/ML (10 MIU/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/23/2013
103132 / 0	7	6/4/1986	22.5 MIU/1.5 ML (22.5 MIU/1.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED PEN	9/23/2013
103132 / 0	8	6/4/1986	37.5 MIU/1.5 ML (37.5 MIU/1.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED PEN	9/23/2013
103132 / 0	9	6/4/1986	75 MIU/1.5 ML (75 MIU/1.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED PEN	9/23/2013

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	6/13/2018

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 (67.5 MCG/PEN) POWDER / SUBCUTANEOUS / PREFILLED PEN	10/14/2016

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

Trade Name: PEGINTRON

103949 / 0	6	1/19/2001	108 MCG (108 MCG/PEN)	10/14/2016
POWDER / SUBCUTANEOUS / PREFILLED PEN				
103949 / 0	7	1/19/2001	118.4 MCG (118.4 MCG/VIAL)	10/1/2016
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				
103949 / 0	8	1/19/2001	162 MCG (162 MCG/PEN)	10/14/2016
POWDER / SUBCUTANEOUS / PREFILLED PEN				
103949 / 0	9	1/19/2001	177.6 MCG (177.6 MCG/VIAL)	10/1/2016
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				
103949 / 0	10	1/19/2001	202.5 MCG (202.5 MCG/PEN)	10/14/2016
POWDER / SUBCUTANEOUS / PREFILLED PEN				
103949 / 0	11	1/19/2001	222 MCG (222 MCG/VIAL)	10/1/2016
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	Date added to Discontinued List
103949 / 5153	4	3/29/2011	888 MCG (888 MCG/VIAL)	5/23/2019
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

Applicant/License No: MICROBIX BIOSYSTEMS INC / 2191

Trade Name: KINLYTIC

Proper Name: UROKINASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021846 / 0	1	1/16/1978	250000 IU/VIAL (250000 IU/VIAL)	8/25/2009
POWDER / INTRAVENOUS / MULTI-DOSE VIAL				

Applicant/License No: MICROBIX BIOSYSTEMS INC / 2191

Trade Name: KINLYTIC

021846 / 0	2	1/16/1978	9000 IU/VIAL (9000 IU/VIAL)	8/25/2009
POWDER / INTRAVENOUS / SINGLE-DOSE VIAL				

021846 / 0	3	1/16/1978	5000 IU/VIAL (5000 IU/VIAL)	6/30/2003
POWDER / INTRAVENOUS / 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	Date added to Discontinued List
125319 / 0	1	6/17/2009	180 MG/VIAL (180 MG/VIAL) / /	5/25/2018

125319 / 88	2	12/22/2016	150 MG (150 MG/VIAL)	5/25/2018
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

Applicant/License No: NOVO NORDISK INC / 1261

Trade Name: LEVEMIR FLEXPEN

Proper Name: INSULIN DETEMIR RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021536 / 0	2	6/16/2005	300 UNITS/3 ML (100 UNITS/ML)	3/2/2016
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN				

Trade Name: LEVEMIR INNOLET

Proper Name: INSULIN DETEMIR RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021536 / 0	3	6/16/2005	300 UNITS/3 ML (100 UNITS/ML)	12/12/2012
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN				

Trade Name: LEVEMIR PENFILL

Applicant/License No: NOVO NORDISK INC / 1261

Trade Name: LEVEMIR PENFILL

Proper Name: INSULIN DETEMIR RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021536 / 0	4	6/16/2005	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE	12/12/2012

Trade Name: NORDITROPIN

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021148 / 0	1	6/20/2000	5MG/1.5ML (3.33MG/ML) SOLUTION / SUBCUTANEOUS /	8/10/2012
021148 / 0	2	6/20/2000	10MG/1.5ML (6.67MG/ML) SOLUTION / SUBCUTANEOUS /	8/10/2012
021148 / 0	3	6/20/2000	15MG/1.5ML (10MG/ML) SOLUTION / SUBCUTANEOUS /	9/25/2012

Trade Name: NORDITROPIN NORDIFLEX

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021148 / 0	4	10/1/2004	5MG/1.5ML (3.33MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	9/25/2012
021148 / 0	5	10/1/2004	10MG/1.5ML (6.67MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	9/25/2012
021148 / 0	6	10/1/2004	15MG/1.5ML (10MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/21/2015
021148 / 0	7	3/10/2009	30MG/3ML (10MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/21/2015

