User Fee Billable Biologic Products and Potencies Approved Under Section 351 of the PHS Act

This list is intended to include all CBER user fee billable biologic products and potencies approved under Section 351 of the Public Health Service Act** and subject to the Prescription Drug User Fee Act (PDUFA).

A program fee is assessed for each prescription drug product that is identified in an approved human drug application as of October 1 of each fiscal year. Applicants may not be assessed more than five prescription drug program fees for prescription drug products identified in a single approved application.

In certain circumstances, products which are not marketed but are still licensed are not assessed program fees. These products are identified on CBER's Discontinued List. Generally, a licensed product is added to the Discontinued List when the Applicant informs CBER that the product is not being marketed and submits a request to have the product placed on CBER's Discontinued List.

The potency information contained in this list is based on current information in CBER's regulatory database. Companies are responsible for alerting CBER to any discrepancies regarding potency or proprietary name information. Any such discrepancies should be reported to FDA's PDUFA User Fee Staff at FDAUserFees@fda.hhs.gov.

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

**A number of therapeutic biologic products are regulated by the Center for Drug Evaluation and Research (CDER). To view the listing of CDER regulated biologics, see the CDER Billable Biologic Product List.

*****User Fee Billable Biologic Products and Potencies Approved Under Section 351 of the PHS Act*****

Applicant/License No: ABEONA THERAPEUTICS INC / 2329

Trade Name: ZEVASKYN
Proper Name: PRADEMAGENE ZAMIKERACEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125807 / 0	1	4/28/2025	SINGLE DOSE OF UP TO 12 CELLULAR SHEETS MEASURING 41.25 CM^2 (5.5 CM X 7.5 CM) (SINGLE DOSE OF UP TO 12 CELLULAR SHEETS LIQUID / TOPICAL /

Applicant/License No: ADMA BIOLOGICS INC / 2019

Trade Name: ASCENIV
Proper Name: IMMUNE GLOBULIN INTRAVENOUS, HUMAN-SLRA 10%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125590 / 0	1	4/1/2019	5000 MG/50 ML (100 MG/ML) LIQUID / INTRAVENOUS / SINGLE-USE VIAL

Trade Name: BIVIGAM
Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%

Applicant/License No: ADMA BIOLOGICS INC / 2019

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125389 / 0	1	12/19/2012	10 GM/100 ML (10 GM/100 ML) LIQUID / INTRAVENOUS / SINGLE-USE VIAL
125389 / 0	2	12/19/2012	5 GM/50 ML (10 GM/100 ML) LIQUID / INTRAVENOUS / SINGLE-USE VIAL

Trade Name: NABI-HB
Proper Name: HEPATITIS B IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103945 / 0	2	10/23/2001	>1560 IU/5 ML (>312 IU/ML) LIQUID / INTRAMUSCULAR / SINGLE-USE VIAL

Applicant/License No: AIMMUNE THERAPEUTICS INC / 2109

Trade Name: VOWST
Proper Name: FECAL MICROBIOTA SPORES, LIVE-BRPK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125757 / 0	1	4/26/2023	BETWEEN 1X10^6 AND 3X10^7 FIRMICUTES SPORES CFU/CAPSULE (BETWEEN 1X10^6 AND 3X10^7 FIRMICUTES SPORES CFU/CAPSULE) CAPSULE / ORAL / SINGLE-USE BOTTLE

Applicant/License No: AMGEN INC / 1080

Trade Name: IMLYGIC
Proper Name: TALIMOGENE IAHERPAREPVEC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125518 / 0	1	10/27/2015	1 MILLION PFU/ML (1 MILLION PFU/ML) SUSPENSION / INTRALESIONAL / SINGLE-DOSE VIAL
125518 / 0	2	10/27/2015	100 MILLION PFU/ML (100 MILLION PFU/ML) SUSPENSION / INTRALESIONAL / SINGLE-DOSE VIAL

