CDER Therapeutic Biologic Products

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

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

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

The list is updated three times a year. (Latest Update – April 2026)

********** 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) 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) CAPSULE, DELAYED RELEASE / ORAL /

Trade Name: EMRELIS

Proper Name: TELISOTUZUMAB VEDOTIN-TLLV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761384 / 0	1	5/14/2025	20 MG (20 MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
761384 / 0	2	5/14/2025	100 MG (100 MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: HUMIRA

Proper Name: ADALIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125057 / 0	2	11/23/2015	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	5	12/31/2002	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
125057 / 0	6	12/31/2002	10 MG/0.1 ML (10 MG/0.1 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	7	12/31/2002	20 MG/0.2 ML (20 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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125057 / 0	8	12/31/2002	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
125057 / 0	9	12/31/2002	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125057 / 0	10	12/31/2002	80 MG/0.8 ML (80 MG/0.8 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
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
761105 / 0	4	6/16/2022	360 MG/2.4ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / KIT
761105 / 0	5	3/22/2023	90 MG/ML (90 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761105 / 0	6	9/23/2022	180 MG/1.2ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / KIT
761105 / 0	7	9/3/2025	180 MG/1.2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

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

761262 / 0	1	6/16/2022	600 MG/10 ML (60 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: SURVANTA

Proper Name: BERACTANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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
761112 / 0	1	2/6/2019	11 MG (11 MG/VIAL) 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
125019 / 0	1	2/19/2002	3.2 MG/2 ML (1.6 MG/ML) 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
761196 / 0	1	4/23/2021	10MG (10MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **AKESO BIOPHARMA CO LTD / 2253**

Trade Name:

Proper Name: PENPULIMAB-KCQX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761258 / 0	1	4/23/2025	100 MG/10 ML (10 MG/ML) SOLUTION / 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	300 MG/30 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: STRENSIQ

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

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 (18 MG/0.45 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125513 / 0	2	10/23/2015	80 MG/0.8 ML (80 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125513 / 0	3	10/23/2015	28 MG/0.7 ML (28 MG/0.7 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125513 / 0	4	10/23/2015	40 MG/ML (40 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: ULTOMIRIS

Proper Name: RAVULIZUMAB-CWVZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761108 / 0	2	10/9/2020	300 MG/3 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761108 / 0	3	10/9/2020	1,100 MG/11 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: BOTOX

Proper Name: BOTULINUM TOXIN TYPE A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103000 / 0	1	12/9/1991	100 U (100 U/VIAL) POWDER / INTRAMUSCULAR, INTRADERMAL, INTRADETRUSOR / SINGLE-DOSE VIAL
103000 / 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: **ALTOR BIOSCIENCE LLC AN INDIRECT WHOLLY OWNED SUBSIDIARY OF IMMUNITYBI**

Trade Name: ANKTIVA

Proper Name: NOGAPENDEKIN ALFA INBAKICEPT PMLN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761336 / 0	1	4/22/2024	400 MCG/0.4 ML (400 MCG/0.4 ML) SOLUTION / INTRAVESICAL / SINGLE-DOSE VIAL

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

Trade Name: AIMOVIG

Proper Name: ERENUMAB-AOOE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761077 / 0	2	5/17/2018	70 MG (70 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
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
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
103951 / 0	8	9/17/2001	25 MCG/0.42 ML (25 MCG/0.42 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

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

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

Trade Name: BLINCYTO

Proper Name: BLINATUMOMAB

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

Trade Name: EPOGEN

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

Proper Name: EPOETIN ALFA

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

Proper Name: EPOETIN ALFA - PRESERVATIVE FREE

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

Trade Name: EVENITY

Proper Name: ROMOSOZUMAB-AQQG

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

Trade Name: IMDELLTRA

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

Proper Name: TARLATAMAB-DLLE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761344 / 0	1	5/16/2024	1 MG/VIAL (1 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
761344 / 0	2	5/16/2024	10 MG/VIAL (10 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: NEULASTA

Proper Name: PEGFILGRASTIM

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

Trade Name: NEULASTA ONPRO

Proper Name: PEGFILGRASTIM

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

Trade Name: NEUPOGEN

Proper Name: FILGRASTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103353 / 0	1	2/20/1991	300 MCG/ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

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

103353 / 0	2	2/20/1991	300 MCG/0.5 ML (300 MCG/0.5 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 (480 MCG/0.8 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

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

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

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 / 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
125147 / 0	1	9/27/2006	100 MG/5 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125147 / 0	3	9/27/2006	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: XGEVA

Proper Name: DENOSUMAB

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

Applicant/License No: **AMICUS THERAPEUTICS US LLC / 2224**

Trade Name: POMBILITI

Proper Name: CIPAGLUCOSIDASE ALFA-ATGA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761204 / 0	1	9/28/2023	105 MG (105 MG) POWDER / INTRAVENOUS / 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
021665 / 0	1	10/26/2004	150 UNITS/ML (150 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **ARGENX BV / 2217**

Trade Name: VYVGART

Proper Name: EFGARTIGIMOD ALFA-FCAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761195 / 0	1	12/17/2021	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: VYVGART HYTRULO

Proper Name: EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761304 / 0	1	6/20/2023	1008 MG AND 11200 UNITS/5.6 ML (180 MG AND 2000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **ARGENX BV / 2217**

761304 / 0	2	4/10/2025	1000 MG AND 10000 UNITS/5 ML (200 MG AND 2000 UNITS/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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
761137 / 0	1	12/18/2019	20 MG (20 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
761137 / 0	2	12/18/2019	30 MG (30 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: VYLOY

Proper Name: ZOLBETUXIMAB-CLZB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761365 / 0	1	10/18/2024	100 MG (100 MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
761365 / 0	2	3/24/2025	300 MG (300 MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: BEYFORTUS

Proper Name: NIRSEVIMAB-ALIP

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761328 / 0	1	7/17/2023	50 MG/0.5 ML (50 MG/0.5 ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
761328 / 0	2	7/17/2023	100 MG/ML (100 MG/ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: IMJUDO

Proper Name: TREMELIMUMAB-ACTL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761270 / 0	1	11/10/2022	25 MG/1.25 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761270 / 0	2	11/10/2022	300 MG/15 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: SAPHNELO

Proper Name: ANIFROLUMAB-FNIA

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

Trade Name: TEZSPIRE

Proper Name: TEZEPELUMAB-EKKO

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

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

761224 / 0	1	12/17/2021	210 MG/1.91 ML (110 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
761224 / 0	2	2/1/2023	210 MG/1.91 ML (110 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

Trade Name: FASENRA

Proper Name: BENRALIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761070 / 0	1	11/14/2017	30 MG/ML (30 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761070 / 0	2	10/3/2019	30 MG/ML (30 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761070 / 0	3	4/8/2024	10 MG/0.5 ML (10 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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: **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: **BEONE MEDICINES USA INC / 2232**

Trade Name: TEVIMBRA

Proper Name: TISLELIZUMAB-JSGR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761232 / 0	1	3/13/2024	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: AVONEX

