

CDER Therapeutic Biologic Products

This list is intended to include all the Center for Drug Evaluation and Research (CDER) user fee billable therapeutic biological products and potencies approved under Section 351 of the Public Health Service Act. The Orange Book includes a section entitled "Drug Products with Approval under Section 505 of the Act Administered by CDER." Included on that list are several products that have been transferred to CDER which would be considered billable also.

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

The potency information contained in this list is based on information in our database. Companies are responsible for alerting CDER to any discrepancies regarding potency information. For product approvals after October 1, 2005, the Biologics License Application Submission Tracking Number (BLA STN) approval date reflects the approval date of the product. For product approvals prior to October 1, 2005, the BLA STN approval date reflects the approval date of the original BLA. Product Number is the FDA assigned number to identify the application products. Each strength is a separate product.

The list is updated three times a year. (Latest Update – November 2021)

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

Applicant/License No: ABBVIE INC / 1889

Trade Name: CREON

Proper Name: PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration)
			Dosage Form/Route/Presentation
020725 / 0	1	4/30/2009	30,000USP UNITS; 6,000USP UNITS; 19,000USP UNITS (30,000USP UNITS; 6,000USP UNITS; 19,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
020725 / 0	2	4/30/2009	60,000USP UNITS; 12,000USP UNITS; 38,000USP UNITS (60,000USP UNITS; 12,000USP UNITS; 38,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /
020725 / 0	3	4/30/2009	120,000USP UNITS; 24,000USP UNITS; 76,000USP UNITS (120,000USP UNITS; 24,000USP UNITS; 76,000USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /

Applicant/License No: ABBVIE INC / 1889

020725 / 0	4	7/12/2011	15,000USP UNITS; 3,000USP UNITS; 9,500USP UNITS (15,000USP UNITS; 3,000USP UNITS; 9,500USP UNITS)
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CAPSULE, DELAYED RELEASE / ORAL /

020725 / 0	5	3/14/2013	180,000USP UNITS; 36,000USP UNITS; 114,000USP UNITS (180,000USP UNITS; 36,000USP UNITS; 114,000USP UNITS)
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CAPSULE, DELAYED RELEASE / ORAL /

Trade Name: HUMIRA**Proper Name:** ADALIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125057 / 0	1	12/31/2002	40 MG/0.8 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125057 / 394	2	11/23/2015	40 MG/0.4 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	3	12/31/2002	10 MG/0.2 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	4	12/31/2002	20 MG/0.4 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	5	12/31/2002	40 MG/0.8 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
125057 / 0	6	12/31/2002	10 MG/0.1 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: ABBVIE INC / 1889

125057 / 0 7 12/31/2002 20 MG/0.2 ML (100 MG/ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

125057 / 0 8 12/31/2002 40 MG/0.4 ML (100 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

125057 / 0 9 12/31/2002 80 MG/0.8 ML (100 MG/ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

125057 / 0 10 12/31/2002 80 MG/0.8 ML (100 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: SKYRIZI**Proper Name:** RISANKIZUMAB-RZAA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761105 / 0 1 4/23/2019 75 MG/0.83 ML (90 MG/ ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

761105 / 0 2 4/26/2021 150 MG/ML (150 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

761105 / 0 3 4/26/2021 150 MG/ML (150 MG/ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: SURVANTA**Proper Name:** BERACTANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: ABBVIE INC / 1889

020032 / 0 1 7/1/1991 100 MG/4 ML & 200 MG/ 8 ML (25 MG/ML)

SUSPENSION / INTRATRACHEAL / SINGLE-DOSE VIAL

Applicant/License No: ABLYNX NV / 2085

Trade Name: CABLIVI

Proper Name: CAPLACIZUMAB-YHDP

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

Applicant/License No: ACROTECH BIOPHARMA LLC / 2159

Trade Name: ZEVALIN

Proper Name: IBRITUMOMAB TIUXETAN

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

Applicant/License No: ADC THERAPEUTICS SA / 2166

Trade Name: ZYNLONTA

Proper Name: LONCASTUXIMAB TESIRINE-LPYL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761196 / 0	1	4/23/2021	10MG (10MG)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: ALEXION PHARMACEUTICALS INC / 1743**Trade Name:** KANUMA**Proper Name:** SEBELIPASE ALFA

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

Trade Name: SOLIRIS**Proper Name:** ECULIZUMAB

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

Trade Name: STRENSIQ**Proper Name:** ASFOTASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125513 / 0	1	10/23/2015	18 MG/0.45 ML (40 MG/ML)
SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL			
125513 / 0	2	10/23/2015	80 MG/0.8 ML (100 MG/ML)
SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL			
125513 / 0	3	10/23/2015	28 MG/0.7 ML (40 MG/ML)
SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL			

Applicant/License No: ALEXION PHARMACEUTICALS INC / 1743

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

Trade Name: ULTOMIRIS**Proper Name:** RAVULIZUMAB-CWVZ

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

761108 / 0	2	10/9/2020	300 MG/3 ML (100 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

761108 / 0	3	10/9/2020	1,100 MG/11 ML (100 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: ALLERGAN INC / 1145**Trade Name:** BOTOX**Proper Name:** BOTULINUM TOXIN TYPE A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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103000 / 0	1	12/9/1991	100 U (100 U/VIAL)
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POWDER / INTRAMUSCULAR, INTRADERMAL, INTRADETRUSOR / SINGLE-DOSE VIAL

103000 / 5101	3	4/14/2005	50 U (50 U/VIAL)
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POWDER / INTRAMUSCULAR, INTRADERMAL, INTRADETRUSOR / SINGLE-DOSE VIAL

Applicant/License No: ALLERGAN INC / 1145

103000 / 5122 5 11/10/2005 200 U (200 U/VIAL)

POWDER / INTRAMUSCULAR, INTRADERMAL, INTRADETRUSOR / SINGLE-DOSE VIAL

Trade Name: BOTOX COSMETIC**Proper Name:** BOTULINUM TOXIN TYPE A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103000 / 5000	2	4/12/2002	100 U (100 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
103000 / 5101	4	4/14/2005	50 U (50 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: ALLERQUEST LLC / 2265**Trade Name:** PRE-PEN**Proper Name:** BENZYL PENICILLOYL POLYLYSINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
050114 / 0	1	7/25/1974	60 UMOL/0.25 ML (240 UMOL/1 ML) SOLUTION / INTRADERMAL / AMPULE