Applicant/License No: AUTOLUS INC / 2339

Trade Name: AUCATZYL
Proper Name: OBECABTAGENE AUTOLEUCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125813 / 0	1	11/8/2024	410 × 10^6 CD19 CAR-POSITIVE VIABLE T CELLS IN THREE TO FIVE INFUSION BAGS (410 × 10^6 CD19 CAR-POSITIVE VIABLE T CELLS IN SUSPENSION / INTRAVENOUS / PLASTIC CONTAINER

Applicant/License No: AXOGEN CORPORATION / 2340

Trade Name: AVANCE
Proper Name: ACELLULAR NERVE ALLOGRAFT-ARWX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125816 / 0	1	12/3/2025	16 SIZES: LENGTHS: 15 MM, 30 MM, 50 MM, 70 MM; DIAMETERS: 1 TO 2 MM, 2 TO 3 MM, 3 TO 4 MM, 4 TO 5 MM (16 SIZES: LENGTHS: 15 MM, 30 IMPLANTATION / IMPLANTATION / PLASTIC CONTAINER

Applicant/License No: BAVARIAN NORDIC AS / 2096

Trade Name: JYNNEOS
Proper Name: SMALLPOX AND MONKEYPOX VACCINE, LIVE, NONREPLICATING

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125678 / 0	1	9/24/2019	0.5-3.95 X 10^8 INFECTIOUS UNITS (INF. U)/0.5 ML DOSE (0.5-3.95 X 10^8 INFECTIOUS UNITS (INF. U)/0.5 ML DOSE) SUSPENSION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125678 / 0	2	3/31/2025	0.5-3.95 X 10^8 INFECTIOUS UNITS (INF. U)/0.5 ML DOSE (0.5-3.95 X 10^8 INFECTIOUS UNITS (INF. U)/0.5 ML DOSE) POWDER / SUBCUTANEOUS / KIT

Trade Name: RABAVERT
Proper Name: RABIES VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103334 / 0	1	10/20/1997	>2.5 U (>2.5 U/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: VAXCHORA
Proper Name: CHOLERA VACCINE LIVE, ORAL

Applicant/License No: BAVARIAN NORDIC AS / 2096

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125597 / 0	1	6/10/2016	4.0x10E8 – 2.0x10E9 CFU (4.0x10E8 – 2.0x10E9 CFU/DOSE) POWDER / ORAL / PACKET

Trade Name: VIMKUNYA
Proper Name: CHIKUNGUNYA VACCINE, RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125820 / 0	1	2/14/2025	0.8 ML/DOSE (0.8 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: VIVOTIF
Proper Name: TYPHOID VACCINE LIVE ORAL TY21A

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103123 / 0	1	12/15/1989	2.0-10.0x10E+9 CFU (2.0-10.0x10E+9 CFU) CAPSULE / ORAL /

Applicant/License No: BAXTER HEALTHCARE CORP / 0140

Trade Name: ARTISS
Proper Name: FIBRIN SEALANT (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125266 / 0	1	3/19/2008	2 ML (2 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE
125266 / 0	5	3/19/2008	4 ML (4 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE
125266 / 0	6	3/19/2008	10 ML (10 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE

Trade Name: RECOTHROM
Proper Name: THROMBIN TOPICAL (RECOMBINANT)

Applicant/License No: BAXTER HEALTHCARE CORP / 0140

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125248 / 0	1	1/17/2008	5000 IU (5000 IU/VIAL) POWDER / TOPICAL / SINGLE-DOSE VIAL
125248 / 0	2	1/17/2008	20000 IU (20000 IU/VIAL) POWDER / TOPICAL / SINGLE-DOSE VIAL

Trade Name: TISSEEL
Proper Name: FIBRIN SEALANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103980 / 5121	4	7/27/2006	4 ML (4 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE
103980 / 0	5	7/27/2006	2 ML (2 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE
103980 / 0	6	7/27/2006	10 ML (10 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE

Trade Name: TISSEEL KIT
Proper Name: FIBRIN SEALANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103980 / 1	1	2/7/2000	2 ML (2 ML) POWDER / TOPICAL / SINGLE-DOSE VIAL
103980 / 1	2	2/7/2000	4 ML (4 ML) POWDER / TOPICAL / SINGLE-DOSE VIAL
103980 / 1	3	2/7/2000	10 ML (10 ML) POWDER / TOPICAL / SINGLE-DOSE VIAL

Applicant/License No: BAYER HEALTHCARE LLC / 0008

Trade Name: JIVI
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED-AUCL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125661 / 0	2	8/29/2018	500 IU/VIAL (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-USE VIAL
125661 / 0	3	8/29/2018	1000 IU/VIAL (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-USE VIAL
125661 / 0	4	8/29/2018	2000 IU/VIAL (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-USE VIAL
125661 / 0	5	8/29/2018	3000 IU/VIAL (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-USE VIAL
125661 / 0	6	12/2/2024	4000 IU/VIAL (4000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-USE VIAL

Trade Name: KOVALTRY
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT), FULL LENGTH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125574 / 0	1	3/16/2016	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125574 / 0	2	3/16/2016	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125574 / 0	3	3/16/2016	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125574 / 0	4	3/16/2016	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: BAYER HEALTHCARE LLC / 0008

125574 / 0	5	3/16/2016	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: BIO PRODUCTS LABORATORY LIMITED / 1811

Trade Name: ALBUMINEX
Proper Name: ALBUMIN (HUMAN)-KJDA 25%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125644 / 0	3	6/19/2018	12.5 GM/50 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125644 / 0	4	6/19/2018	25 GM/100 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Proper Name: ALBUMIN (HUMAN)-KJDA 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125644 / 0	1	6/19/2018	12.5 GM/250 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125644 / 0	2	6/19/2018	25 GM/500 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: COAGADEX
Proper Name: COAGULATION FACTOR X (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125506 / 0	1	10/20/2015	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125506 / 0	2	10/20/2015	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: GAMMAPLEX
Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%

Applicant/License No: BIO PRODUCTS LABORATORY LIMITED / 1811

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125329 / 0	5	2/6/2017	5 GM/50 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125329 / 0	6	2/6/2017	10 GM/100 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125329 / 0	7	2/6/2017	20 GM/200 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE

Applicant/License No: BIONTECH MANUFACTURING GMBH / 2229

Trade Name: COMIRNATY
Proper Name: COVID-19 VACCINE, MRNA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125742 / 0	5	10/17/2023	0.418 ML/SYRINGE (0.3 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
125742 / 0	6	8/27/2025	0.48 ML/VIAL (0.3 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: BIOTEST AG / 2332

Trade Name: YIMMUGO
Proper Name: IMMUNE GLOBULIN INTRAVENOUS HUMAN - DIRA 10% IGG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125810 / 0	1	6/13/2024	5 GM/50 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Proper Name: IMMUNE GLOBULIN INTRAVENOUS HUMAN – DIRA 10% IGG

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

Applicant/License No: BIOTEST AG / 2332

125810 / 0	2	6/13/2024	10 GM/100 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125810 / 0	3	6/13/2024	20 GM/200 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: BIOVERATIV THERAPEUTICS INC / 2078

Trade Name: ALPROLIX
Proper Name: COAGULATION FACTOR IX (RECOMBINANT), FC FUSION PROTEIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125444 / 0	1	2/18/2016	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125444 / 0	2	3/28/2014	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125444 / 0	3	3/28/2014	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125444 / 0	4	3/28/2014	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125444 / 0	5	3/28/2014	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125444 / 286	6	7/14/2016	4000 IU (4000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ALTUVIIIO
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC-VWF-XTEN FUSION PROTEIN-EHTL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125771 / 0	1	2/22/2023	250 IU (250 IU) POWDER / INTRAVENOUS / KIT