Proper Name: INTERFERON BETA 1A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103628 / 0	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 (63 MCG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125499 / 0	2	8/15/2014	125 MCG/0.5 ML (125 MCG/0.5 ML) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / PREFILLED SYRINGE
125499 / 0	3	8/15/2014	63 MCG/0.5 ML (63 MCG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

125499 / 0	4	8/15/2014	94 MCG/0.5 ML (94 MCG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125499 / 0	5	8/15/2014	94 MCG/0.5 ML (94 MCG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
125499 / 0	6	8/15/2014	125 MCG/0.5 ML (125 MCG/0.5 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

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

Trade Name: NAGLAZYME

Proper Name: GALSULFASE

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

Trade Name: PALYNZIQ

Proper Name: PEGVALIASE-PQPZ

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

Trade Name: VIMIZIM

Proper Name: ELOSULFASE ALFA

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

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

Trade Name: PRAXBIND

Proper Name: IDARUCIZUMAB

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

Trade Name: SPEVIGO

Proper Name: SPESOLIMAB-SBZO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761244 / 0	1	9/1/2022	450 MG/7.5 ML (60 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761244 / 0	2	3/18/2024	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761244 / 0	3	5/28/2025	300 MG/2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

Trade Name: EMPLICITI

Proper Name: ELOTUZUMAB

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

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

Trade Name: NULOJIX

Proper Name: BELATACEPT

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

Trade Name: OPDIVO

Proper Name: NIVOLUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125554 / 0	1	12/22/2014	40 MG/4 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125554 / 0	2	12/22/2014	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125554 / 0	3	12/22/2014	240 MG/24 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125554 / 0	4	8/27/2021	120 MG/12 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: OPDIVO QVANTIG

Proper Name: NIVOLUMAB AND HYALURONIDASE-NVHY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761381 / 0	1	12/27/2024	600 MG AND 10,000 UNITS/5 ML (120 MG AND 2,000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: OPDUALAG

Proper Name: NIVOLUMAB AND RELATLIMAB-RMBW

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761234 / 0	1	3/18/2022	240 MG AND 80 MG/20 ML (12 MG AND 4 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 (50 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125118 / 122	3	7/29/2011	87.5 MG/0.7 ML (87.5 MG/0.7 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125118 / 122	4	7/29/2011	125 MG/ML (125 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125118 / 122	5	7/29/2011	125 MG/ML (125 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: YERVOY

Proper Name: IPILIMUMAB

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

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

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

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

Trade Name: VORAXAZE

Proper Name: GLUCARPIDASE

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

Applicant/License No: **CELGENE CORPORATION / 2114**

Trade Name: REBLOZYL

Proper Name: LUSPATERCEPT-AAMT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761136 / 0	1	11/8/2019	25 MG (25 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
761136 / 0	2	11/8/2019	75 MG (75 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **CELLTRION INC / 1996**

Trade Name: ZYMFENTRA

Proper Name: INFLIXIMAB-DYYB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761358 / 0	1	10/20/2023	120 MG/ML (120 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **CELLTRION INC / 1996**

761358 / 0	2	10/20/2023	120 MG/ML (120 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **CHECKPOINT THERAPEUTICS INCORPORATED / 2275**

Trade Name: UNLOXCYT

Proper Name: COSIBELIMAB-IPDL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761297 / 0	1	12/13/2024	300 MG/5 ML (60 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **CHIESI FARMACEUTICI SPA / 2245**

Trade Name: ELFABRIO

Proper Name: PEGUNIGALSIDASE ALFA-IWXJ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761161 / 0	1	5/9/2023	20 MG/10 ML (2 ML/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761161 / 0	2	5/17/2024	5 MG/2.5 ML (2 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: LAMZEDE

Proper Name: VELMANASE ALFA-TYCV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761278 / 0	1	2/16/2023	10 MG/VIAL (10 MG/VIAL) POWDER / INTRAVENOUS / 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: MYALEPT

Proper Name: METRELEPTIN

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

Trade Name: REVCOVI

Proper Name: ELAPEGADEMASE-LVLR

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

Applicant/License No: **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: **CITIUS ONCOLOGY INC / 2290**

Trade Name: LYMPHIR

Proper Name: DENILEUKIN DIFTITOX-CXDL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761312 / 0	1	8/7/2024	300 MCG/VIAL (300 MCG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **COHERUS BIOSCIENCES INC / 2023**

Trade Name: LOQTORZI

Proper Name: TORIPALIMAB-TPZI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761240 / 0	1	10/27/2023	240 MG/6 ML (40 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **CSL BEHRING LLC / 1767**

Trade Name: ANDEMBRY

Proper Name: GARADACIMAB-GXII

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761367 / 0	1	6/16/2025	200 MG/1.2 ML (200 MG/1.2 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761367 / 0	2	6/16/2025	200 MG/1.2 ML (167 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **DAIICHI SANKYO INC / 2128**

Trade Name: DATROWAY

Proper Name: DATOPOTAMAB DERUXTECAN-DLNK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761394 / 0	1	1/17/2025	100 MG (100 MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761464 / 0	1	6/23/2025	100 MG (100 MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ENHERTU

Proper Name: FAM-TRASTUZUMAB DERUXTECAN-NXKI

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

Applicant/License No: **DENALI THERAPEUTICS INC / 2385**

Trade Name: AVLAYAH

Proper Name: TIVIDENOFUSP ALFA-EKNM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761485 / 0	1	3/24/2026	150 MG (150 MG) 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
022175 / 0	1	5/17/2012	30,250USP UNITS; 8,000USP UNITS; 28,750USP UNITS (30,250USP UNITS; 8,000USP UNITS; 28,750USP UNITS) 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) 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) CAPSULE, DELAYED RELEASE / ORAL /
022175 / 0	4	7/13/2017	90,750USP UNITS; 24,000USP UNITS; 86,250USP UNITS (90,750USP UNITS; 24,000USP UNITS; 86,250USP UNITS) 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
761094 / 0	1	8/22/2018	20 MCG/ML (0.002%) SOLUTION / OPHTHALMIC / MULTI-DOSE VIAL

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

Trade Name: KALBITOR

Proper Name: ECALLANTIDE

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

Trade Name: TAKHZYRO

Proper Name: LANADELUMAB-FLYO

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

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

Trade Name: LEQEMBI

Proper Name: LECANEMAB-IRMB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761269 / 0	1	1/6/2023	500 MG/5 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761269 / 0	2	1/6/2023	200 MG/2 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761375 / 0	1	8/29/2025	500 MG/5 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

761375 / 0	2	8/29/2025	200 MG/2 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761375 / 0	3	8/29/2025	360 MG/1.8 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

Trade Name: BASAGLAR KWIKPEN

Proper Name: INSULIN GLARGINE

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

Trade Name: BASAGLAR TEMPO PEN

Proper Name: INSULIN GLARGINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
205692 / 0	2	11/15/2019	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: CYRAMZA

Proper Name: RAMUCIRUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125477 / 0	1	4/21/2014	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125477 / 0	2	4/21/2014	500 MG/50 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: EBGLYSS

Proper Name: LEBRIKIZUMAB-LBKZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761306 / 0	1	9/13/2024	250 MG/2 ML (250 MG/2 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761306 / 0	2	9/13/2024	250 MG/2 ML (250 MG/2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: EMGALITY