Applicant/License No: AMGEN INC / 1080**Trade Name:** AIMOVIG**Proper Name:** ERENUMAB-AOOE

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

Applicant/License No: AMGEN INC / 1080

761077 / 0 2 5/17/2018 70 MG (70 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

761077 / 1 3 3/11/2019 140 MG (140 MG/ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

761077 / 1 4 3/11/2019 140 MG (140 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: ARANESP**Proper Name:** DARBEPOETIN ALFA IN POLYSORBATE SOLUTION

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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103951 / 0 1 9/17/2001 25 MCG/ML (25 MCG/ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

103951 / 0 2 9/17/2001 40 MCG/ML (40 MCG/ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

103951 / 0 3 9/17/2001 60 MCG/ML (60 MCG/ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

103951 / 0 4 9/17/2001 100 MCG/ML (100 MCG/ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

103951 / 0 6 9/17/2001 200 MCG/ML (200 MCG/ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: AMGEN INC / 1080

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

Applicant/License No: AMGEN INC / 1080

103951 / 0 31 9/17/2001 10 MCG/0.4 ML (10 MCG/0.4 ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: BLINCYTO**Proper Name:** BLINATUMOMAB

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

Trade Name: EPOGEN**Proper Name:** EPOETIN ALFA

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

103234 / 0	7	6/1/1989	20,000 U/ML (10,000 U/ML)
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SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

Proper Name: EPOETIN ALFA - PRESERVATIVE FREE

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

103234 / 0	2	6/1/1989	3000 U/ML (3000 U/ML)
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SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: AMGEN INC / 1080

103234 / 0 3 6/1/1989 4000 U/ML (4000 U/ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

103234 / 0 4 6/1/1989 10,000 U/ML (10,000 U/ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: EVENITY**Proper Name:** ROMOSUZUMAB-AQQG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761062 / 0 1 4/9/2019 105 MG/1.17 ML (90 MG/ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: NEULASTA**Proper Name:** PEGFILGRASTIM

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

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: NEULASTA ONPRO**Proper Name:** PEGFILGRASTIM

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

SOLUTION / SUBCUTANEOUS / KIT

Trade Name: NEUPOGEN**Proper Name:** FILGRASTIM

Applicant/License No: AMGEN INC / 1080

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

Trade Name: NPLATE**Proper Name:** ROMIPLOSTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125268 / 0	1	8/22/2008	250 MCG (250 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
125268 / 0	2	8/22/2008	500 MCG (500 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
125268 / 165	3	7/22/2019	125 MCG (125 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: PROCRIT**Proper Name:** EPOETIN ALFA - PRESERVATIVE FREE

Applicant/License No: AMGEN INC / 1080

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

Trade Name: PROLIA**Proper Name:** DENOSUMAB

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

Trade Name: REPATHA**Proper Name:** EVOLOCUMAB

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

Trade Name: VECTIBIX**Proper Name:** PANITUMUMAB

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

125147 / 0 1 9/27/2006 100 MG/5 ML (20 MG/ML)

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

125147 / 0 3 9/27/2006 400 MG/20 ML (20 MG/ML)

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: XGEVA**Proper Name:** DENOSUMAB

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

SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: AMPHASTAR PHARMACEUTICAL INC / 2179**Trade Name:** AMPHADASE**Proper Name:** HYALURONIDASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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021665 / 0 1 10/26/2004 150 UNITS/ML (150 UNITS/ML)

SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: AMRYT PHARMACEUTICALS DAC / 2208**Trade Name:** MYALEPT**Proper Name:** METRELEPTIN

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

POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: ASCENDIS PHARMA ENDOCRINOLOGY DIVISION AS / 2165**Trade Name:** SKYTROFA**Proper Name:** LONAPEGSOMATROPIN-TCGD

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761177 / 0	1	8/26/2021	3 MG (3 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
761177 / 0	2	8/26/2021	3.6 MG (3.6 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
761177 / 0	3	8/26/2021	4.3 MG (4.3 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
761177 / 0	4	8/26/2021	5.2 MG (5.2 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
761177 / 0	5	8/26/2021	6.3 MG (6.3 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
761177 / 0	6	8/26/2021	7.6 MG (7.6 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
761177 / 0	7	8/26/2021	9.1 MG (9.1 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
761177 / 0	8	8/26/2021	11 MG (11 MG) POWDER / SUBCUTANEOUS / CARTRIDGE

Applicant/License No: ASCENDIS PHARMA ENDOCRINOLOGY DIVISION AS / 2165

761177 / 0 9 8/26/2021 13.3 MG (13.3 MG)

POWDER / SUBCUTANEOUS / CARTRIDGE

Applicant/License No: ASTELLAS PHARMA US INC / 2124**Trade Name:** PADCEV**Proper Name:** ENFORTUMAB VEDOTIN-EJFV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761137 / 0	1	12/18/2019	20 MG (20 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

761137 / 0	2	12/18/2019	30 MG (30 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: ASTRAZENECA AB / 2059**Trade Name:** SAPHNELO**Proper Name:** ANIFROLUMAB-FNIA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761123 / 0	1	7/30/2021	300 MG/2 ML (150 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: ASTRAZENECA UK LTD / 2043**Trade Name:** IMFINZI**Proper Name:** DURVALUMAB

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

Applicant/License No: AUXILIUM PHARMACEUTICALS INC / 1816**Trade Name:** XIAFLEX**Proper Name:** CLOSTRIDIAL COLLAGENASE HISTOLYTICUM

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

Applicant/License No: BAUSCH AND LOMB INC / 2180**Trade Name:** VITRASE**Proper Name:** HYALURONIDASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021640 / 0	2	12/2/2004	200 UNITS/ML (200 UNITS/ML) SOLUTION / INTERSTITIAL, INTRAMUSCULAR, INTRAOCULAR, PERIBULBAR, RETROBULBAR, SOFT TISSUE, SUBCUTANEOUS / SINGLE- DOSE VIAL

Applicant/License No: BAXTER HEALTHCARE CORP / 0140**Trade Name:** MYXREDLIN**Proper Name:** INSULIN HUMAN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
208157 / 0	1	6/20/2019	100 UNITS/100 ML (100 UNITS/100 ML)

SOLUTION / INTRAVENOUS / SINGLE DOSE CONTAINER

Applicant/License No: BAYER HEALTHCARE PHARMACEUTICALS INC / 1778**Trade Name:** BETASERON**Proper Name:** INTERFERON BETA-1B