Applicant/License No: BIOVERATIV THERAPEUTICS INC / 2078

125771 / 0	2	2/22/2023	500 IU (500 IU) POWDER / INTRAVENOUS / KIT
125771 / 0	3	2/22/2023	750 IU (750 IU) POWDER / INTRAVENOUS / KIT
125771 / 0	4	2/22/2023	1000 IU (1000 IU) POWDER / INTRAVENOUS / KIT
125771 / 0	5	2/22/2023	2000 IU (2000 IU) POWDER / INTRAVENOUS / KIT
125771 / 0	6	2/22/2023	3000 IU (3000 IU) POWDER / INTRAVENOUS / KIT
125771 / 0	7	2/22/2023	4000 IU (4000 IU) POWDER / INTRAVENOUS / KIT

Trade Name: ELOCTATE
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125487 / 0	1	6/6/2014	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125487 / 0	2	6/6/2014	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125487 / 0	3	6/6/2014	750 IU (750 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125487 / 0	4	6/6/2014	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: BIOVERATIV THERAPEUTICS INC / 2078

125487 / 0	5	6/6/2014	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125487 / 0	6	6/6/2014	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125487 / 0	7	6/6/2014	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125487 / 450	8	1/27/2017	4000 IU (4000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125487 / 450	9	1/27/2017	5000 IU (5000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125487 / 450	10	1/27/2017	6000 IU (6000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: BTG INTERNATIONAL INC / 1861

Trade Name: CROFAB
Proper Name: CROTALIDAE POLYVALENT IMMUNE FAB (OVINE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103788 / 0	1	10/2/2000	1 GM (1 GM/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: CALIFORNIA DEPARTMENT OF PUBLIC HEALTH / 1797

Trade Name: BABYBIG
Proper Name: BOTULISM IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125034 / 0	1	10/23/2003	100 MG (100 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **CELGENE CORPORATION A BRISTOL MYERS SQUIBB COMPANY / 2252**

Trade Name: ABECMA

Proper Name: IDECABTAGENE VICLEUCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125736 / 0	1	3/26/2021	50 ML/BAG (300 TO 460 x10^6 CAR-POSITIVE T CELLS/1 OR MORE BAGS) SUSPENSION / INTRAVENOUS / KIT
125736 / 0	2	3/26/2021	250 ML/BAG (300 TO 460 x10^6 CAR-POSITIVE T CELLS/1 OR MORE BAGS) SUSPENSION / INTRAVENOUS / KIT
125736 / 0	3	3/26/2021	500 ML/BAG (300 TO 460 x10^6 CAR-POSITIVE T CELLS/1 OR MORE BAGS) SUSPENSION / INTRAVENOUS / KIT

Applicant/License No: **CELLTRANS INC / 2213**

Trade Name: LANTIDRA

Proper Name: DONISLECEL-JUJN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125734 / 0	1	6/28/2023	1x10^6 EIN/400 ML/BAG (1x10^6 EIN/400 ML/BAG) SUSPENSION / INTRAVENOUS / KIT

Applicant/License No: **CORZA MEDICAL GMBH / 2294**

Trade Name: TACHOSIL

Proper Name: FIBRIN SEALANT PATCH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125351 / 0	2	4/5/2010	4.8 CM X 4.8 CM (170.5 MG/62.2 UNITS) (4.8 CM X 4.8 CM (170.5 MG/62.2 UNITS)) PATCH / TOPICAL / PACKET
125351 / 0	3	4/5/2010	9.5 CM X 4.8 CM (337.4 MG/123.1 UNITS) (9.5 CM X 4.8 CM (337.4 MG/123.1 UNITS)) PATCH / TOPICAL / PACKET

Applicant/License No: CSL BEHRING AG / 1766

Trade Name: ALBURX
Proper Name: ALBUMIN (HUMAN) 25%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
102366 / 0	3	7/23/1976	12.5 GM/50 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
102366 / 0	4	7/23/1976	25 GM/100 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Proper Name: ALBUMIN (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
102366 / 0	1	7/23/1976	12.5 GM/250 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
102366 / 0	2	7/23/1976	25 GM/500 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: HIZENTRA
Proper Name: IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% LIQUID