Proper Name: GALCANEZUMAB-GNLM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761063 / 0	1	9/27/2018	120 MG/ML (120 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761063 / 0	2	9/27/2018	120 MG/ML (120 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761063 / 3	3	6/4/2019	100 MG/ML (100 MG/ML) 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

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

020563 / 0	2	8/6/1998	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE
020563 / 0	6	9/20/2019	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / 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
205747 / 0	1	5/26/2015	600 UNITS/3 ML (200 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: HUMALOG KWIKPEN JUNIOR

Proper Name: INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020563 / 0	4	6/6/2017	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

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

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

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: HUMALOG TEMPO PEN

Proper Name: INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020563 / 0	5	11/15/2019	300 UNITS/3ML (100 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	5	2/4/1999	6 MG (6 MG) POWDER / SUBCUTANEOUS / CARTRIDGE
019640 / 0	6	2/4/1999	12 MG (12 MG) POWDER / SUBCUTANEOUS / CARTRIDGE

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

019640 / 0	7	2/4/1999	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

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: KISUNLA

Proper Name: DONANEMAB-AZBT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761248 / 0	1	7/2/2024	350 MG/20 ML (17.5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

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
761109 / 0	6	6/15/2020	600 UNITS/3 ML (200 UNITS/ML) 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
761109 / 0	4	6/15/2020	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: OMVOH

Proper Name: MIRIKIZUMAB-MRKZ

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

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

761279 / 0	1	10/26/2023	300 MG/15 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761279 / 0	2	10/26/2023	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761279 / 0	3	4/29/2024	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761279 / 0	4	1/15/2025	200 MG/2 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761279 / 0	5	1/15/2025	200 MG/2 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: TALTZ

Proper Name: IXEKIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125521 / 0	1	3/22/2016	80 MG/ML (80 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125521 / 0	2	3/22/2016	80 MG/ML (80 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: TRULICITY

Proper Name: DULAGLUTIDE

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

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

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
761049 / 0	1	3/23/2017	200 MG/10 ML (20 MG/ML) 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

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

020378 / 0	4	2/28/2001	1,050 IU/VIAL (600 IU/ML) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL
020378 / 0	5	3/26/2004	450 IU/VIAL (600 IU/ML) POWDER / SUBCUTANEOUS / MULTI-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
021684 / 0	1	5/25/2004	300 IU/0.5ML (300 IU/0.5ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
021684 / 0	2	5/25/2004	450 IU/0.75 ML (450 IU/0.75 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

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

103780 / 0	1	3/7/2002	8.8 MCG/0.2 ML (8.8 MCG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103780 / 0	2	3/7/2002	8.8 MCG/0.2 ML (8.8 MCG/0.2 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
103780 / 0	3	3/7/2002	22 MCG/0.5 ML (22 MCG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103780 / 0	4	3/7/2002	22 MCG/0.5 ML (22 MCG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
103780 / 0	5	3/7/2002	44 MCG/0.5 ML (44 MCG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103780 / 0	6	3/7/2002	44 MCG/0.5 ML (44 MCG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: SEROSTIM

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020604 / 0	1	8/23/1996	6 MG/VIAL (6 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
020604 / 0	2	8/23/1996	5 MG/VIAL (5 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
020604 / 0	3	7/25/1997	4 MG/VIAL (4 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL

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

Trade Name: EBANGA

Proper Name: ANSUVIMAB-ZYKL

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

Trade Name: RAXIBACUMAB

Proper Name: RAXIBACUMAB

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

Applicant/License No: **ETON PHARMACEUTICALS INC / 2393**

Trade Name: INCRELEX

Proper Name: MECASERMIN RECOMBINANT

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

Applicant/License No: **EVIVE BIOTECHNOLOGY SINGAPORE PTE LTD / 2248**

Trade Name: RYZNEUTA

Proper Name: EFBEMALENOGRASTIM ALFA-VUXW

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761134 / 0	1	11/16/2023	20 MG/ML (20 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

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	2	1/4/2002	5 MG/VIAL (5 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL

Applicant/License No: **FERRING PHARMACEUTICALS INC / 2112**

019774 / 0	3	3/7/2012	10 MG/VIAL (10 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL

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
017067 / 0	2	3/5/1973	10000 UNITS/VIAL (10000 UNITS/VIAL) POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL

Applicant/License No: **GALDERMA LABORATORIES LP / 2289**

Trade Name: NEMLUVIO

Proper Name: NEMOLIZUMAB-ILTO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761390 / 0	1	8/12/2024	30 MG (30 MG) POWDER / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

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

125276 / 0	3	1/8/2010	400 MG/20 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125472 / 1	1	10/21/2013	162 MG/0.9 ML (162 MG/0.9 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125472 / 29	2	11/19/2018	162 MG/0.9 ML (162 MG/0.9 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
103172 / 0	2	11/13/1987	50 MG (50 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103172 / 0	3	3/2/1992	100 MG (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: AVASTIN

Proper Name: BEVACIZUMAB

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

Trade Name: CATHFLO ACTIVASE

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

Proper Name: ALTEPLASE

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

Trade Name: COLUMVI

Proper Name: GLOFITAMAB-GXBM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761309 / 0	1	6/15/2023	2.5 MG/2.5 ML (1 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761309 / 0	2	6/15/2023	10 MG/10 ML (1 MG/ML) SOLUTION / INTRAVENOUS / 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

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

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 (60 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761083 / 0	3	11/16/2017	105 MG/0.7 ML (105 MG/0.7 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761083 / 0	4	11/16/2017	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761083 / 0	5	3/16/2023	300 MG/2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761083 / 0	6	1/31/2024	12 MG/0.4 ML (12 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: HERCEPTIN

Proper Name: TRASTUZUMAB

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

Trade Name: HERCEPTIN HYLECTA

Proper Name: TRASTUZUMAB AND HYALURONIDASE-OYSK

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

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

761106 / 0	1	2/28/2019	600 MG AND 10000 UNITS/5ML (120 MG AND 2000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: KADCYLA

Proper Name: ADO-TRASIUZUMAB EMTANSINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125427 / 0	1	2/22/2013	100 MG (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125427 / 0	2	2/22/2013	160 MG (160 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: LUCENTIS

Proper Name: RANIBIZUMAB

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

Trade Name: LUNSUMIO

Proper Name: MOSUNETUZUMAB-AXGB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761263 / 0	1	12/22/2022	1 MG/ML (1 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

761263 / 0	2	12/22/2022	30 MG/30 ML (1 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: OCREVUS

Proper Name: OCRELIZUMAB

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

Trade Name: OCREVUS ZUNOVO

Proper Name: OCRELIZUMAB AND HYALURONIDASE-OCSQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761371 / 0	1	9/13/2024	920 MG AND 23,000 UNITS/23 ML (40 MG AND 1,000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: PERJETA