Applicant/License No: NOVO NORDISK INC / 1261

Trade Name: NOVOLOG FLEXTOUCH

Proper Name: INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020986 / 0	5	10/31/2013	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	1/17/2018

Trade Name: NOVOLOG INNOLET

Proper Name: INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020986 / 0	4	4/23/2004	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	12/12/2012

Trade Name: NOVOLOG MIX 50/50 - FLEXPEN

Proper Name: INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021810 / 0	2	8/26/2008	150 UNITS/ML; 150 UNITS/3 ML (50 UNITS/ML; 50 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	11/25/2008

Trade Name: NOVOLOG MIX 50/50 - PENFILL

Proper Name: INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021810 / 0	1	8/26/2008	150 UNITS/ML; 150 UNITS/3 ML (50 UNITS/ML; 50 UNITS/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE	11/25/2008

Trade Name: NOVOLOG MIX 70/30 PENFILL

Proper Name: INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021172 / 0	2	11/1/2001	210 UNITS/3ML; 90 UNITS/3 ML (70 UNITS/ML; 30 UNITS/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE	12/12/2012

Applicant/License No: NOVO NORDISK INC / 1261

Trade Name: NOVOLOG MIX 70/30 PFS

Proper Name: INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021172 / 0	3	11/1/2001	210 UNITS/3 ML; 90 UNITS/3 ML (70 UNITS/ML; 30 UNITS/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	12/12/2012

Trade Name: RYZODEG 70/30

Proper Name: INSULIN ASPART; INSULIN DEGLUDEC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
203313 / 0	1	9/25/2015	90 UNITS/3 ML; 210 UNITS/3 ML (30 UNITS/ML; 70 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	1/12/2018

Applicant/License No: ORGANON USA INC / 2193

Trade Name: COTAZYM

Proper Name: PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020580 / 0	1	12/9/1996	30,000USP UNITS; 8,000USP UNITS; 30,000USP UNITS (30,000USP UNITS; 8,000USP UNITS; CAPSULE, DELAYED RELEASE / ORAL /	9/27/2001

Trade Name: FOLLISTIM

Proper Name: FOLLITROPIN ALFA/BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020582 / 0	1	9/29/1997	75 IU/VIAL (75 IU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/1/2004
020582 / 0	2	9/29/1997	150 IU/VIAL (150 IU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/1/2004

Trade Name: FOLLISTIM AQ

Proper Name: FOLLITROPIN ALFA/BETA

Applicant/License No: ORGANON USA INC / 2193

Trade Name: FOLLISTIM AQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021211 / 0	3	3/23/2004	175 IU/0.21 ML (833.33 IU/ML) SOLUTION / SUBCUTANEOUS /	6/27/2006

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021273 / 0	1	8/26/2005	75 IU/0.5 ML (150 IU/ML) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	6/3/2016

021273 / 0	2	8/26/2005	150 IU/0.5 ML (300 IU/ML) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	6/3/2016
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Trade Name: HUMEGON

Proper Name: MENOTROPINS (FSH;LH)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020328 / 0	1	9/1/1994	75 IU/VIAL (75 IU/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	12/19/2001

020328 / 0	2	9/1/1994	150 IU/VIAL (150 IU/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	12/19/2001
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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 (0.25 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/22/2008

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	6/15/2018

Applicant/License No: PFIZER INC / 2001

Trade Name: ELASE-CHLOROMYCETIN

Proper Name: CHLORAMPHENICOL; DESOXYRIBONUCLEASE; FIBRINOLYSIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
050294 / 0	1	4/1/1964	(10MG/GM; 666 UNITS/GM; 1 UNITS/GM) OINTMENT / TOPICAL /	12/3/2003

Applicant/License No: PHARMACIA AND UPJOHN CO / 1216

Trade Name: GENOTROPIN PRESERVATIVE FREE

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020280 / 0	4	8/24/1995	1.5 MG/VIAL (1.5 MG/VIAL) POWDER / SUBCUTANEOUS / PREFILLED SYRINGE	6/26/2018

Applicant/License No: PHARMALUCENCE INC / 2203

Trade Name: MICROLITE

Proper Name: TECHNETIUM TC-99M ALBUMIN COLLOID KIT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
018263 / 0	1	3/25/1983	N/A (N/A) / /	6/25/2002

