

# 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 – July 2024 )

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

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

**Trade Name:** CREON

**Proper Name:** PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

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

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

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

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

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125057 / 0	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
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

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


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 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

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BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761105 / 0	2	4/26/2021	150 MG/ML ( 150 MG/ML )
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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761105 / 0	3	4/26/2021	150 MG/ML ( 150 MG/ML )
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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761105 / 0	4	6/16/2022	360 MG/2.4ML ( 150 MG/ML )
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SOLUTION / SUBCUTANEOUS / KIT

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761105 / 0	5	3/22/2023	90 MG/ML ( 90 MG/ML )
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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761105 / 0	6	9/23/2022	180 MG/1.2ML ( 150 MG/ML )
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SOLUTION / SUBCUTANEOUS / CARTRIDGE

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BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761262 / 0	1	6/16/2022	600 MG/10 ML ( 60 MG/ML )
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

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: 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**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

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


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125513 / 0	2	10/23/2015	80 MG/0.8 ML ( 80 MG/0.8 ML )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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

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

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

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

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

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

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

**Trade Name:** ARANESP

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

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



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

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

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

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**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

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

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:** ROMOSUZUMAB-AQQG

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

**Trade Name:** IMDELLTRA**Proper Name:** TARLATAMAB-DLLE

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

761344 / 0	2	5/16/2024	10 MG/VIAL ( 10 MG/VIAL )
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

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
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

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

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

125522 / 0	1	8/27/2015	140 MG/ML ( 140 MG/ML )
			SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
125522 / 1	2	7/11/2016	420 MG/3.5 ML ( 120 MG/ML )
			SOLUTION / SUBCUTANEOUS / KIT
125522 / 0	3	8/27/2015	140 MG/ML ( 140 MG/ML )
			SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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: AMRYT PHARMACEUTICALS DAC / 2208****Trade Name:** MYALEPT**Proper Name:** METRELEPTIN

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

POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

**Applicant/License No: ARGENX BV / 2217****Trade Name:** VYVGART**Proper Name:** EFGARTIGIMOD ALFA-FCAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761195 / 0	1	12/17/2021	400 MG/20 ML ( 20 MG/ML )
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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
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761304 / 0	1	6/20/2023	1008 MG/11200 UNITS/5.6 ML ( 180 MG/2000 UNITS/ML )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761177 / 0	1	8/26/2021	3 MG ( 3 MG )
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POWDER / SUBCUTANEOUS / CARTRIDGE

761177 / 0	2	8/26/2021	3.6 MG ( 3.6 MG )
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POWDER / SUBCUTANEOUS / CARTRIDGE

761177 / 0	3	8/26/2021	4.3 MG ( 4.3 MG )
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POWDER / SUBCUTANEOUS / CARTRIDGE



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

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
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

**Applicant/License No: ASTELLAS PHARMA US INC / 2124**

761137 / 0      2      12/18/2019      30 MG ( 30 MG/VIAL )

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

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
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761224 / 0      1      12/17/2021      210 MG/1.91 ML ( 110 MG/ML )

SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

761224 / 0      2      12/17/2021      210 MG/1.91 ML ( 110 MG/ML )

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

761224 / 0      3      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
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761070 / 0      1      11/14/2017      30 MG/ML ( 30 MG/ML )

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

761070 / 5      2      10/3/2019      30 MG/ML ( 30 MG/ML )

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

**Trade Name:** IMFINZI**Proper Name:** DURVALUMAB

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

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: BEIGENE 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:** ADUHELM**Proper Name:** ADUCANUMAB-AVWA

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

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

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

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125499 / 0	1	8/15/2014	63 MCG/0.5 ML ( 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
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

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

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

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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125104 / 0	1	11/23/2004	300 MG/15 ML ( 20 MG/ML )
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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
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125058 / 0	1	4/30/2003	2.9 MG/5 ML ( 0.58 MG/ML )
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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
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761052 / 0	1	4/27/2017	150 MG/5 ML ( 30 MG/ML )
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SOLUTION / INTRAVENTRICULAR / SINGLE-DOSE VIAL

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

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


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

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

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

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

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

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

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



**Applicant/License No: BIOVERATIV THERAPEUTICS INC / 2078****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

**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 )
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

**Trade Name:** EMLICITI

**Proper Name:** ELOTUZUMAB

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

**Trade Name:** NULOJIX

**Proper Name:** BELATACEPT

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

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


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125554 / 0	3	12/22/2014	240 MG/24 ML ( 10 MG/ML )
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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125554 / 0	4	8/27/2021	120 MG/12 ML ( 10 MG/ML )
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

**Trade Name:** OPDUALAG**Proper Name:** NIVOLUMAB AND RELATLIMAB-RMBW

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

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

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

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

125377 / 0 2 3/25/2011 200 MG/40 ML ( 5 MG/ML )

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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
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761358 / 0      1      10/20/2023      120 MG/ML ( 120 MG/ML )

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

761358 / 0      2      10/20/2023      120 MG/ML ( 120 MG/ML )

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

**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
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761161 / 0      1      5/9/2023      20 MG/10 ML ( 2 ML/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
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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:** 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: 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: DAIICHI SANKYO INC / 2128****Trade Name:** ENHERTU**Proper Name:** FAM-TRASTUZUMAB DERUXTECAN-NXKI