Proper Name: PERTUZUMAB

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

Trade Name: PHESGO

Proper Name: PERTUZUMAB, TRASTUZUMAB, AND HYALURONIDASE-ZZXF

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

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

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

Trade Name: PIASKY

Proper Name: CROVALIMAB-AKKZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761388 / 0	1	6/20/2024	340 MG/2 ML (170 MG/ML) SOLUTION / INTRAVENOUS, 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
761121 / 0	2	9/18/2020	30 MG (30 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PULMOZYME

Proper Name: DORNASE ALFA

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

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

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: SUSVIMO

Proper Name: RANIBIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761197 / 0	1	10/22/2021	100 MG/ML (100 MG/ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL

Trade Name: TECENTRIQ

Proper Name: ATEZOLIZUMAB

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

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

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

Trade Name: TECENTRIQ HYBREZA

Proper Name: ATEZOLIZUMAB AND HYALURONIDASE-TQJS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761347 / 0	1	9/12/2024	1,875 MG ATEZOLIZUMAB AND 30,000 UNITS HYALURONIDASE PER 15 ML (125 MG/2,000 UNITS PER ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: TNKASE

Proper Name: TENECTEPLASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103909 / 0	1	6/2/2000	50 MG (50 MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103909 / 0	2	2/28/2025	25 MG (25 MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: VABYSMO

Proper Name: FARICIMAB-SVOA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761235 / 0	1	1/28/2022	120 MG/ML (120 MG/ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: XOLAIR

Proper Name: OMALIZUMAB

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

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

103976 / 0	1	6/20/2003	150 MG/VIAL (150 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
103976 / 5231	3	9/28/2018	75 MG/0.5 ML (75 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103976 / 5231	4	9/28/2018	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103976 / 0	5	8/17/2023	300MG/2ML (300MG/2ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
103976 / 0	6	8/17/2023	75 MG/0.5 ML (75 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
103976 / 0	7	8/17/2023	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
103976 / 0	8	8/17/2023	300 MG/2 ML (300 MG/2 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **GENMAB US INC / 2293**

Trade Name: EPKINLY

Proper Name: EPCORITAMAB-BYSP

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761324 / 0	1	5/19/2023	4 MG/0.8 ML (4 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761324 / 0	2	5/19/2023	48 MG/0.8 ML (48 MG/0.8 ML) SOLUTION / 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
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
103948 / 5139	2	11/14/2014	12 MG/1.2 ML (10MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: LUMIZYME

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

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: **GILEAD SCIENCES INC / 2258**

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: **GLAXOSMITHKLINE LLC / 1727**

Trade Name: BENLYSTA

Proper Name: BELIMUMAB

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761043 / 0	1	7/20/2017	200 MG/ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761043 / 0	2	7/20/2017	200 MG/ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: BLENREP

Proper Name: BELANTAMAB MAFODOTIN-BLMF

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761440 / 0	1	10/23/2025	70 MG/VIAL (70 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: EXDENSUR

Proper Name: DEPEMOKIMAB-ULAA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761458 / 0	1	12/17/2025	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

761458 / 0	2	12/17/2025	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: JEMPERLI

Proper Name: DOSTARLIMAB-GXLY

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

Trade Name: NUCALA

Proper Name: MEPOLIZUMAB

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761122 / 0	1	6/6/2019	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761122 / 0	2	6/6/2019	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761122 / 0	3	1/22/2022	40 MG/0.4 ML (40 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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
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: **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 (100 MCG/0.5 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

Trade Name: UPLIZNA

Proper Name: INEBILIZUMAB-CDON

Applicant/License No: **HORIZON THERAPEUTICS IRELAND DAC / 2022**

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: **HUGEL INC / 2237**

Trade Name: LETYBO

Proper Name: LETIBOTULINUMTOXINA-WLBG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761225 / 0	1	2/29/2024	50 UNITS/VIAL (50 UNITS/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
761225 / 0	2	2/29/2024	100 UNITS/VIAL (100 UNITS/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

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

Trade Name: ERBITUX

Proper Name: CETUXIMAB

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

Applicant/License No: **IMMEDICA PHARMA AB / 2342**

Trade Name: LOARGYS

Proper Name: PEGZILARGINASE-NBLN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761211 / 0	1	2/23/2026	2 MG/0.4 ML (2 MG/0.4 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL
761211 / 0	2	2/23/2026	5 MG/ML (5 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / 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 (25 MG/0.5 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: **IMMUNOCORE LIMITED / 2239**

Trade Name: KIMMTRAK

Proper Name: TEBENTAFUSP-TEBN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761228 / 0	1	1/25/2022	100 MCG/0.5 ML (100 MCG/0.5 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **IMMUNOGEN INC / 2288**

Trade Name: ELAHERE

Proper Name: MIRVETUXIMAB SORAVTANSINE-GYNX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761310 / 0	1	11/14/2022	100 MG/20 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **INCYTE CORPORATION / 2228**

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

Trade Name: NIKTIMVO

Proper Name: AXATILIMAB-CSFR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761411 / 0	1	8/14/2024	50 MG/ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **INCYTE CORPORATION / 2228**

761411 / 0	2	1/14/2025	9 MG/0.18 ML (9 MG/0.18 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761411 / 0	3	1/14/2025	22 MG/0.44 ML (22 MG/0.44 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ZYNYZ

Proper Name: RETIFANLIMAB-DLWR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761334 / 0	1	3/22/2023	500 MG/20ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **IOVANCE BIOTHERAPEUTICS MANUFACTURING LLC / 2353**

Trade Name: PROLEUKIN

Proper Name: ALDESLEUKIN

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

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

Trade Name: DYSPORT

Proper Name: ABOBOTULINUMTOXINA

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

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

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

Applicant/License No: **ISO TEX DIAGNOSTICS INC / 2189**

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	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: IMAAVY

Proper Name: NIPOCALIMAB-AAHU

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761430 / 0	1	4/29/2025	300 MG/1.62 ML (185 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761430 / 0	2	4/29/2025	1200 MG/6.5 ML (185 MG/ML) SOLUTION / INTRAVENOUS / 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
761210 / 0	1	5/21/2021	350 MG/7 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: RYBREVANT FASPRO

Proper Name: AMIVANTAMAB AND HYALURONIDASE-LPUJ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761433 / 0	1	12/17/2025	1,600 MG AND 20,000 UNITS/10 ML (160 MG AND 2,000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761433 / 0	2	12/17/2025	2,240 MG AND 28,000 UNITS/14 ML (160 MG AND 2,000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

761433 / 0	3	2/13/2026	2,400 MG AND 30,0000 UNITS/15ML (160 MG AND 2,000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761433 / 0	4	2/13/2026	3,520 MG AND 44,0000 UNITS/22ML (160 MG AND 2,000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: SIMPONI

Proper Name: GOLIMUMAB

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

Trade Name: SIMPONI ARIA

Proper Name: GOLIMUMAB

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

Trade Name: STELARA

Proper Name: USTEKINUMAB

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 / SUBCUTANEOUS / PREFILLED SYRINGE
125261 / 0	2	9/25/2009	45 MG/0.5 ML (45 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE

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 / SINGLE-DOSE VIAL

Trade Name: TALVEY

Proper Name: TALQUETAMAB-TGVS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761342 / 0	1	8/9/2023	3 MG/1.5 ML (2 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761342 / 0	2	8/9/2023	40 MG/ML (40 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: TECVAYLI