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

POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: BIOGEN INC / 1697**Trade Name:** ADUHELM**Proper Name:** ADUCANUMAB-AVWA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761178 / 0	1	6/7/2021	170 MG/1.7 ML (100 MG/ML)

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

761178 / 0	2	6/7/2021	300 MG/3 ML (100 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: AVONEX**Proper Name:** INTERFERON BETA 1A

Applicant/License No: BIOGEN INC / 1697

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

Trade Name: PLEGRIDY**Proper Name:** PEGINTERFERON BETA-1A

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

Applicant/License No: BIAGEN INC / 1697

125499 / 0 6 8/15/2014 125 MCG/0.5 ML (250 MCG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: TYSABRI**Proper Name:** NATALIZUMAB

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: BIOMARIN PHARMACEUTICAL INC / 1649**Trade Name:** ALDURAZYME**Proper Name:** LARONIDASE

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: BRINEURA**Proper Name:** CERLIPONASE ALFA

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

SOLUTION / INTRAVENTRICULAR / SINGLE-DOSE VIAL

Trade Name: NAGLAZYME**Proper Name:** GALSULFASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: BIOMARIN PHARMACEUTICAL INC / 1649

125117 / 0	1	5/31/2005	5 MG/ 5ML (1 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PALYNZIQ**Proper Name:** PEGVALIASSE-PQPZ

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

761079 / 0	2	5/24/2018	10 MG (20 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

761079 / 0	3	5/24/2018	20 MG (20 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: VIMIZIM**Proper Name:** ELOSULFASE ALFA

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

Applicant/License No: BOEHRINGER INGELHEIM PHARMACEUTICALS INC / 2006**Trade Name:** PRAXBIND**Proper Name:** IDARUCIZUMAB

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

Applicant/License No: BRISTOL MYERS SQUIBB CO / 1713**Trade Name:** EMPLICITI**Proper Name:** ELOTUZUMAB

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

761035 / 0	2	11/30/2015	400 MG (400 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: NULOJIX**Proper Name:** BELATACEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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125288 / 0	1	6/15/2011	250 MG (250 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: OPDIVO**Proper Name:** NIVOLUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: BRISTOL MYERS SQUIBB CO / 1713

125554 / 0	1	12/22/2014	40 MG/4 ML (10 MG/ML)	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125554 / 0	2	12/22/2014	100 MG/10 ML (10 MG/ML)	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125554 / 0	3	12/22/2014	240 MG/24 ML (10 MG/ML)	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125554 / 0	4	8/27/2021	120 MG/12 ML (10 MG/ML)	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ORENCIA**Proper Name:** ABATACEPT

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

Applicant/License No: BRISTOL MYERS SQUIBB CO / 1713

125118 / 122 5 7/29/2011 125 MG/ML (125 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: YERVOY**Proper Name:** IPILIMUMAB

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

125377 / 0	2	3/25/2011	200 MG/40 ML (5 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: BTG INTERNATIONAL INC / 1861**Trade Name:** VORAXAZE**Proper Name:** GLUCARPIDASE

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

Applicant/License No: CELGENE CORPORATION / 2114**Trade Name:** REBLOZYL**Proper Name:** LUSPATERCEPT-AAMT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761136 / 0	1	11/8/2019	25 MG (25 MG/VIAL)
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: CELGENE CORPORATION / 2114

761136 / 0	2	11/8/2019	75 MG (75 MG/VIAL)
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: CHIESI USA INC / 2150**Trade Name:** CUROSURF**Proper Name:** PORACTANT ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020744 / 0	1	11/18/1999	120 MG/1.5ML & 240 MG/3ML (80 MG/ML)

SUSPENSION / INTRATRACHEAL / SINGLE-DOSE VIAL

Trade Name: REVCIVI**Proper Name:** ELAPEGADEMASE-LVLR

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

SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: CIS BIO INTERNATIONAL / 2204**Trade Name:** PULMOTECH MAA**Proper Name:** TECHNETIUM TC 99M ALBUMIN AGGREGATED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
210089 / 0	1	3/20/2020	2 MG (2 MG)

POWDER / INTRAVENOUS, INTRAPERITONEAL / MULTI-DOSE VIAL

Applicant/License No: CLINIGEN INC / 2154**Trade Name:** PROLEUKIN**Proper Name:** ALDESLEUKIN

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

Applicant/License No: DAIICHI SANKYO INC / 2128**Trade Name:** ENHERTU**Proper Name:** FAM-TRASTUZUMAB DERUXTECAN-NXKI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761139 / 0	1	12/20/2019	100 MG (100 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: DIGESTIVE CARE INC / 2184**Trade Name:** PERTZYE**Proper Name:** PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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022175 / 0	1	5/17/2012	30,250USP UNITS; 8,000USP UNITS; 28,750USP UNITS (30,250USP UNITS; 8,000USP UNITS; 28,750USP UNITS)
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CAPSULE, DELAYED RELEASE / ORAL /

022175 / 0	2	5/17/2012	60,500USP UNITS; 16,000USP UNITS; 57,500USP UNITS (60,500USP UNITS; 16,000USP UNITS; 57,500USP UNITS)
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CAPSULE, DELAYED RELEASE / ORAL /

022175 / 0	3	10/6/2016	15,125USP UNITS; 4,000USP UNITS; 14,375USP UNITS (15,125USP UNITS; 4,000USP UNITS; 14,375USP UNITS)
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CAPSULE, DELAYED RELEASE / ORAL /

Applicant/License No: DIGESTIVE CARE INC / 2184

022175 / 0	4	7/13/2017	90,750USP UNITS; 24,000USP UNITS; 86,250USP UNITS (90,750USP UNITS; 24,000USP UNITS; 86,250USP UNITS)
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CAPSULE, DELAYED RELEASE / ORAL /

Applicant/License No: DOMPE FARMACEUTICI SPA / 2074**Trade Name:** OXERVATE**Proper Name:** CENEGERMIN-BKBJ

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

Applicant/License No: DYAX CORPORATION / 1789**Trade Name:** KALBITOR**Proper Name:** ECALLANTIDE

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

Trade Name: TAKHZYRO**Proper Name:** LANADELUMAB-FLYO

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

Applicant/License No: EKR THERAPEUTICS INC / 1814**Trade Name:** RETAVASE**Proper Name:** RETEPLASE