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

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 )
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CAPSULE, DELAYED RELEASE / ORAL /

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

**Applicant/License No: DIGESTIVE CARE INC / 2184**

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

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

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

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

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

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
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**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
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761063 / 3	3	6/4/2019	100 MG/ML ( 100 MG/ML )  SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
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**Trade Name:** HUMALOG

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

**Proper Name:** INSULIN LISPRO RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020563 / 0	1	6/14/1996	1000 UNITS/10 ML ( 100 UNITS/ML )  SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL
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
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**Applicant/License No: ELI LILLY AND CO / 1891**

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

**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

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

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
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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

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


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 018780 / 0      2            12/29/2015      1500 UNITS/3 ML ( 500 UNITS/ML )

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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 761109 / 0      1            6/15/2020      1000 UNITS/10 ML ( 100 UNITS/ML )

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

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 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
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 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
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 761109 / 0      2            6/15/2020      300 UNITS/3 ML ( 100 UNITS/ML )

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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


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

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

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

**Trade Name:** OMVOH**Proper Name:** MIRIKIZUMAB-MRKZ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761279 / 0	1	10/26/2023	300 MG/15 ML ( 20 MG/ML )
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

761279 / 0	2	10/26/2023	100 MG/ML ( 100 MG/ML )
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

761279 / 0	3	4/29/2024	100 MG/ML ( 100 MG/ML )
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

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


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125547 / 0	1	11/24/2015	800 MG/50 ML ( 16 MG/ML )
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

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

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

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

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125469 / 0	4	9/18/2014	1.5 MG/0.5 ML ( 1.5 MG/0.5 ML )
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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125469 / 36	5	9/3/2020	3 MG/0.5 ML ( 3 MG/0.5 ML )
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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125469 / 36	6	9/3/2020	4.5 MG/0.5 ML ( 4.5 MG/0.5 ML )
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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
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 )
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POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL

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

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


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 021765 / 0      2      3/25/2004      75 IU/VIAL ( 75 IU/VIAL )

POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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

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

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
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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
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125349 / 0      1      12/14/2012      1700 MG/34 ML ( 50 MG/ML )

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

**Applicant/License No: EUSA PHARMA UK LIMITED / 2145****Trade Name:** SYLVANT**Proper Name:** SILTUXIMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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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: 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
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**Applicant/License No: FERRING PHARMACEUTICALS INC / 2112**


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017016 / 0	6	1/15/1974	5000 UNITS/VIAL ( 5000 UNITS/VIAL )
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POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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019774 / 0	2	1/4/2002	5 MG/VIAL ( 5 MG/VIAL )
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POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL

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019774 / 0	3	3/7/2012	10 MG/VIAL ( 10 MG/VIAL )
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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
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017067 / 0	2	3/5/1973	10000 UNITS/VIAL ( 10000 UNITS/VIAL )
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POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL

**Applicant/License No: GENENTECH INC / 1048****Trade Name:** ACTEMRA**Proper Name:** TOCILIZUMAB

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

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


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125276 / 0	2	1/8/2010	200 MG/10 ML ( 20 MG/ML )
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

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125472 / 29	2	11/19/2018	162 MG/0.9 ML ( 162 MG/0.9 ML )
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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103172 / 0	2	11/13/1987	50 MG ( 50 MG/VIAL )
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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

**Trade Name:** AVASTIN**Proper Name:** BEVACIZUMAB

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

125085 / 0	1	2/26/2004	100 MG/4 ML ( 25 MG/ML )
			SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

125085 / 0	2	2/26/2004	400 MG/16 ML ( 25 MG/ML )
			SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

**Trade Name:** 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



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


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761149 / 0	1	8/14/2020	120 MG/ML ( 120 MG/ML )
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

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

**Trade Name:** HEMLIBRA**Proper Name:** EMICIZUMAB-KXWH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761083 / 0	1	11/16/2017	30 MG/ML ( 30 MG/ML )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

761083 / 0	2	11/16/2017	60 MG/0.4 ML ( 60 MG/0.4 ML )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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

761083 / 0	5	3/16/2023	300 MG/2 ML ( 150 MG/ML )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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


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761083 / 0	6	1/31/2024	12 MG/0.4 ML ( 12 MG/0.4 ML )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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

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

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

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

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

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

**Trade Name:** LUCENTIS**Proper Name:** RANIBIZUMAB

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

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

**Trade Name:** NUTROPIN AQ NUSPIN**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
020522 / 0	3	1/3/2008	5 MG/2ML ( 2.5 MG/ML )  SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN
020522 / 0	4	1/3/2008	20 MG/2ML ( 10 MG/ML )  SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

020522 / 0      5      1/3/2008      10 MG/2ML ( 5 MG/ML )

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

**Trade Name:** OCREVUS**Proper Name:** OCRELIZUMAB

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

**Trade Name:** PERJETA**Proper Name:** PERTUZUMAB

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

SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

761170 / 0      2      6/29/2020      1200 MG, 600 MG, 30000 UNITS/15 ML ( 80 MG, 40 MG, 2000 UNITS/ML )

SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

**Trade Name:** PIASKY**Proper Name:** CROVALIMAB-AKKZ

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

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
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**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
103705 / 0	1	11/26/1997	100 MG/10 ML ( 10 MG/ML )  SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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


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 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

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 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**


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761034 / 18    2    3/8/2019    840 MG/14 ML ( 60 MG/ML )

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

**Trade Name:** TNKASE

**Proper Name:** TENECTEPLASE

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

**Trade Name:** VABYSMO

**Proper Name:** FARICIMAB-SVOA

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

**Trade Name:** XOLAIR

**Proper Name:** OMALIZUMAB

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

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

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

103976 / 5231 4 9/28/2018 150 MG/ML ( 150 MG/ML )

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

**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
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761324 / 0	1	5/19/2023	4 MG/0.8 ML ( 4 MG/0.8 ML )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

761324 / 0	2	5/19/2023	48 MG/0.8 ML ( 48 MG/0.8 ML )
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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
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103948 / 0	1	5/7/2001	30 MG/ML ( 30 MG/ML )
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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



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

**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

**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

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

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

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

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:** 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
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

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

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
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021859 / 0	1	12/2/2005	150 UNITS/VIAL ( 150 UNITS/ML )
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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
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103836 / 0	1	2/25/1999	100 MCG/0.5 ML ( 100 MCG/0.5 ML )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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

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

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

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

**Trade Name:** UPLIZNA**Proper Name:** INEBILIZUMAB-CDON

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761142 / 0	1	6/11/2020	100 MG/10 ML ( 10 MG/ML )
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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
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761225 / 0	1	2/29/2024	50 UNITS/VIAL ( 50 UNITS/VIAL )
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POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

761225 / 0	2	2/29/2024	100 UNITS/VIAL ( 100 UNITS/VIAL )
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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: 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

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

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:** ZYNYZ

**Applicant/License No: INCYTE CORPORATION / 2228****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
125274 / 0	2	4/29/2009	500 UNITS ( 500 UNITS/VIAL )  POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL



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

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

SOLUTION / SUBCUTANEOUS / MULTI-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 )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

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

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

**Trade Name:** REMICADE**Proper Name:** INFLIXIMAB

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

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761210 / 0	1	5/21/2021	350 MG/7 ML ( 50 MG/ML )  SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

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


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

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125289 / 0	4	4/24/2009	100 MG/ML ( 100 MG/ML )
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

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

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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125261 / 0	1	9/25/2009	90 MG/ML ( 90 MG/ML )
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SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

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

**Trade Name:** TALVEY

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

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

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

SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

**Applicant/License No: JUBILANT DRAXIMAGE INC / 2186****Trade Name:** DRAXIMAGE MAA**Proper Name:** TECHNETIUM TC 99M ALBUMIN AGGREGATED KIT

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

POWDER / INTRAVENOUS / MULTI-DOSE VIAL

**Applicant/License No: KINIKSA PHARMACEUTICALS 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

**Applicant/License No: LEO PHARMA AS / 2169**

761180 / 0      2      6/12/2024      300 MG/2 ML ( 150 MG/ML )

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

POWDER / INHALATION / CARTRIDGE

**Applicant/License No: MANNKIND CORP / 2190**

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: MEDIWOUND LTD / 2215****Trade Name:** NEXOBRID**Proper Name:** ANACAULASE-BCDB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761192 / 0	1	12/28/2022	2 GM LYOPHILIZED POWDER/20 GM GEL ( 8.8% W/W (2 GM LYOPHILIZED POWDER/20 GM GEL) )  GEL / TOPICAL / KIT
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: MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002****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:** WINREVAIR**Proper Name:** SOTATERCEPT-CSRK

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



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

761363 / 0	1	3/26/2024	45 MG/VIAL ( 45 MG/VIAL )
			POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

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

**Trade Name:** ZINPLAVA

**Proper Name:** BEZLOTOXUMAB

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

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

**Trade Name:** XEOMIN

**Proper Name:** INCOBOTULINUMTOXINA

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

125360 / 0	2	7/30/2010	100 U ( 100 U/VIAL )
			POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

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

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
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

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

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
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**Trade Name:** SIMULECT**Proper Name:** BASILIXIMAB

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

103764 / 0	2	5/12/1998	20 MG ( 20 MG/VIAL )  POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
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**Applicant/License No: NOVO NORDISK INC / 1261****Trade Name:** FIASP**Proper Name:** INSULIN ASPART

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
208751 / 0	1	9/27/2017	1000 UNITS/10 ML ( 100 UNITS/ML )

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

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

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

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

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

SOLUTION / SUBCUTANEOUS / CARTRIDGE

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

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

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

SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021536 / 0	2	6/16/2005	300 UNITS/3 ML ( 100 UNITS/ML )

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

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

021148 / 0	10	3/1/2010	15MG/1.5ML ( 10MG/ML )
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

021148 / 0	11	1/23/2015	30MG/3ML ( 10MG/ML )
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SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

**Trade Name:** NOVOLOG

**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	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

**Proper Name:** INSULIN ASPART RECOMBINANT

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

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



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

203314 / 0      3      11/21/2018      1000 UNITS/10 ML ( 100 UNITS/ML )

SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL

**Trade Name:** XULTOPHY 100/3.6

**Proper Name:** INSULIN DEGLUDEC; LIRAGLUTIDE

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

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

**Trade Name:** NATPARA

**Proper Name:** PARATHYROID HORMONE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125511 / 1	1	1/23/2015	0.4 MG/CARTRIDGE ( 25 MCG/DOSE )

POWDER / SUBCUTANEOUS / CARTRIDGE

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

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

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

**Applicant/License No:** ONY INC / 2192

**Trade Name:** INFASURF PRESERVATIVE FREE

**Proper Name:** CALFACTANT

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

**Applicant/License No:** ORGANON USA 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

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: PARTNER THERAPEUTICS INC / 2087****Trade Name:** LEUKINE**Proper Name:** SARGRAMOSTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103362 / 0	1	3/5/1991	250 MCG ( 250 MCG/VIAL )

POWDER / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL

**Applicant/License No: PFIZER INC / 2001****Trade Name:** ELELYSO**Proper Name:** TALIGLUCERASE ALFA

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

POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

**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 )
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SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

**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

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

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

**Trade Name: SOMAVERT**

**Applicant/License No: PHARMACIA AND UPJOHN CO / 1216****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
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	1	4/9/1998	1003000 IU/118 ML ( 8500 IU/ML )  SOLUTION / ORAL / MULTI-DOSE VIAL
020772 / 0	2	5/25/2022	17,000 IU/2 ML ( 8500 IU/ML )  SOLUTION / ORAL / SINGLE DOSE CONTAINER

**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

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

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
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



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

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) )
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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 )
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

125559 / 0	4	7/24/2015	150 MG/ML ( 150 MG/ML )
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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
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761339 / 0	1	8/18/2023	400 MG/2 ML ( 200 MG/ML )
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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
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761127 / 0	1	9/7/2022	50 UNITS/VIAL ( 50 UNITS/VIAL )
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POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

761127 / 0	2	9/7/2022	100 UNITS/VIAL ( 100 UNITS/VIAL )
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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
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021426 / 0	1	5/30/2006	5.8 MG/VIAL ( 5.8 MG/VIAL )
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

**Applicant/License No: SANDOZ INC / 2003**

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:** ADLYXIN**Proper Name:** LIXISENATIDE

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

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

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

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

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

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

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021629 / 0	1	4/16/2004	1000 UNITS/10 ML ( 100 UNITS/ML )

SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
021629 / 0	3	2/24/2009	300 UNITS/3 ML ( 100 UNITS/ML )

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

**Trade Name:** ELITEK**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 )
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POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

**Trade Name:** KEVZARA

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

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

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

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

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

**Trade Name:** SARCLISA

**Proper Name:** ISATUXIMAB-IRFC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
761113 / 0	1	3/2/2020	100 MG/5 ML ( 20 MG/ML )  SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
761113 / 0	2	3/2/2020	500 MG/25 ML ( 20 MG/ML )  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

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


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 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
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 125418 / 0      1              8/3/2012              100 MG/4 ML ( 25 MG/ML )

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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 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
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 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
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 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
103411 / 0	1	2/1/1994	3750 IU/5 ML ( 750 IU/ML )

SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL

**Applicant/License No: SHIRE HUMAN GENETIC THERAPIES INC / 1593****Trade Name:** ELAPRASE**Proper Name:** IDURSULFASE

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

SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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

POWDER / INTRAVENOUS / SINGLE-DOSE VIAL



**Applicant/License No: SICOR BIOTECH UAB / 1803****Trade Name:** GRANIX**Proper Name:** TBO-FILGRASTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125294 / 0	1	8/29/2012	300 MCG/0.5 ML ( 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
125294 / 45	4	7/31/2018	480MCG/1.6 ML ( 300 MCG/ML )  SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

**Applicant/License No: SMITH AND NEPHEW INC / 2004****Trade Name:** REGRANEX**Proper Name:** BECAPLERMIN

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

**Trade Name:** SANTYL**Proper Name:** COLLAGENASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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**Applicant/License No: SMITH AND NEPHEW INC / 2004**

101995 / 0      1      6/4/1965      30 GM &amp; 90 GM TUBE ( 250 U/GM )

OINTMENT / TOPICAL /

**Applicant/License No: SOLSTICE NEUROSCIENCES LLC / 1718****Trade Name:** MYOBLOC**Proper Name:** RIMABOTULINUM TOXIN B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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103846 / 0      1      12/8/2002      2500 IU/0.5 ML ( 2500 IU/0.5 ML )

SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

103846 / 0      3      12/8/2002      10,000 IU/2 ML ( 5000 IU/ML )

SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

**Proper Name:** RIMABOTULINUMTOXINB

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

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

**Applicant/License No: SWEDISH ORPHAN BIOVITRUM AB / 1859****Trade Name:** KEPIVANCE**Proper Name:** PALIFERMIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125103 / 0	1	12/15/2004	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 )
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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
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 / PREFILLED PEN

**Applicant/License No: TEVA PHARMACEUTICALS USA INC / 2016****Trade Name:** AJOVY**Proper Name:** FREMANEZUMAB-VFRM

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

SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE

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

761089 / 2      2      1/27/2020      225MG/1.5 ML ( 150 MG/ML )

SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN

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

**Trade Name:** CINQAIR

**Proper Name:** RESLIZUMAB

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

**Applicant/License No: TG THERAPEUTICS INC / 2090**

**Trade Name:** BRIUMVI

**Proper Name:** UBLITUXIMAB-XIY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761238 / 0	1	12/28/2022	150 MG/6 ML ( 25 MG/ML )
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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
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022505 / 0	2	11/10/2010	2MG BASE/VIAL ( 2MG BASE/VIAL )
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POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

**Trade Name:** TROGARZO

**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: 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

**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

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
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761286 / 0	1	6/26/2023	280 MG/2 ML ( 140 MG/ML )
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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
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761047 / 0	1	11/15/2017	10 MG/5 ML ( 2 MG/ML )
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SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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

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



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

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

**Applicant/License No: VIFOR INTERNATIONAL AG / 2039****Trade Name:** MIRCERA**Proper Name:** METHOXPOLYETHYLENE 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

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

125164 / 0	6	11/14/2007	250 MCG/0.3 ML ( 250 MCG/0.3 ML )
			SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE
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 INC / 2197**Trade Name:** PANCREAZE**Proper Name:** PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
022523 / 0	1	4/12/2010	24,600USP UNITS; 4,200USP UNITS; 14,200USP UNITS ( 24,600USP UNITS; 4,200USP UNITS; 14,200USP UNITS )  CAPSULE, DELAYED RELEASE / ORAL /
022523 / 0	2	4/12/2010	61,500USP UNITS; 10,500USP UNITS; 35,500USP UNITS ( 61,500USP UNITS; 10,500USP UNITS; 35,500USP UNITS )  CAPSULE, DELAYED RELEASE / ORAL /
022523 / 0	3	4/12/2010	98,400USP UNITS; 16,800USP UNITS; 56,800USP UNITS ( 98,400USP UNITS; 16,800USP UNITS; 56,800USP UNITS )  CAPSULE, DELAYED RELEASE / ORAL /
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 /
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 & PREFILLED SYRINGE	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	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:** ARANESP

**Proper Name:** DARBEPOETIN ALFA (ALBUMIN SOLUTION)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103951 / 0	16	9/17/2001	25 MCG/ML ( 25 MCG/ML ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/27/2012
103951 / 0	17	9/17/2001	25 MCG/0.42 ML ( 25 MCG/0.42 ML ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	9/27/2012
103951 / 0	18	9/17/2001	40 MCG/ML ( 40 MCG/ML ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/27/2012
103951 / 0	19	9/17/2001	40 MCG/0.4 ML ( 40 MCG/0.4 ML ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	9/27/2012



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

**Trade Name:** ARANESP

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				
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

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

**Trade Name:** ARANESP

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 ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	12/20/2018
103951 / 0	7	9/17/2001	300 MCG/ML ( 300 MCG/ML ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	4/30/2024

**Trade Name:** VECTIBIX

**Proper Name:** PANITUMUMAB

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

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

**Trade Name:** PROSTASCINT

**Proper Name:** CAPROMAB PENDETIDE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103608 / 0	1	10/28/1996	0.5 MG/ML ( 0.5 MG/ML ) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	5/16/2019

**Applicant/License No: BAUSCH AND LOMB INC / 2180**

**Trade Name:** VITRASE

**Proper Name:** HYALURONIDASE

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

**Applicant/License No: BAUSCH AND LOMB INC / 2180**

**Trade Name:** VITRASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
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: BAUSCH HEALTH US LLC / 2181**

**Trade Name:** IPRIVASK

**Proper Name:** DESIRUDIN RECOMBINANT

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

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

**Trade Name:** TRASYLOL

**Proper Name:** APROTININ

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

**Applicant/License No: BEL MAR LABORATORIES INC / 2182**

**Trade Name:** CHORIONIC GONADOTROPIN

**Proper Name:** GONADOTROPIN, CHORIONIC

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

**Applicant/License No: BEL MAR LABORATORIES INC / 2182**

**Trade Name:** CHORIONIC GONADOTROPIN

017054 / 0	2	3/26/1974	10000 UNITS/VIAL ( 10000 UNITS/VIAL )	1/1/1990
/ /				

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

**Trade Name:** AVONEX

**Proper Name:** INTERFERON BETA 1A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103628 / 0	1	5/17/1996	30 MCG ( 30 MCG/VIAL ) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/30/2018

**Applicant/License No: 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: 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: 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
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:** HUMATROPE

**Proper Name:** SOMATROPIN RECOMBINANT

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

**Trade Name:** HUMATROPE

019640 / 0	1	6/23/1987	2 MG/VIAL ( 2 MG/VIAL )	1/1/1900
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

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

**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 )	6/28/2018
SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE				

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

**Trade Name:** XIGRIS

**Proper Name:** DROTRECOGIN ALFA (ACTIVATED)

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

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

**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

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

**Trade Name:** GONAL-F

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

**Trade Name:** GONAL-F RFF REDI-JECT

**Proper Name:** FOLLITROPIN ALFA/BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021684 / 0	4	11/25/2019	150 IU/0.25 ML ( 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