Proper Name: TECLISTAMAB-CQYV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761291 / 0	1	10/25/2022	30 MG/3 ML (10 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

761291 / 0	2	10/25/2022	153 MG/1.7ML (90 MG/ML) SOLUTION / 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
761061 / 0	4	9/11/2024	200 MG/2 ML (200 MG/2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761061 / 0	5	9/11/2024	200 MG/20 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: TREMFYA PEN

Proper Name: GUSELKUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761061 / 0	2	9/11/2024	100 MG/ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761061 / 0	3	9/11/2024	200 MG/2 ML (200 MG/2 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

Trade Name: ZIIHERA

Proper Name: ZANIDATAMAB-HRII

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761416 / 0	1	11/20/2024	300 MG (300 MG) POWDER / INTRAVENOUS / 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 UK LTD / 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: **LEO PHARMA AS / 2169**

Trade Name: ADBRY

Proper Name: TRALOKINUMAB-LDRM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761180 / 0	1	12/27/2021	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761180 / 0	2	6/12/2024	300 MG/2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **LIB THERAPEUTICS INC / 2352**

Trade Name: LEROCHOL

Proper Name: LERODALCIBEP-LIGA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761427 / 0	1	12/12/2025	300 MG/1.2 ML (250 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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: **MANNKIND CORP / 2190**

Trade Name: AFREZZA

Proper Name: INSULIN RECOMBINANT HUMAN

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

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

Trade Name: ENFLONSIA

Proper Name: CLESROVIMAB-CFOR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761432 / 0	1	6/9/2025	105 MG/0.7 ML (105 MG/0.7 ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: KEYTRUDA

Proper Name: PEMBROLIZUMAB

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

Trade Name: KEYTRUDA QLEX

Proper Name: PEMBROLIZUMAB AND BERAHYALURONIDASE ALFA-PMPH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761467 / 0	1	9/19/2025	395 MG AND 4,800 UNITS/2.4 ML (165 MG AND 2,000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761467 / 0	2	9/19/2025	790 MG AND 9,600 UNITS/4.8 ML (165 MG AND 2,000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: WINREVAIR

Proper Name: SOTATERCEPT-CSRK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761363 / 0	1	3/26/2024	45 MG/VIAL (45 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

761363 / 0	2	3/26/2024	60 MG/VIAL (60 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

Trade Name: XEOMIN

Proper Name: INCOBOTULINUMTOXINA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125360 / 0	1	7/30/2010	50 U (50 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
125360 / 0	2	7/30/2010	100 U (100 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
125360 / 3	3	11/20/2015	200 U (200 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

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

Trade Name: 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

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

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 (6 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL

Trade Name: COSENTYX

Proper Name: SECUKINUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125504 / 0	2	1/21/2015	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125504 / 0	3	1/21/2015	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
125504 / 0	4	5/28/2021	75 MG/0.5 ML (75 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125504 / 0	5	5/11/2023	300 MG/2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125504 / 0	6	5/11/2023	300 MG/2 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761349 / 0	1	10/6/2023	125 MG/5 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: EXTAVIA

Proper Name: INTERFERON BETA-1B

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

Trade Name: ILARIS

Proper Name: CANAKINUMAB

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

Trade Name: KESIMPTA

Proper Name: OFATUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125326 / 70	3	8/20/2020	20 MG/0.4 ML (20 MG/0.4 ML) 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

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

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: ALHEMO

Proper Name: CONCIZUMAB-MTCI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761315 / 0	1	12/20/2024	60 MG/1.5 ML (40 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761315 / 0	2	12/20/2024	150 MG/1.5 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761315 / 0	3	12/20/2024	300 MG/3 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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: FIASP PUMPCART

Proper Name: INSULIN ASPART

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
208751 / 0	4	6/21/2023	160 UNITS/1.6 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE

Trade Name: NORDITROPIN FLEXPRO

Proper Name: SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021148 / 0	8	3/1/2010	5MG/1.5ML (3.33MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
021148 / 0	9	3/1/2010	10 MG/1.5ML (6.67 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
021148 / 0	10	3/1/2010	15MG/1.5ML (10MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **NOVO NORDISK INC / 1261**

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

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

Applicant/License No: **NOVO NORDISK INC / 1261**

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
761156 / 0	2	10/1/2021	5 MG/1.5 ML (3.3 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761156 / 0	3	4/28/2023	15 MG/1.5ML (10 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
203314 / 0	3	11/21/2018	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Applicant/License No: **NOVO NORDISK INC / 1261**

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: **OMEROS CORPORATION / 2141**

Trade Name: YARTEMLEA

Proper Name: NARSOPLIMAB-WUUG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761152 / 0	1	12/23/2025	370 MG/2 ML (185 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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 LLC A SUBSIDIARY OF ORGANON AND CO / 2331**

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	300 IU/0.36 ML (300 IU/0.36 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
021211 / 0	2	3/23/2004	600 IU/0.72 ML (600 IU/0.72 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
021211 / 0	4	2/11/2005	900 IU/1.08 ML (900 IU/1.08 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Trade Name: PREGNYL

Proper Name: GONADOTROPIN, CHORIONIC

Applicant/License No: **ORGANON USA LLC A SUBSIDIARY OF ORGANON AND CO / 2331**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
017692 / 0	1	10/20/1976	10000 UNITS/VIAL (10000 UNITS/VIAL) POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL

Applicant/License No: **OTSUKA PHARMACEUTICAL COMPANY LTD / 2387**

Trade Name: VOYXACT

Proper Name: SIBEPRENLIMAB-SZSI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761434 / 0	1	11/25/2025	400 MG/2 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

Trade Name: BIZENGRI

Proper Name: ZENOCUTUZUMAB-ZBCO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761352 / 0	1	12/4/2024	375 MG/18.75 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: ELREXFIO

Proper Name: ELRANATAMAB-BCMM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761345 / 0	1	8/14/2023	76 MG/1.9 ML (40 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761345 / 0	2	8/14/2023	44 MG/1.1 ML (40 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: HYMPAVZI

Proper Name: MARSTACIMAB-HNCQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761369 / 0	2	10/11/2024	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **PFIZER IRELAND PHARMACEUTICALS / 2060**

Trade Name: NGENLA

Proper Name: SOMATROGON-GHLA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761184 / 0	1	6/29/2023	24 MG/1.2 ML (20 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761184 / 0	2	6/29/2023	60 MG/1.2 ML (50 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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
021106 / 0	1	3/25/2003	10MG/VIAL (10MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **PHARMACIA AND UPJOHN CO / 1216**

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: **PHARMAESSENTIA CORPORATION / 2155**

Trade Name: BESREMI

Proper Name: ROPEGINTERFERON ALFA-2B-NJFT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761166 / 0	1	11/12/2021	500 MCG/ML (500 MCG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Applicant/License No: **PROVENTION BIO INC / 2170**

Trade Name: TZIELD

Proper Name: TEPLIZUMAB-MZWV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761183 / 0	1	11/17/2022	2 MG/2 ML (1 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **QOL MEDICAL LLC / 2195**