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

Applicant/License No: ELI LILLY AND CO / 1891**Trade Name:** BASAGLAR**Proper Name:** INSULIN GLARGINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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205692 / 0	1	12/16/2015	300 UNITS/3 ML (100 UNITS/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: CYRAMZA**Proper Name:** RAMUCIRUMAB

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

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

Trade Name: EMGALITY**Proper Name:** GALCANEZUMAB-GNLM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: ELI LILLY AND CO / 1891

761063 / 0	1	9/27/2018	120 MG/ML (120 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

761063 / 0	2	9/27/2018	120 MG/ML (120 MG/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

761063 / 3	3	6/4/2019	100 MG/ML (100 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: HUMALOG**Proper Name:** INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020563 / 0	1	6/14/1996	1000 UNITS/10 ML (100 UNITS/ML)

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: HUMALOG KWIKPEN**Proper Name:** INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020563 / 0	3	9/6/2007	300 UNITS/3 ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
205747 / 0	1	5/26/2015	600 UNITS/3 ML (200 UNITS/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: HUMALOG KWIKPEN JUNIOR

Applicant/License No: ELI LILLY AND CO / 1891**Proper Name:** INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020563 / 176	4	6/6/2017	300 UNITS/3 ML (100 UNITS/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: HUMALOG MIX 50/50**Proper Name:** INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021018 / 0	1	12/22/1999	500 UNITS/10 ML; 500 UNITS/10 ML (50 UNITS/ML; 50 UNITS/ML)

SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: HUMALOG MIX 50/50 KWIKPEN**Proper Name:** INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021018 / 0	2	12/22/1999	150 UNITS/3 ML; 150 UNITS/3 ML (50 UNITS/ML; 50 UNITS/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: HUMALOG MIX 75/25**Proper Name:** INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021017 / 0	1	12/22/1999	750 UNITS/10 ML; 250 UNITS/10 ML (75 UNITS/ML; 25 UNITS/ML)

SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: HUMALOG MIX 75/25 KWIKPEN**Proper Name:** INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT

Applicant/License No: ELI LILLY AND CO / 1891

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021017 / 0	2	9/6/2007	225 UNITS/3 ML; 75 UNITS/3 ML (75 UNITS/ML; 25 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: HUMATROPE**Proper Name:** SOMATROPIN RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
019640 / 0	4		5 MG/VIAL (5 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
019640 / 0	5		6 MG (6 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
019640 / 0	6		12 MG (12 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
019640 / 0	7		24 MG (24 MG) POWDER / SUBCUTANEOUS / CARTRIDGE

Trade Name: HUMULIN R**Proper Name:** INSULIN HUMAN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
018780 / 0	4	3/31/1994	10000 UNITS/20 ML (500 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: HUMULIN R KWIKPEN

Applicant/License No: ELI LILLY AND CO / 1891**Proper Name:** INSULIN HUMAN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
018780 / 0	2	12/29/2015	1500 UNITS/3 ML (500 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: LYUMJEV**Proper Name:** INSULIN LISPRO-AABC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761109 / 0	1	6/15/2020	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL
761109 / 0	5	6/15/2020	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE

Trade Name: LYUMJEV JUNIOR KWIKPEN**Proper Name:** INSULIN LISPRO-AABC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761109 / 0	3	6/15/2020	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: LYUMJEV KWIKPEN**Proper Name:** INSULIN LISPRO-AABC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761109 / 0	2	6/15/2020	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: ELI LILLY AND CO / 1891

761109 / 0	6	6/15/2020	600 UNITS/3 ML (200 UNITS/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: LYUMJEV TEMPO PEN**Proper Name:** INSULIN LISPRO-AABC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761109 / 0	4	6/15/2020	300 UNITS/3 ML (100 UNITS/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: PORTRAZZA**Proper Name:** NECITUMUMAB

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

Trade Name: TALTZ**Proper Name:** IXEKIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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125521 / 0	1	3/22/2016	80 MG/ML (80 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

Trade Name: TRULICITY**Proper Name:** DULAGLUTIDE

Applicant/License No: ELI LILLY AND CO / 1891

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125469 / 0	3	9/18/2014	0.75 MG/0.5 ML (0.75 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
125469 / 0	4	9/18/2014	1.5 MG/0.5 ML (1.5 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
125469 / 36	5	9/3/2020	3 MG/0.5 ML (3 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
125469 / 36	6	9/3/2020	4.5 MG/0.5 ML (4.5 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: ELUSYS THERAPEUTICS INC / 1907**Trade Name:** ANTHIM**Proper Name:** OBILTOXAXIMAB

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

Applicant/License No: EMD SERONO INC / 1773**Trade Name:** BAVENCIO**Proper Name:** AVELUMAB

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

Trade Name: GONAL-F**Proper Name:** FOLLITROPIN ALFA/BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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020378 / 0	4	2/28/2001	1,050 IU/VIAL (600 IU/ML)
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POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL

020378 / 0	5	3/26/2004	450 IU/VIAL (600 IU/ML)
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POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: GONAL-F RFF**Proper Name:** FOLLITROPIN ALFA/BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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021765 / 0	2	3/25/2004	82 IU/VIAL (82 IU/VIAL)
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

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
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Applicant/License No: EMD SERONO INC / 1773

021684 / 0 1 5/25/2004 300 IU/0.5ML (600 IU/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

021684 / 0 2 5/25/2004 450 IU/0.75 ML (600 IU/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

021684 / 0 3 5/25/2004 900 IU/1.5 ML (600 IU/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: OVIDREL**Proper Name:** CHORIOGONADOTROPIN ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021149 / 0	2	9/20/2000	0.25 MG /0.5 ML (0.25 MG/0.5 ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: REBIF**Proper Name:** INTERFERON BETA 1A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103780 / 0	1	3/7/2002	8.8 MCG/0.2 ML (44 MCG/ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

103780 / 0 2 3/7/2002 8.8 MCG/0.2 ML (44 MCG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

103780 / 0 3 3/7/2002 22 MCG/0.5 ML (44 MCG/ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: EMD SERONO INC / 1773

103780 / 0	4	3/7/2002	22 MCG/0.5 ML (44 MCG/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

103780 / 0	5	3/7/2002	44 MCG/0.5 ML (88 MCG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