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

**Trade Name:** PERGONAL

017646 / 0	2	8/22/1975	150 IU/VIAL ( 150 IU/VIAL )	6/7/2004
POWDER / /				

**Trade Name:** SAIZEN

**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
019764 / 0	1	10/8/1996	6 MG/VIAL ( 6 MG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	6/7/2004
019764 / 0	2	10/8/1996	5 MG/VIAL ( 5 MG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	6/20/2022
019764 / 0	3	8/29/2000	8.8 MG/VIAL ( 8.8 MG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	6/20/2022
019764 / 0	5	1/16/2007	4 MG/VIAL ( 4 MG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	6/7/2004

**Trade Name:** SEROSTIM

**Proper Name:** SOMATROPIN

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

**Trade Name:** SEROSTIM LQ

**Proper Name:** SOMATROPIN

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

**Trade Name:** ZORBTIVE



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

**Trade Name:** ZORBTIVE

**Proper Name:** SOMATROPIN RECOMBINANT

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

**Proper Name:** UROFOLLITROPIN

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

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

**Trade Name:** BRAVELLE

021484 / 0	1	82.5 IU/VIAL ( 82.5 IU/VIAL )	6/5/2018
POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL			

**Trade Name:** NOVAREL

**Proper Name:** GONADOTROPIN, CHORIONIC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017016 / 0	4	1/15/1974	20000 UNITS/VIAL ( 20000 UNITS/VIAL ) POWDER / /	10/12/1994
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
017067 / 0	4	3/5/1973	20000 UNITS/VIAL ( 20000 UNITS/VIAL ) POWDER / INTRAMUSCULAR / MULTI-DOSE VIAL	6/23/1994

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

**Trade Name:** HERCEPTIN

**Proper Name:** TRASTUZUMAB

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

**Trade Name:** NUTROPIN

**Proper Name:** SOMATROPIN

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

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

**Trade Name:** NUTROPIN

020168 / 0	1	11/17/1993	5 MG/VIAL ( 5 MG/VIAL )	7/2/2015
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

020168 / 0	2	11/17/1993	10 MG/VIAL ( 10 MG/VIAL )	7/2/2015
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020656 / 0	1	12/30/1996	5 MG/VIAL ( 5 MG/VIAL )	7/1/2015
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

020656 / 0	2	12/30/1996	10 MG/VIAL ( 10 MG/VIAL )	7/8/2015
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

**Trade Name:** NUTROPIN AQ NUSPIN

**Proper Name:** SOMATROPIN

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

**Trade Name:** NUTROPIN AQ PEN

**Proper Name:** SOMATROPIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
020522 / 0	2	4/22/2002	10 MG/2ML ( 5 MG/ML )	6/28/2018
SOLUTION / SUBCUTANEOUS / CARTRIDGE				

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

**Trade Name:** RAPTIVA

**Proper Name:** EFALIZUMAB

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

**Trade Name:** RAPTIVA

125075 / 0	1	10/27/2003	125 MG ( 125 MG/VIAL )	9/1/2009
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

**Trade Name:** XOLAIR

**Proper Name:** OMALIZUMAB

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

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

**Trade Name:** CAMPATH

**Proper Name:** ALEMTUZUMAB

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

**Trade Name:** CEREZYME

**Proper Name:** IMIGLUCERASE

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

**Trade Name:** MYOZYME

**Proper Name:** ALGLUCOSIDASE ALFA

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

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

**Trade Name:** BEXXAR THERAPEUTIC REGIME

**Proper Name:** TOSITUMOMAB AND IODINE I-131 TOSITUMOMAB

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

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

**Trade Name:** ALFERON N INJECTION

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

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

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

**Trade Name:** ROFERON A

**Proper Name:** INTERFERON ALFA-2A

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

**Trade Name:** ZENAPAX

**Proper Name:** DACLIZUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
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**Applicant/License No: HOFFMANN LA ROCHE INC / 0136**

**Trade Name:** ZENAPAX

103749 / 0	1	12/10/1997	25 MG/5 ML ( 25 MG/5 ML )	7/7/2011
SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL				

**Applicant/License No: INSMED INC / 2188**

**Trade Name:** IPLEX

**Proper Name:** MECASERMIN RINFABATE RECOMBINANT

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

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

**Trade Name:** CHROMALBIN

**Proper Name:** ALBUMIN CHROMATED CR-51 SERUM

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

**Trade Name:** MEGATOPE

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
017837 / 0	1	2/23/1976	0.5mCi/VIAL ( 0.5mCi/VIAL )	9/29/2022
SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL				



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

**Trade Name:** MEGATOPE

017837 / 0	3	2/23/1976	2mCi/VIAL ( 2mCi/VIAL )	1/1/1900
SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL				
017837 / 0	4	2/23/1976	5uCi/AMP ( 5uCi/AMP )	1/1/1900
SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL				
017837 / 0	5	2/23/1976	20uCi/AMP ( 20uCi/AMP )	6/7/2002
SOLUTION / INTRAVENOUS / MULTI-DOSE VIAL				