Trade Name: SUCRAID

Proper Name: SACROSIDASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020772 / 0	2	5/25/2022	17,000 IU/2 ML (8500 IU/ML) SOLUTION / ORAL / SINGLE DOSE CONTAINER

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

Trade Name: ENJAYMO

Proper Name: SUTIMLIMAB-JOME

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761164 / 0	1	2/4/2022	1,100 MG/22 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: SYLVANT

Proper Name: SILTUXIMAB

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

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

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

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

125387 / 0	1	11/18/2011	2 MG/0.05 ML (2 MG/0.05 ML) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: EYLEA HD

Proper Name: AFLIBERCEPT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761355 / 0	1	8/18/2023	8 MG (0.07 ML OF 114.3 MG/ML) (8 MG (0.07 ML OF 114.3 MG/ML)) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL

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
761169 / 0	2	9/29/2021	483.3 MG/483.3 MG/483.3 MG/14.5 ML (33.33 MG/33.33 MG/33.33 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: LIBTAYO

Proper Name: CEMIPLIMAB-RWLC

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

Trade Name: LYNOZYFIC

Proper Name: LINVOSELTAMAB-GCPT

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

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

761400 / 0	1	7/2/2025	5 MG/2.5 ML (2 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761400 / 0	2	7/2/2025	200 MG/10 ML (20 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

Trade Name: VEOPOZ

Proper Name: POZELIMAB-BBFG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761339 / 0	1	8/18/2023	400 MG/2 ML (200 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: **REVANCE THERAPEUTICS INC / 2101**

Trade Name: DAXXIFY

Proper Name: DAXIBOTULINUMTOXINA-LANM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761127 / 0	2	9/7/2022	100 UNITS/VIAL (100 UNITS/VIAL) POWDER / INTRAMUSCULAR / 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
021426 / 0	1	5/30/2006	5.8 MG/VIAL (5.8 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
021426 / 0	3	1/16/2008	5 MG/1.5ML (3.33 MG/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE
021426 / 0	4	8/25/2008	10 MG/1.5 ML (6.67 MG/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE

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

Trade Name: ADMELOG

Proper Name: INSULIN LISPRO

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

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
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

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

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

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
021081 / 0	1	4/20/2000	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: LANTUS SOLOSTAR

Proper Name: INSULIN GLARGINE RECOMBINANT

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

Trade Name: SARCLISA

Proper Name: ISATUXIMAB-IRFC

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

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

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

Trade Name: SOLIQUA 100/33

Proper Name: INSULIN GLARGINE; LIXISENATIDE

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

Trade Name: TOUJEO MAX SOLOSTAR

Proper Name: INSULIN GLARGINE RECOMBINANT

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

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

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: ADCETRIS

Proper Name: BRENTUXIMAB VEDOTIN

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

Trade Name: TIVDAK

Proper Name: TISOTUMAB VEDOTIN-TFTV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761208 / 0	1	9/22/2021	40 MG/VIAL (40 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: ASPARLAS

Proper Name: CALASPARGASE PEGOL-MKNL

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

Trade Name: ONCASPAR

Proper Name: PEGASPARGASE

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

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

103411 / 0	1	2/1/1994	3750 IU/5 ML (750 IU/ML)
			SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL

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

Trade Name: ELAPRASE

Proper Name: IDURSULFASE

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

Trade Name: VPRIV

Proper Name: VELAGLUCERASE ALFA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
022575 / 0	1	2/26/2010	400 UNITS/VIAL (400 UNITS/VIAL)
			POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **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

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

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: RIMABOTULINUMTOXINB

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

Applicant/License No: **SPECTRUM PHARMACEUTICALS INC / 2312**

Trade Name: ROLVEDON

Proper Name: EFLAPEGRASTIM-XNST

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761148 / 0	1	9/9/2022	13.2 MG/0.6ML (13.2 MG/0.6 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

Trade Name: ELZONRIS

Proper Name: TAGRAXOFUSP-ERZS

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

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

Trade Name: ILUMYA

Proper Name: TILDRAKIZUMAB-ASMN

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

Applicant/License No: **SWEDISH ORPHAN BIOVITRUM AB / 1859**

Trade Name: GAMIFANT

Proper Name: EMAPALUMAB-LZSG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761107 / 0	1	11/20/2018	10 MG/2 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761107 / 0	2	11/20/2018	50 MG/10 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761107 / 0	3	6/26/2020	100 MG/20 ML (5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: KEPIVANCE

Proper Name: PALIFERMIN

Applicant/License No: **SWEDISH ORPHAN BIOVITRUM AB / 1859**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125103 / 0	1	12/15/2004	5.16 MG/VIAL (5.16 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: KINERET

Proper Name: ANAKINRA

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

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 (50 MG/0.5 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

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

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

761133 / 0	2	9/27/2023	108 MG/0.68 ML (108 MG/0.68 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

Trade Name: ENTYVIO PEN

Proper Name: VEDOLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761133 / 0	3	9/27/2023	108 MG/0.68 ML (108 MG/0.68 ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

Applicant/License No: **TERSERA THERAPEUTICS LLC / 2383**

Trade Name: MARGENZA

Proper Name: MARGETUXIMAB-CMKB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761150 / 0	1	12/16/2020	250 MG/10 ML (25 MG/ML) SOLUTION / 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: **TG THERAPEUTICS INC / 2090**

Trade Name: BRIUMVI

Proper Name: UBLITUXIMAB-XIIY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761238 / 0	1	12/28/2022	150 MG/6 ML (25 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: EGRIFTA WR

Proper Name: TESAMORELIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
022505 / 0	3	3/25/2025	11.6 MG/VIAL (11.6 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: TROGARZO

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

Proper Name: IBALIZUMAB-UIYK

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

Applicant/License No: **UAB TEVA BALTICS / 1803**

Trade Name: GRANIX

Proper Name: TBO-FILGRASTIM

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

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

Trade Name: BIMZELX

Proper Name: BIMEKIZUMAB-BKZX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761151 / 0	1	10/17/2023	160 MG/ML (160 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
761151 / 0	2	10/17/2023	160 MG/ML (160 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

761151 / 0	3	10/11/2024	320 MG/2 ML (160 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
761151 / 0	4	10/11/2024	320 MG/2 ML (160 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

Trade Name: RYSTIGGO

Proper Name: ROZANOLIXIZUMAB-NOLI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761286 / 0	1	6/26/2023	280 MG/2 ML (140 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761286 / 0	2	6/14/2024	420 MG/3 ML (140 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761286 / 0	3	6/14/2024	560 MG/4 ML (140 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
761286 / 0	4	6/14/2024	840 MG/6 ML (140 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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: **VERICEL CORPORATION / 2010**

Trade Name: NEXOBRID

Proper Name: ANACAULASE-BCDB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761192 / 0	2	12/28/2022	5 GM LYOPHILIZED POWDER/50 GM GEL (8.8% W/W (5 GM LYOPHILIZED POWDER/50 GM GEL)) GEL / TOPICAL / KIT