103780 / 0	6	3/7/2002	44 MCG/0.5 ML (88 MCG/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: SAIZEN**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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019764 / 0	3	8/29/2000	8.8 MG/VIAL (8.8 MG/VIAL)
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: SEROSTIM**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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020604 / 0	3	7/25/1997	4 MG/VIAL (4 MG/VIAL)
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POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: ZORBTIVE**Proper Name:** SOMATROPIN RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: EMD SERONO INC / 1773

021597 / 0 4 12/1/2003 8.8 MG/VIAL (8.8 MG/VIAL)

POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL

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
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125349 / 0	1	12/14/2012	1700 MG/34 ML (50 MG/ML)
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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
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761146 / 0	1	7/6/2020	0.92 MG (0.92 MG/VIAL)
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

761146 / 0	2	7/6/2020	1.84 MG (1.84 MG/VIAL)
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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:** 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

Applicant/License No: FERRING PHARMACEUTICALS INC / 2112

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

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
125276 / 0	3	1/8/2010	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

Trade Name: ACTIVASE**Proper Name:** ALTEPLASE

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

Applicant/License No: GENENTECH INC / 1048

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

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

Applicant/License No: GENENTECH INC / 1048

761083 / 0	3	11/16/2017	105 MG/0.7 ML (150 MG/ML)
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

761083 / 0	4	11/16/2017	150 MG/ML (150 MG/ML)
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: HERCEPTIN**Proper Name:** TRASTUZUMAB

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

Trade Name: HERCEPTIN HYLECTA**Proper Name:** TRASTUZUMAB AND HYALURONIDASE-OYSK

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

Trade Name: KADCYLA**Proper Name:** ADO-TRASTUZUMAB EMTANSINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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125427 / 0	1	2/22/2013	100 MG (100 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: GENENTECH INC / 1048

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
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

Applicant/License No: GENENTECH INC / 1048

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
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
761121 / 0	1	6/10/2019	140 MG (140 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PULMOZYME

Applicant/License No: GENENTECH INC / 1048**Proper Name:** DORNASE ALFA

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

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

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

Trade Name: RITUXAN HYCELA**Proper Name:** RITUXIMAB AND HYALURONIDASE HUMAN

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

Trade Name: TECENTRIQ**Proper Name:** ATEZOLIZUMAB

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

761034 / 0	1	5/18/2016	1200 MG/20 ML (60 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

761034 / 18	2	3/8/2019	840 MG/14 ML (60 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: TNKASE**Proper Name:** TENECTEPLASE

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

Trade Name: XOLAIR**Proper Name:** OMALIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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103976 / 0	1	6/20/2003	150 MG (150 MG/VIAL)
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

103976 / 5231	3	9/28/2018	75 MG/0.5 ML (150 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

103976 / 5231	4	9/28/2018	150 MG/ML (150 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: GENZYME CORP / 1596**Trade Name:** CAMPATH**Proper Name:** ALEMTUZUMAB

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

Trade Name: CEREZYME**Proper Name:** IMIGLUCERASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020367 / 0	2	9/22/1999	400 UNITS/VIAL (400 UNITS/VIAL)
POWDER / INTRAVENOUS / SINGLE-DOSE VIAL			

Trade Name: FABRAZYME**Proper Name:** AGALSIDASE BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103979 / 0	1	4/24/2003	5 MG (5 MG/VIAL)
POWDER / INTRAVENOUS / SINGLE-DOSE VIAL			
103979 / 0	2	4/24/2003	35 MG (35 MG/VIAL)
POWDER / INTRAVENOUS / SINGLE-DOSE VIAL			

Trade Name: LEMTRADA**Proper Name:** ALEMTUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: GENZYME CORP / 1596

103948 / 5139 2 11/14/2014 12 MG/1.2 ML (10MG/ML)

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: LUMIZYME**Proper Name:** ALGLUCOSIDASE ALFA

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

POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: NEXVIAZYME**Proper Name:** AVALGLUCOSIDASE ALFA-NGPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761194 / 0	1	8/6/2021	100 MG/VIAL (100 MG/VIAL)

POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: THYROGEN**Proper Name:** THYROTROPIN ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020898 / 0	1	11/30/1998	0.9 MG/VIAL (0.9 MG/VIAL)

POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: GLAXOSMITHKLINE INTELLECTUAL PROPERTY DEVELOPMENT LTD ENGLAND / 2148**Trade Name:** BLENREP**Proper Name:** BELANTAMAB MAFODOTIN-BLMF

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761158 / 0	1	8/5/2020	100 MG (100 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: GLAXOSMITHKLINE LLC / 1727**Trade Name:** JEMPERLI**Proper Name:** DOSTARLIMAB-GXLY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761174 / 0	1	4/22/2021	500 MG/10 ML (50 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761223 / 0	1	8/17/2021	500 MG/10 ML (50 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: NUCALA**Proper Name:** MEPOLIZUMAB

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: GLAXOSMITHKLINE LLC / 1727

761122 / 0 1 6/6/2019 100 MG (100 MG/ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

761122 / 0 2 6/6/2019 100 MG (100 MG/ML)

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: HALOZYME THERAPEUTICS INC / 2187**Trade Name:** HYLENEX RECOMBINANT**Proper Name:** HYALURONIDASE RECOMBINANT HUMAN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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021859 / 0 1 12/2/2005 150 UNITS/VIAL (150 UNITS/ML)SOLUTION / INTERSTITIAL, INTRAMUSCULAR, INTRAOCULAR,
PERIBULBAR, RETROBULBAR, SOFT TISSUE, SUBCUTANEOUS / SINGLE-
DOSE VIAL**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
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103964 / 0 1 10/16/2002 180 MCG/ML (180 MCG/ML)

SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

103964 / 0 2 10/16/2002 180 MCG/0.5 ML (360 MCG/ML)

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: HORIZON THERAPEUTICS IRELAND DAC / 2022**Trade Name:** ACTIMMUNE**Proper Name:** INTERFERON GAMMA-1B

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

SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: KRYSTEXXA**Proper Name:** PEGLOTICASE

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: TEPEZZA**Proper Name:** TEPROTUMUMAB-TRBW

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761143 / 0	1	1/21/2020	500 MG (500 MG/VIAL)

POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: HUMAN GENOME SCIENCES INC / 1820**Trade Name:** BENLYSTA**Proper Name:** BELIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125370 / 0	1	3/9/2011	120 MG (120 MG/VIAL)

POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: HUMAN GENOME SCIENCES INC / 1820

125370 / 0	2	3/9/2011	400 MG (400 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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

761043 / 0	2	7/20/2017	200 MG/ML (200 MG/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: IMCLONE LLC / 1827**Trade Name:** ERBITUX**Proper Name:** CETUXIMAB

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

125084 / 0	2	2/12/2004	200 MG/100 ML (2 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: IMMUNEX CORP / 1132**Trade Name:** ENBREL**Proper Name:** ETANERCEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103795 / 0	1	11/2/1998	25 MG (25 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL
103795 / 5184	2	9/27/2004	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103795 / 0	3	9/27/2004	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
103795 / 5184/	4	9/27/2004	25 MG/0.5 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
103795 / 5556	5	9/14/2017	50 MG/ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE

Applicant/License No: IMMUNOMEDICS INC / 1737**Trade Name:** TRODELVY**Proper Name:** SACITUZUMAB GOVITECAN-HZIY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761115 / 0	1	4/22/2020	180 MG (180 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: INNATE PHARMA INC / 2206**Trade Name:** LUMOXITI**Proper Name:** MOXETUMOMAB PASUDOTOX-TDFK

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

Applicant/License No: IPSEN BIOPHARM LIMITED / 1787**Trade Name:** DYSPORT**Proper Name:** ABOBOTULINUMTOXINA

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

125274 / 0	2	4/29/2009	500 UNITS (500 UNITS/VIAL)
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POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: IPSEN BIOPHARMACEUTICALS INC / 2194**Trade Name:** INCRELEX**Proper Name:** MECASERMIN RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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021839 / 0	1	8/30/2005	40 MG/4 ML (10MG/ML)
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SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Applicant/License No: ISO TEX DIAGNOSTICS INC / 2189**Trade Name:** JEANATOPE**Proper Name:** ALBUMIN IODINATED I-125 SERUM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
017836 / 0	1	2/23/1976	500uCi/0.5 ML (1000uCi/ML) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL
017836 / 0	2	2/23/1976	1,000uCi/ML (1,000uCi/ML) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL
017836 / 0	3	6/8/2004	100uCi/10 ML (10uCi/ML) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL

Trade Name: MEGATOPE**Proper Name:** ALBUMIN IODINATED I-131 SERUM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
017837 / 0	1	2/23/1976	0.5mCi/VIAL (0.5mCi/VIAL) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL
017837 / 0	2	2/23/1976	1mCi/VIAL (1mCi/VIAL) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL

Applicant/License No: JANSSEN BIOTECH INC / 1864**Trade Name:** DARZALEX**Proper Name:** DARATUMUMAB

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

Trade Name: 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: RYBREVANT**Proper Name:** AMIVANTAMAB-VMJW

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

761210 / 0 1 5/21/2021 350 MG/7 ML (50 MG/ML)

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

125289 / 0	4	4/24/2009	100 MG/ML (100 MG/ML)
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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)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: STELARA**Proper Name:** USTEKINUMAB

Applicant/License No: JANSSEN BIOTECH INC / 1864

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125261 / 0	1	9/25/2009	90 MG/ML (90 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125261 / 0	2	9/25/2009	45 MG/0.5 ML (90 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125261 / 0	3	9/25/2009	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761044 / 0	1	9/23/2016	130 MG/26 ML (5 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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

Applicant/License No: JAZZ PHARMACEUTICALS IRELAND LIMITED / 2167**Trade Name:** RYLAZE**Proper Name:** ASPARAGINASE ERWINIA CHRYSANTHEMI (RECOMBINANT)-RYWN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761179 / 0	1	6/30/2021	10 MG/0.5 ML (10 MG/0.5 ML)

SOLUTION / 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
017881 / 0	1	12/30/1987	2.5 MG/VIAL (2.5 MG/VIAL)

POWDER / INTRAVENOUS / MULTI-DOSE VIAL

Applicant/License No: KINIKSA PHARMACEUTICALS GMBH / 2236**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

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
761068 / 0	1	4/17/2018	10 MG/ML (10 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761068 / 0	2	4/17/2018	20 MG/ML (20 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761068 / 0	3	4/17/2018	30 MG/ML (30 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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

Applicant/License No: 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
761119 / 0	1	2/21/2020	100 MG/ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: MACROGENICS INC / 2139**Trade Name:** MARGENZATM**Proper Name:** MARGETUXIMAB-CMKB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761150 / 0	1	12/16/2020	250 MG/10 ML (25 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

022472 / 0	2	6/27/2014	8 UNITS/INH (8 UNITS/INH)
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POWDER / INHALATION / CARTRIDGE

022472 / 0	3	4/17/2015	12 UNITS/INH (12 UNITS/INH)
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POWDER / INHALATION / CARTRIDGE

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
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103132 / 0	1	6/4/1986	10 MIU (10 MIU/VIAL)
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POWDER / INTRAMUSCULAR, SUBCUTANEOUS, INTRALESIONAL,
INTRAVENOUS / SINGLE-DOSE VIAL

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

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

Trade Name: KEYTRUDA**Proper Name:** PEMBROLIZUMAB

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

Trade Name: ZINPLAVA**Proper Name:** BEZLOTUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761046 / 0	1	10/21/2016	1000 MG/40 ML (25 MG/ML)
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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
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125360 / 0	1	7/30/2010	50 U (50 U/VIAL)
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POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: MERZ PHARMACEUTICALS GMBH / 1830

125360 / 0 2 7/30/2010 100 U (100 U/VIAL)

POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

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:** MONJUVI**Proper Name:** TAFASITAMAB-CXIX

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

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
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Applicant/License No: NOVARTIS PHARMACEUTICALS CORP / 1244

125504 / 0	1	1/21/2015	150 MG (150 MG/VIAL)
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

125504 / 0	2	1/21/2015	150 MG/ML (150 MG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

125504 / 0	3	1/21/2015	150 MG/ML (150 MG/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

125504 / 0	4	5/28/2021	75 MG/0.5 ML (75 MG/0.5 ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

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

Trade Name: ILARIS**Proper Name:** CANAKINUMAB

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

Trade Name: KESIMPTA**Proper Name:** OFATUMUMAB

Applicant/License No: NOVARTIS PHARMACEUTICALS CORP / 1244

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

Applicant/License No: NOVO NORDISK INC / 1261

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

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: NORDITROPIN FLEXPOR**Proper Name:** SOMATROPIN