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

**Trade Name:** REOPRO

**Proper Name:** ABCIXIMAB

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

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

**Trade Name:** ERWINAZE

**Proper Name:** ASPARAGINASE ERWINIA CHRYSANTHEMI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125359 / 0	1	11/18/2011	10000 IU ( 10000 IU/VIAL )	7/23/2021
POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL				

**Applicant/License No: JUBILANT DRAXIMAGE INC / 2186**

**Trade Name:** PULMOLITE

**Proper Name:** TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

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

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

**Trade Name:** INFERGEN

**Proper Name:** INTERFERON ALFACON-1

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103663 / 0	1	10/6/1997	9 MCG/0.3 ML ( 9 MCG/0.3 ML )  SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL	7/25/2013

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

**Trade Name:** ADAGEN

**Proper Name:** PEGADEMASE BOVINE

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

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

**Trade Name:** INTRON A

**Proper Name:** INTERFERON ALFA-2B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103132 / 0	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 )	3/26/2021
POWDER / INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS / SINGLE-DOSE VIAL				
103132 / 0	3	6/4/1986	50 MIU ( 50 MIU/VIAL )	3/26/2021
POWDER / INTRAMUSCULAR, SUBCUTANEOUS, INTRAVENOUS / SINGLE-DOSE VIAL				
103132 / 0	4	6/4/1986	22.8 MIU/3.8 ML ( 6 MIU/ML )	3/26/2021
SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL				
103132 / 0	5	6/4/1986	32 MIU/3.2 ML ( 10 MIU/ML )	3/26/2021
SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS, INTRALESIONAL / MULTI-DOSE VIAL				
103132 / 0	6	6/4/1986	10 MIU/ML ( 10 MIU/ML )	9/23/2013
SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL				
103132 / 0	7	6/4/1986	22.5 MIU/1.5 ML ( 22.5 MIU/1.5 ML )	9/23/2013
SOLUTION / SUBCUTANEOUS / PREFILLED PEN				
103132 / 0	8	6/4/1986	37.5 MIU/1.5 ML ( 37.5 MIU/1.5 ML )	9/23/2013
SOLUTION / SUBCUTANEOUS / PREFILLED PEN				
103132 / 0	9	6/4/1986	75 MIU/1.5 ML ( 75 MIU/1.5 ML )	9/23/2013
SOLUTION / SUBCUTANEOUS / PREFILLED PEN				

**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 )	6/13/2018
POWDER / INTRAVENOUS / SINGLE-DOSE VIAL				

**Trade Name:** PEGINTRON

**Proper Name:** PEGINTERFERON ALFA-2B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
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**Applicant/License No: MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002**

**Trade Name:** PEGINTRON

103949 / 0	1	1/19/2001	74 MCG ( 74 MCG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	3/26/2021
103949 / 0	5	1/19/2001	67.5 MCG ( 67.5 MCG/PEN ) POWDER / SUBCUTANEOUS / PREFILLED PEN	10/14/2016
103949 / 0	6	1/19/2001	108 MCG ( 108 MCG/PEN ) POWDER / SUBCUTANEOUS / PREFILLED PEN	10/14/2016
103949 / 0	7	1/19/2001	118.4 MCG ( 118.4 MCG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	10/1/2016
103949 / 0	8	1/19/2001	162 MCG ( 162 MCG/PEN ) POWDER / SUBCUTANEOUS / PREFILLED PEN	10/14/2016
103949 / 0	9	1/19/2001	177.6 MCG ( 177.6 MCG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	10/1/2016
103949 / 0	10	1/19/2001	202.5 MCG ( 202.5 MCG/PEN ) POWDER / SUBCUTANEOUS / PREFILLED PEN	10/14/2016
103949 / 0	11	1/19/2001	222 MCG ( 222 MCG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	10/1/2016

**Trade Name:** SYLATRON

**Proper Name:** PEGINTERFERON ALFA-2B

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103949 / 5153	2	3/29/2011	296 MCG ( 296 MCG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	12/13/2017
103949 / 5153	3	3/29/2011	444 MCG ( 444 MCG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	12/13/2017

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

**Trade Name:** SYLATRON

103949 / 5153	4	3/29/2011	888 MCG ( 888 MCG/VIAL )	5/23/2019
POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL				

**Applicant/License No: MICROBIX BIOSYSTEMS INC / 2191**

**Trade Name:** KINLYTIC

**Proper Name:** UROKINASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021846 / 0	1	1/16/1978	250000 IU/VIAL ( 250000 IU/VIAL ) POWDER / INTRAVENOUS / MULTI-DOSE VIAL	8/25/2009
021846 / 0	2	1/16/1978	9000 IU/VIAL ( 9000 IU/VIAL ) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	8/25/2009
021846 / 0	3	1/16/1978	5000 IU/VIAL ( 5000 IU/VIAL ) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	6/30/2003

**Applicant/License No: MYLAN PHARMACEUTICALS INC / 2210**

**Trade Name:** SEMGLEE

**Proper Name:** INSULIN GLARGINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
210605 / 0	1	6/11/2020	1000 UNITS/10 ML ( 100 UNITS/ML ) SOLUTION / SUBCUTANEOUS / MULTI-DOSE VIAL	9/27/2022
210605 / 0	2	6/11/2020	300 UNITS/3 ML ( 100 UNITS/ML ) SOLUTION / SUBCUTANEOUS / AUTOINJECTOR-PREFILLED PEN	9/27/2022