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 (50 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	2	11/14/2007	75 MCG/0.3 ML (75 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	3	11/14/2007	100 MCG/0.3 ML (100 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	4	11/14/2007	150 MCG/0.3 ML (150 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	5	11/14/2007	200 MCG/0.3 ML (200 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 0	6	11/14/2007	250 MCG/0.3 ML (250 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE

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

125164 / 073	7	4/28/2016	30 MCG/0.3 ML (30 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 073	8	4/28/2016	120 MCG/0.3 ML (120 MCG/0.3 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
125164 / 073	9	4/28/2016	360 MCG/0.6 ML (360 MCG/0.6 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 LLC / 2197**

Trade Name: PANCREAZE

Proper Name: PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

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

Applicant/License No: **VIVUS LLC / 2197**

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

Applicant/License No: **ZENPEP LLC / 2198**

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 /
022210 / 0	8	10/27/2023	252,600USP UNITS; 60,000USP UNITS; 189,600USP UNITS (252,600USP UNITS; 60,000USP UNITS; 189,600USP UNITS) CAPSULE, DELAYED RELEASE / ORAL /

Applicant/License No: **ZR PHARMA AND GMBH / 2291**

Trade Name: PEGASYS

Proper Name: PEGINTERFERON ALFA 2A

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

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

Trade Name: HUMIRA

Proper Name: ADALIMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125057 / 0	1	12/31/2002	40 MG/0.8 ML (40 MG/0.8 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/18/2022
125057 / 0	3	12/31/2002	10 MG/0.2 ML (10 MG/0.2 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	7/23/2020
125057 / 0	4	12/31/2002	20 MG/0.4 ML (20 MG/0.4 ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	7/23/2020

Trade Name: SKYRIZI

Proper Name: RISANKIZUMAB-RZAA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761105 / 0	1	4/23/2019	75 MG/0.83ML (75 MG/0.83ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	6/7/2023

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: **ALEXION PHARMACEUTICALS INC / 1743**

Trade Name: ULTOMIRIS

Proper Name: RAVULIZUMAB-CWVZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761108 / 0	1	12/21/2018	300 MG/30 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	5/30/2025
761108 / 0	4	7/22/2022	245 MG/3.5ML (70 MG/ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE	6/3/2024

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	Date added to Discontinued List
103000 / 5101	3	4/14/2005	50 U (50 U/VIAL) POWDER / INTRAMUSCULAR, INTRADERMAL, INTRADETRUSOR / SINGLE-DOSE VIAL	8/22/2022

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	Date added to Discontinued List
761077 / 0	1	5/17/2018	70 MG (70 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	9/26/2025
761077 / 1	3	3/11/2019	140 MG (140 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	9/26/2025

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

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

Trade Name: ARANESP

103951 / 0	16	9/17/2001	25 MCG/ML (25 MCG/ML)	9/27/2012
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	
103951 / 0	17	9/17/2001	25 MCG/0.42 ML (25 MCG/0.42 ML)	9/27/2012
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	
103951 / 0	18	9/17/2001	40 MCG/ML (40 MCG/ML)	9/27/2012
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	
103951 / 0	19	9/17/2001	40 MCG/0.4 ML (40 MCG/0.4 ML)	9/27/2012
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	
103951 / 0	20	9/17/2001	60 MCG/ML (60 MCG/ML)	9/27/2012
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	
103951 / 0	21	9/17/2001	60 MCG/0.3 ML (60 MCG/0.3 ML)	9/27/2012
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	
103951 / 0	22	9/17/2001	100 MCG/ML (100 MCG/ML)	9/27/2012
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	
103951 / 0	23	9/17/2001	100 MCG/0.5 ML (100 MCG/0.5 ML)	9/27/2012
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	
103951 / 0	24	9/17/2001	150 MCG/0.75 ML (150 MCG/0.75 ML)	9/27/2012
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	
103951 / 0	25	9/17/2001	150 MCG/0.3 ML (150 MCG/0.3 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	

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

Trade Name: ARANESP

103951 / 0	27	9/17/2001	200 MCG/0.4 ML (200 MCG/0.4 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 (300 MCG/0.6 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	
103951 / 0	7	9/17/2001	300 MCG/ML (300 MCG/ML)	4/30/2024
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	

Trade Name: REPATHA

Proper Name: EVOLOCUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125522 / 1	2	7/11/2016	420 MG/3.5 ML (120 MG/ML)	3/25/2024
			SOLUTION / SUBCUTANEOUS / KIT	

Trade Name: VECTIBIX

Proper Name: PANITUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125147 / 0	2	9/27/2006	200 MG/10 ML (20 MG/ML)	6/29/2017
			SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	

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

Trade Name: PROSTASCINT

Proper Name: CAPROMAB PENDETIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	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
021640 / 0	2	12/2/2004	200 UNITS/ML (200 UNITS/ML) SOLUTION / INTERSTITIAL, INTRAMUSCULAR, INTRAOCULAR, PERIBULBAR, RETROBULBAR, SOFT TISSUE, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/15/2023

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: **BEONE MEDICINES USA INC / 2232**

Trade Name: TEVIMBRA

Proper Name: TISLELIZUMAB-JSGR

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761417 / 0	1	12/26/2024	100 MG/10 ML (10 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	12/26/2024

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: **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: **BRISTOL MYERS SQUIBB CO / 1713**

Trade Name: OPDIVO QVANTIG

Proper Name: NIVOLUMAB AND HYALURONIDASE-NVHY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761429 / 0	1	12/27/2024	600 MG AND 10,000 UNITS/5 ML (120 MG AND 2,000 UNITS/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL	8/21/2025

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 INC / 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: **EKR THERAPEUTICS INC / 1814**

Trade Name: RETAVASE

Proper Name: RETEPLASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103786 / 0	1	5/6/1998	10 U (10 U/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	7/2/2024

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

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	Date added to Discontinued List
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	6/22/2023

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

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

Trade Name: HUMALOG MIX 75/25 PEN

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 TEMPO PEN

Proper Name: INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
205747 / 0	2	5/7/2025	600 UNITS/3 ML (200 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	9/19/2025

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
019640 / 0	4		5 MG/VIAL (5 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	5/27/2022

Trade Name: PORTRAZZA

Proper Name: NECITUMUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125547 / 0	1	11/24/2015	800 MG/50 ML (16 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	9/25/2025

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

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

Trade Name: TRULICITY

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

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

Proper Name: FOLLITROPIN ALFA/BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021765 / 0	2	3/25/2004	75 IU/VIAL (75 IU/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	3/28/2025

Trade Name: GONAL-F RFF REDI-JECT

Proper Name: FOLLITROPIN ALFA/BETA

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

Trade Name: GONAL-F RFF REDI-JECT

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 (150 IU/0.25 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

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: 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

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

Trade Name: SEROSTIM LQ

020604 / 0	5	2/11/2005	6 MG/0.5 ML (6 MG/0.5 ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE	5/14/2008

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
021597 / 0	4	12/1/2003	8.8 MG/VIAL (8.8 MG/VIAL) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL	9/30/2021

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	Date added to Discontinued List
761146 / 0	1	7/6/2020	0.92 MG (0.92 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	12/15/2022
761146 / 0	2	7/6/2020	1.84 MG (1.84 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	12/15/2022