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

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
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
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
021172 / 0	1	11/1/2001	700 UNITS/10ML; 300 UNITS/10 ML (70 UNITS/ML; 30 UNITS/ML)

SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

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

Applicant/License No: NOVO NORDISK INC / 1261

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: 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**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

Applicant/License No: NOVO NORDISK INC / 1261

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

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
020280 / 0	1	1/27/1998	0.2 MG/VIAL (0.2 MG/VIAL)
POWDER / SUBCUTANEOUS / PREFILLED SYRINGE			
020280 / 0	2	1/27/1998	0.4 MG/VIAL (0.4 MG/VIAL)
POWDER / SUBCUTANEOUS / PREFILLED SYRINGE			

Applicant/License No: PHARMACIA AND UPJOHN CO / 1216

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

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

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

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:** 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
761055 / 0	4	6/14/2021	200 MG/1.14 ML (175 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: EVKEEZA**Proper Name:** EVINACUMAB-DGNB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761181 / 0	1	2/11/2021	345 MG/2.3ML (150 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761181 / 0	2	2/11/2021	1200 MG/8 ML (150 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: EYLEA**Proper Name:** AFLIBERCEPT

Applicant/License No: REGENERON PHARMACEUTICALS INC / 1760

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: INMAZEB**Proper Name:** ATOLTIVIMAB, MAFTIVIMAB, AND ODESIVIMAB-EBGN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761169 / 0	1	10/14/2020	241.7 MG/ 241.7 MG/ 241.7 MG/ 14.5 ML (16.67 MG/ 16.67 MG/ 16.67 MG/ ML)
SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL			

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

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

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125559 / 0	3	7/24/2015	75 MG/ML (75 MG/ML)
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN			
125559 / 0	4	7/24/2015	150 MG/ML (150 MG/ML)
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN			

Applicant/License No: RIDGEBACK BIOTHERAPEUTICS / 2162**Trade Name:** EBANGA**Proper Name:** ANSUVIMAB-ZYKL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761172 / 0	1	12/21/2020	400 MG/VIAL (400 MG/VIAL)
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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)
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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)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

Applicant/License No: SANOFI AVENTIS US LLC / 1752

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
209196 / 0	1	12/11/2017	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL
209196 / 0	3	10/19/2018	300 UNITS/3 ML (100 UNITS/ML) 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
209196 / 0	2	12/11/2017	300 UNITS/3 ML (100 UNITS/ML) 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
021629 / 0	1	4/16/2004	1000 UNITS/10 ML (100 UNITS/ML) 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
021629 / 0	3	2/24/2009	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: ELITEK

Applicant/License No: SANOFI AVENTIS US LLC / 1752**Proper Name:** RASBURICASE

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

Trade Name: KEVZARA**Proper Name:** SARILUMAB

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

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

021081 / 0	1	4/20/2000	1000 UNITS/10 ML (100 UNITS/ML)
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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
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021081 / 0	2	4/27/2007	300 UNITS/3 ML (100 UNITS/ML)
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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
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761113 / 0	1	3/2/2020	100 MG/5 ML (20 MG/ML)
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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
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208673 / 0	1	11/21/2016	300 UNITS/3 ML; 99MCG/3 ML (100 UNITS/ML; 33MCG/ML)
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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: SEAGEN INC / 2257**Trade Name:** TIVDAK**Proper Name:** TISOTUMAB VEDOTIN-TFTV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761208 / 0	1	9/22/2021	40 MG/VIAL (40 MG/VIAL)
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POWDER / 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
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125388 / 1	1	8/19/2011	50 MG (50 MG/VIAL)
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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
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761102 / 0	1	12/20/2018	3750 UNITS/5 ML (750 UNITS/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ONCASPAR**Proper Name:** PEGASPARGASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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Applicant/License No: SERVIER PHARMACEUTICALS LLC / 2125

103411 / 0	1	2/1/1994	3750 IU/5 ML (750 IU/ML)
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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
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125151 / 0	1	7/24/2006	6 MG/3 ML (2 MG/ML)
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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
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022575 / 0	1	2/26/2010	400 UNITS/VIAL (400 UNITS/VIAL)
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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
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125294 / 0	1	8/29/2012	300 MCG/0.5 ML (600 MCG/ML)
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

125294 / 0	2	8/29/2012	480 MCG/0.8 ML (600 MCG/ML)
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: SICOR BIOTECH UAB / 1803

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

Applicant/License No: SOLSTICE NEUROSCIENCES LLC / 1718

103846 / 0	3	12/8/2002	10,000 IU/2 ML (5000 IU/ML)
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SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Proper Name: RIMABOTULINUMTOXINB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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103846 / 0	2	12/8/2002	5000 IU/ML (5000 IU/ML)
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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
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761116 / 0	1	12/21/2018	1000 MCG/ML (1000 MCG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: STRATATECH CORPORATION / 2144**Trade Name:** FASENRA**Proper Name:** BENRALIZUMAB

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

761070 / 5	2	10/3/2019	30 MG/ML (30 MG/ML)
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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
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761067 / 0	1	3/20/2018	100 MG/ML (100 MG/ML)
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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
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761107 / 0	1	11/20/2018	10 MG/2 ML (5 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

761107 / 0	2	11/20/2018	50 MG/10 ML (5 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

761107 / 0	3	6/26/2020	100 MG/20 ML (5 MG/ML)
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: KEPIVANCE**Proper Name:** PALIFERMIN

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

Trade Name: KINERET

Applicant/License No: SWEDISH ORPHAN BIOVITRUM AB / 1859**Proper Name:** ANAKINRA

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

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

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

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

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

Applicant/License No: THERATECHNOLOGIES INC / 2091

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

Applicant/License No: UCB INC / 1736**Trade Name:** CIMZIA**Proper Name:** CERTOLIZUMAB PEGOL

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

Applicant/License No: ULTRAGENYX PHARMACEUTICAL INC / 2040**Trade Name:** MEPSEVII**Proper Name:** VESTRONIDASE ALFA-VJBK

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

Applicant/License No: UNITED THERAPEUTICS CORP / 1993**Trade Name:** UNITUXIN**Proper Name:** DINUTUXIMAB

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: VALEANT PHARMACEUTICALS LUXEMBOURG SARL / 2053**Trade Name:** SILIQ**Proper Name:** BRODALUMAB