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

**Trade Name:** ILARIS

**Proper Name:** CANAKINUMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125319 / 0	1	6/17/2009	180 MG/VIAL ( 180 MG/VIAL ) / /	5/25/2018
125319 / 88	2	12/22/2016	150 MG ( 150 MG/VIAL ) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	5/25/2018

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

**Trade Name:** LEVEMIR 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

**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

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

**Trade Name:** NORDITROPIN

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

**Trade Name:** NORDITROPIN NORDIFLEX

**Proper Name:** SOMATROPIN

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

**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

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

**Trade Name:** NOVOLOG INNOLET

**Proper Name:** INSULIN ASPART RECOMBINANT

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

**Trade Name:** NOVOLOG MIX 50/50 - FLEXPEN

**Proper Name:** INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

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

**Trade Name:** NOVOLOG MIX 50/50 - PENFILL

**Proper Name:** INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

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

**Trade Name:** NOVOLOG MIX 70/30 PENFILL

**Proper Name:** INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

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

**Trade Name:** NOVOLOG MIX 70/30 PFS

**Proper Name:** INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT

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



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

**Trade Name:** RYZODEG 70/30

**Proper Name:** INSULIN ASPART; INSULIN DEGLUDEC

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

**Applicant/License No: ORGANON USA INC A SUBSIDIARY OF MERCK AND CO INC / 2193**

**Trade Name:** COTAZYM

**Proper Name:** PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

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

**Trade Name:** FOLLISTIM

**Proper Name:** FOLLITROPIN ALFA/BETA

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

**Trade Name:** FOLLISTIM AQ

**Proper Name:** FOLLITROPIN ALFA/BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
021273 / 0	1	8/26/2005	75 IU/0.5 ML ( 75 IU/0.5 ML ) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	6/3/2016
021273 / 0	2	8/26/2005	150 IU/0.5 ML ( 150 IU/0.5 ML ) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL	6/3/2016

**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: PALATIN TECHNOLOGIES INC / 1588**

**Trade Name:** NEUTROSPEC TECHNETIUM (99M TC)

**Proper Name:** FANOLESOMAB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103928 / 0	1	7/2/2004	0.25 MG ( 0.25 MG/VIAL ) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/22/2008

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

**Trade Name:** LEUKINE

**Proper Name:** SARGRAMOSTIM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103362 / 0	2	3/5/1991	500 MCG/ML ( 500 MCG/ML ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / MULTI-DOSE VIAL	6/15/2018

**Applicant/License No: PFIZER INC / 2001**

**Trade Name:** ELASE-CHLOROMYCETIN

**Proper Name:** CHLORAMPHENICOL; DESOXYRIBONUCLEASE; FIBRINOLYSIN

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

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

**Trade Name:** GENOTROPIN PRESERVATIVE FREE

**Proper Name:** SOMATROPIN

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

**Applicant/License No: PHARMALUCENCE INC / 2203**

**Trade Name:** MICROLITE

**Proper Name:** TECHNETIUM TC-99M ALBUMIN COLLOID KIT

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

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

**Trade Name:** ELSPAR

**Proper Name:** ASPARAGINASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
101063 / 0	1	1/10/1978	10000 IU ( 10000 IU/VIAL ) POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	4/9/2014

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

**Trade Name:** 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

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

**Trade Name:** PRALUENT

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

**Applicant/License No: SANDOZ INC / 2003**

**Trade Name:** OMNITROPE

**Proper Name:** SOMATROPIN

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

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

**Trade Name:** APIDRA

**Proper Name:** INSULIN GLULISINE RECOMBINANT

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

**Trade Name:** LANTUS

**Proper Name:** INSULIN GLARGINE RECOMBINANT

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

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

**Trade Name:** LANTUS

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

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

**Trade Name:** PEGINTRON/REBETOL COMBO PACK

**Proper Name:** PEGINTERFERON ALFA-2B AND RIBAVIRIN

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

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

**Trade Name:** VPRIV

**Proper Name:** VELAGLUCERASE ALFA

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

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

**Trade Name:** JETREA

**Proper Name:** OCRIPLASMIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125422 / 038	1	2/22/2017	0.375 MG/0.3 ML ( 0.375 MG/0.3 ML ) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL	5/31/2020
125422 / 0	2	10/17/2012	0.5 MG ( 2.5 MG/ML ) SOLUTION / INTRAVITREAL / SINGLE-DOSE VIAL	8/8/2017

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

**Trade Name:** MIRCERA

**Proper Name:** METHOXYPOLYETHYLENE GLYCOL EPOETIN BETA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125164 / 0	10	11/14/2007	50 MCG/ML ( 50 MCG/ML ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	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
125164 / 0	14	11/14/2007	400 MCG/ML ( 400 MCG/ML ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-DOSE VIAL	9/24/2008
125164 / 0	15	11/14/2007	400 MCG/0.6 ML ( 400 MCG/0.6 ML ) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / PREFILLED SYRINGE	9/24/2008

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

**Trade Name:** MIRCERA

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				