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	4/9/2014

Applicant/License No: REGENERON PHARMACEUTICALS INC / 1760

Trade Name: PRALUENT

Proper Name: ALIROCUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125559 / 0	1	7/24/2015	75 MG/ML (75 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	9/25/2020
125559 / 0	2	7/24/2015	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	9/25/2020

Applicant/License No: SANOFI AVENTIS US LLC / 1752

Trade Name: APIDRA

Proper Name: INSULIN GLULISINE RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021629 / 0	2	12/20/2005	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	9/25/2018

Trade Name: LANTUS

Proper Name: INSULIN GLARGINE RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021081 / 0	3	4/20/2000	500 UNITS/5 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL	4/20/2000

Applicant/License No: SANOFI AVENTIS US LLC / 1752

Trade Name: LANTUS

021081 / 0	4	4/20/2000	300 UNITS/3 ML (100 UNITS/ML)	3/31/2011
SOLUTION / SUBCUTANEOUS / CARTRIDGE				

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 /	6/25/2009
125196 / 0	2	6/13/2008	(4 (150 MCG/0.5ML) REDIPEN & 168 (200 MG) CAPSULES RIBAVIRIN) POWDER & CAPSULE (COMBO KIT) / SUBCUTANEOUS, ORAL /	6/25/2009
125196 / 0	3	6/13/2008	(4 (150 MCG/0.5ML) REDIPEN & 196 (200 MG) CAPSULES RIBAVIRIN) POWDER & CAPSULE (COMBO KIT) / SUBCUTANEOUS, ORAL /	6/25/2009
125196 / 0	4	6/13/2008	(4 (50 MCG/0.5ML) REDIPEN & 112 (200 MG) CAPSULES RIBAVIRIN) POWDER & CAPSULE (COMBO KIT) / SUBCUTANEOUS, ORAL /	6/25/2009
125196 / 0	5	6/13/2008	(4 (80 MCG/0.5ML) REDIPEN & 112 (200 MG) CAPSULES RIBAVIRIN) POWDER & CAPSULE (COMBO KIT) / SUBCUTANEOUS, ORAL /	6/25/2009

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

Trade Name: VPRIV

Proper Name: VELAGLUCERASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
022575 / 0	2	2/26/2010	200 UNITS/VIAL (200 UNITS/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	10/6/2011

Applicant/License No: THERATECHNOLOGIES INC / 2091

Trade Name: EGRIFTA

Proper Name: TESAMORELIN ACETATE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
022505 / 0	1	11/10/2010	1MG BASE/VIAL (1MG BASE/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/31/2020

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 / 038	1	2/22/2017	0.375 MG/0.3 ML (1.25 MG/ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL	5/31/2020
125422 / 0	2	10/17/2012	0.5 MG (2.5 MG/ML) SOLUTION / INTRAVETREAL / SINGLE-DOSE VIAL	8/8/2017

Applicant/License No: VIFOR INTERNATIONAL AG / 2039

Trade Name: MIRCERA

Proper Name: METHOXPOLYETHYLENE 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	9/24/2008
125164 / 0	11	11/14/2007	100 MCG/ML (100 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/24/2008
125164 / 0	12	11/14/2007	200 MCG/ML (200 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/24/2008

Applicant/License No: VIFOR INTERNATIONAL AG / 2039

Trade Name: MIRCERA

125164 / 0	13	11/14/2007	300 MCG/ML (300 MCG/ML)	9/24/2008
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				
125164 / 0	14	11/14/2007	400 MCG/ML (400 MCG/ML)	9/24/2008
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				
125164 / 0	15	11/14/2007	400 MCG/0.6 ML (400 MCG/0.6 ML)	9/24/2008
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE				
125164 / 0	16	11/14/2007	600 MCG/ML (600 MCG/ML)	9/24/2008
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				
125164 / 0	17	11/14/2007	600 MCG/0.6 ML (600 MCG/0.6 ML)	9/24/2008
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE				
125164 / 0	18	11/14/2007	800 MCG/0.6 ML (800 MCG/0.6 ML)	9/24/2008
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE				
125164 / 0	19	11/14/2007	1000 MCG/ML (1000 MCG/ML)	9/24/2008
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				