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

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: 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 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	2	11/14/2007	75 MCG/0.3 ML (250 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	3	11/14/2007	100 MCG/0.3 ML (333.33 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	4	11/14/2007	150 MCG/0.3 ML (500 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	5	11/14/2007	200 MCG/0.3 ML (666.66 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	6	11/14/2007	250 MCG/0.3 ML (833.33 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 073	7	4/28/2016	30 MCG/0.3 ML (100 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 073	8	4/28/2016	120 MCG/0.3 ML (400 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: VIFOR INTERNATIONAL AG / 2039

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 /
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 /

Applicant/License No: VIVUS INC / 2197

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 /			
022523 / 0	6	4/26/2021	149,900USP UNITS; 37,000USP UNITS; 97,300USP UNITS (149,900USP UNITS; 37,000USP UNITS; 97,300USP 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: Y-MABS THERAPEUTICS INC / 2209**Trade Name:** DANYELZA**Proper Name:** NAXITAMAB-GQGK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration)
			Dosage Form/Route/Presentation
761171 / 0	1	11/25/2020	40 MG/10 ML (4 MG/ML)
SOLUTION / 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 /			

Applicant/License No: ZENPEP LLC / 2198

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: ZORBTIVE

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

Trade Name: ACTHREL

Proper Name: CORTICORELIN OVINE TRIFLUTATE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020162 / 0	1	5/23/1996	100 MCG/VIAL (100MCG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	5/18/2021

Trade Name: BIO-TROPIN

Applicant/License No: FERRING PHARMACEUTICALS INC / 2112

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) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL	3/20/2003

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) POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	6/30/2003

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) POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	6/5/2018

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) POWDER / /	10/12/1994
017016 / 0	9	12/27/1984	2000 UNITS/VIAL (2000 UNITS/VIAL) POWDER / /	1/1/1900
017016 / 0	10	1/15/1974	15000 UNITS/VIAL (15000 UNITS/VIAL) POWDER / /	10/12/1994
017016 / 0	11	2/16/1990	2000 UNITS/VIAL (2000 UNITS/VIAL) POWDER / /	6/28/2002

Trade Name: REPRONEX

Applicant/License No: FERRING PHARMACEUTICALS INC / 2112

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: HERCEPTIN

Proper Name: TRASTUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103792 / 0	1	9/25/1998	420 MG (420 MG/VIAL) POWDER / INTRAVENOUS / MULTI-DOSE VIAL	2/3/2021

Trade Name: NUTROPIN

Proper Name: SOMATROPIN

Applicant/License No: GENENTECH INC / 1048

Trade Name: NUTROPIN

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
BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
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
BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
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: CEREZYME

Proper Name: IMIGLUCERASE

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: GENZYME CORP / 1596

Trade Name: CEREZYME

020367 / 0	1	5/23/1994	200 UNITS/VIAL (200 UNITS/VIAL)	7/30/2021
POWDER / 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
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)	6/27/2013
SOLUTION / INTRALESIONAL / MULTI-DOSE VIAL				

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	3	9/29/2011	135 MCG/0.5 ML (270 MCG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/28/2020
103964 / 5204	4	9/29/2011	180 MCG/0.5 ML (360 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: 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	Date added to Discontinued List
125359 / 0	1	11/18/2011	10000 IU (10000 IU/VIAL) POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	7/23/2021

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: 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	4	6/4/1986	22.8 MIU/3.8 ML (6 MIU/ML) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL	3/26/2021
103132 / 0	5	6/4/1986	32 MIU/3.2 ML (10 MIU/ML) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS, INTRALESIONAL / MULTI-DOSE VIAL	3/26/2021
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	1	1/19/2001	74 MCG (74 MCG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	3/26/2021

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

Trade Name: PEGINTRON

103949 / 0	5	1/19/2001	67.5 MCG (67.5 MCG/PEN)	10/14/2016
POWDER / SUBCUTANEOUS / PREFILLED PEN				
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	2	3/29/2011	296 MCG (296 MCG/VIAL)	12/13/2017
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				
103949 / 5153	3	3/29/2011	444 MCG (444 MCG/VIAL)	12/13/2017
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				
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) POWDER / INTRAVENOUS / MULTI-DOSE VIAL	8/25/2009
021846 / 0	2	1/16/1978	9000 IU/VIAL (9000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	8/25/2009
021846 / 0	3	1/16/1978	5000 IU/VIAL (5000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	6/30/2003

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) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	5/25/2018

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) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	3/2/2016

Trade Name: LEVEMIR INNOLET

Proper Name: INSULIN DETEMIR RECOMBINANT

Applicant/License No: NOVO NORDISK INC / 1261

Trade Name: LEVEMIR INNOLET

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) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	12/12/2012

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

Applicant/License No: NOVO NORDISK INC / 1261

Trade Name: NORDITROPIN NORDIFLEX

021148 / 0	6	10/1/2004	15MG/1.5ML (10MG/ML)	7/21/2015
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN				

021148 / 0	7	3/10/2009	30MG/3ML (10MG/ML)	7/21/2015
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN				

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)	1/17/2018
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN				

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)	12/12/2012
SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN				

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

Applicant/License No: NOVO NORDISK INC / 1261

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

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
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Applicant/License No: ORGANON USA INC / 2193

Trade Name: FOLLISTIM

020582 / 0	1	9/29/1997	75 IU/VIAL (75 IU/VIAL)	9/1/2004
POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL				

020582 / 0	2	9/29/1997	150 IU/VIAL (150 IU/VIAL)	9/1/2004
POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL				

Trade Name: FOLLISTIM AQ

Proper Name: FOLLITROPIN ALFA/BETA

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)	6/27/2006
SOLUTION / SUBCUTANEOUS /				

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

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

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: SANDOZ INC / 2003

Trade Name: OMNITROPE

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021426 / 0	2	5/30/2006	1.5 MG/VIAL (1.5 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/19/2021

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

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

Applicant/License No: SCHERING CORP / 0994

Trade Name: PEGINTRON/REBETOL COMBO PACK

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

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: SWEDISH ORPHAN BIOVITRUM AB / 1859

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
103770 / 0	4	6/19/1998	100 MG (100 MG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	2/28/2007

Applicant/License No: THERATECHNOLOGIES INC / 2091

Trade Name: EGRIFTA SV

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				