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

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: 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

Applicant/License No: **FERRING PHARMACEUTICALS INC / 2112**

Trade Name: NOVAREL

017016 / 0	7	1/15/1974	10000 UNITS/VIAL (10000 UNITS/VIAL) POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL	5/16/2023
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

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

Applicant/License No: **FRESENIUS KABI USA LLC / 2146**

Trade Name: CHORIONIC GONADOTROPIN

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

Applicant/License No: **GALDERMA LABORATORIES LP / 2289**

Trade Name: NEMLUVIO

Proper Name: NEMOLIZUMAB-ILTO

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761391 / 0	1	12/13/2024	30 MG/0.49 ML (30 MG/0.49 ML) POWDER & SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	6/26/2025

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: XOLAIR

Proper Name: OMALIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103976 / 0	2	6/20/2003	125 MG/VIAL (125 MG/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	8/25/2016

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

Trade Name: CAMPATH

Proper Name: ALEMTUZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103948 / 0	3	5/7/2001	10 MG/VIAL (10 MG/VIAL) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	7/6/2011

Trade Name: CEREZYME

Proper Name: IMIGLUCERASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020367 / 0	1	5/23/1994	200 UNITS/VIAL (200 UNITS/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	7/30/2021

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

Trade Name: ALFERON N INJECTION

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103158 / 0	1	10/10/1989	5 MIU/VIAL (5 MIU/VIAL) SOLUTION / INTRALESIONAL / MULTI-DOSE VIAL	6/27/2013

Applicant/License No: **ISO TEX DIAGNOSTICS INC / 2189**

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	1	2/23/1976	0.5mCi/VIAL (0.5mCi/VIAL) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL	9/29/2022
017837 / 0	3	2/23/1976	2mCi/VIAL (2mCi/VIAL) SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL	1/1/1900

Applicant/License No: **ISO TEX DIAGNOSTICS INC / 2189**

Trade Name: MEGATOPE

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: **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: **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	1	6/4/1986	10 MIU (10 MIU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS, INTRALESIONAL, INTRAVENOUS / SINGLE-DOSE VIAL	3/26/2021

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

Trade Name: INTRON A

103132 / 0	2	6/4/1986	18 MIU (18 MIU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS / SINGLE-DOSE VIAL	3/26/2021
103132 / 0	3	6/4/1986	50 MIU (50 MIU/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS / SINGLE-DOSE VIAL	3/26/2021
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: ZINPLAVA

Proper Name: BEZLOTOXUMAB

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

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

Trade Name: ZINPLAVA

761046 / 0	1	10/21/2016	1000 MG/40 ML (25 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	8/9/2024

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: ALHEMO

Proper Name: CONCIZUMAB-MTCI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761428 / 0	1	7/31/2025	60 MG/1.5 ML (40 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/31/2025
761428 / 0	2	7/31/2025	150 MG/1.5 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/31/2025
761428 / 0	3	7/31/2025	300 MG/3 ML (100 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/31/2025

Trade Name: LEVEMIR

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	1	6/16/2005	1000 UNITS/10 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL	12/31/2024

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	4/1/2024

Trade Name: LEVEMIR FLEXTOUCH

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	5	10/31/2013	300 UNITS/3 ML (100 UNITS/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	1/26/2023

Trade Name: LEVEMIR INNOLET

Applicant/License No: **NOVO NORDISK INC / 1261**

Trade Name: LEVEMIR INNOLET

Proper Name: INSULIN DETEMIR RECOMBINANT

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

Applicant/License No: **NOVO NORDISK INC / 1261**

Trade Name: NORDITROPIN NORDIFLEX

021148 / 0	5	10/1/2004	10MG/1.5ML (6.67MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	9/25/2012
021148 / 0	6	10/1/2004	15MG/1.5ML (10MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/21/2015
021148 / 0	7	3/10/2009	30MG/3ML (10MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	7/21/2015

Trade Name: NOVOLOG FLEXTOUCH

Proper Name: INSULIN ASPART RECOMBINANT

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

Trade Name: NOVOLOG INNOLET

Proper Name: INSULIN ASPART RECOMBINANT

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

Trade Name: NOVOLOG MIX 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

Applicant/License No: **NOVO NORDISK INC / 1261**

Trade Name: NOVOLOG MIX 70/30 PFS

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 LLC A SUBSIDIARY OF ORGANON AND CO / 2331**

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	150 IU/0.18 ML (150 IU/0.18 ML) SOLUTION / SUBCUTANEOUS / CARTRIDGE	6/27/2006

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: HYMPAVZI

Proper Name: MARSTACIMAB-HNCQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761369 / 0	1	10/11/2024	150 MG/ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE	6/25/2025

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: **QOL MEDICAL LLC / 2195**

Trade Name: SUCRAID

Proper Name: SACROSIDASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020772 / 0	1	4/9/1998	1003000 IU/118 ML (8500 IU/ML) SOLUTION / ORAL / MULTI-DOSE VIAL	10/7/2024

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: DUPIXENT

Proper Name: DUPILUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761055 / 0	5	10/20/2021	100 MG/0.67 ML (150 MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	4/12/2024

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: **REVANCE THERAPEUTICS INC / 2101**

Trade Name: DAXXIFY

Proper Name: DAXIBOTULINUMTOXINA-LANM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761127 / 0	1	9/7/2022	50 UNITS/VIAL (50 UNITS/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	5/30/2025

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: ADLYXIN

Proper Name: LIXISENATIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
208471 / 0	1	7/27/2016	0.15MG/3ML (0.05MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	2/22/2023
208471 / 0	2	7/27/2016	0.3MG/3ML (0.1MG/ML) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	2/22/2023

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: **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: **TAKEDA PHARMACEUTICALS USA INC / 1898**

Trade Name: ENTYVIO

Proper Name: VEDOLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761133 / 0	1	9/27/2023	300 MG (300 MG) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	5/15/2024

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: **UAB TEVA BALTICS / 1803**

Trade Name: GRANIX

Proper Name: TBO-FILGRASTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125294 / 45	4	7/31/2018	480MCG/1.6 ML (300 MCG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/25/2025

Applicant/License No: **VERICEL CORPORATION / 2010**

Trade Name: NEXOBRID

Proper Name: ANACAULASE-BCDB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
761192 / 0	1	12/28/2022	2 GM LYOPHILIZED POWDER/20 GM GEL (8.8% W/W (2 GM LYOPHILIZED POWDER/20 GEL / TOPICAL / KIT	11/26/2024

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

Trade Name: MIRCERA

Proper Name: METHOXYPOLYETHYLENE GLYCOL EPOETIN BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125164 / 0	10	11/14/2007	50 MCG/ML (50 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	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
125164 / 0	13	11/14/2007	300 MCG/ML (300 MCG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/24/2008

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

Trade Name: MIRCERA

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	

Applicant/License No: **ZR PHARMA AND GMBH / 2291**

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 (135 MCG/0.5 ML)	7/28/2020
			SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	
103964 / 5204	4	9/29/2011	180 MCG/0.5 ML (180 MCG/0.5 ML)	7/28/2020
			SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	