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125350 / 0	1	3/4/2010	1000 MG/5 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125350 / 0	2	3/4/2010	2000 MG/10 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125350 / 0	3	3/4/2010	4000 MG/20 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125350 / 0	4	3/4/2010	10000 MG/50 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: PRIVIGEN

Applicant/License No: CSL BEHRING AG / 1766

Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN), 10% LIQUID

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125201 / 0	1	10/2/2009	2.5 GM/25 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125201 / 0	2	7/26/2007	5 GM/50 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125201 / 0	3	7/26/2007	10 GM/100 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125201 / 0	4	7/26/2007	20 GM/200 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125201 / 0	5	2/7/2013	40 GM/400 ML (10 GM/100 MG) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: RHOPHYLAC
Proper Name: RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125070 / 0	1	2/12/2004	300 MCG/2 ML (150 MCG/ML) SOLUTION / INTRAVENOUS, INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: CSL BEHRING GMBH / 1765

Trade Name: BERINERT
Proper Name: C1 ESTERASE INHIBITOR (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125287 / 0	1	10/9/2009	500 UNITS (500 UNITS/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: CORIFACT
Proper Name: FACTOR XIII CONCENTRATE (HUMAN)

Applicant/License No: CSL BEHRING GMBH / 1765

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125385 / 0	1	2/17/2011	1000-1600 U (1000-1600 U/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: HAEGARDA
Proper Name: C1 ESTERASE INHIBITOR SUBCUTANEOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125606 / 0	1	6/22/2017	2000 IU (2000 IU/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
125606 / 0	2	6/22/2017	3000 IU (3000 IU/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: HUMATE-P
Proper Name: ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103960 / 0	1	4/11/2000	600 IU & 250 IU (600 IU & 250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103960 / 0	2	4/11/2000	1200 IU & 500 IU (1200 IU & 500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103960 / 0	3	4/11/2000	2400 IU& 1000 IU (2400 IU & 1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: KCENTRA
Proper Name: PROTHROMBIN COMPLEX CONCENTRATE (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125421 / 0	1	4/29/2013	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: CSL BEHRING GMBH / 1765

125421 / 0	2	4/29/2013	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: RIASTAP
Proper Name: FIBRINOGEN CONCENTRATE (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125317 / 0	1	1/16/2009	900-1300 MG (900-1300 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125317 / 0	2	12/19/2025	1800-2600 MG (1800-2600 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: CSL BEHRING LENGNAU AG / 2009

Trade Name: AFSTYLA
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT), SINGLE CHAIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125591 / 0	1	5/25/2016	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125591 / 0	2	5/25/2016	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125591 / 0	3	5/25/2016	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125591 / 0	4	5/25/2016	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125591 / 0	5	5/25/2016	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125591 / 47	6	3/31/2017	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: CSL BEHRING LENGNAU AG / 2009

125591 / 47	7	3/31/2017	2500 IU (2500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: IDELVION
Proper Name: COAGULATION FACTOR IX (RECOMBINANT), ALBUMIN FUSION PROTEIN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125582 / 0	1	3/4/2016	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125582 / 0	2	3/4/2016	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125582 / 0	3	3/4/2016	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125582 / 0	4	3/4/2016	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125582 / 116	5	5/30/2018	3500 IU (3500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: CSL BEHRING LLC / 1767

Trade Name: HEMGENIX
Proper Name: ETRANACOGENE DEZAPARVOVEC-DRLB

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125772 / 0	1	11/22/2022	1 X 10^13 GC/ML/VIAL (NLT 10 ML/VIAL) - 100 ML - 480 ML KIT (1 X 10^13 GC/ML/VIAL (NLT 10 ML/VIAL)) SUSPENSION / INTRAVENOUS / KIT

Trade Name: ZEMAIRA
Proper Name: ALPHA-1 PROTEINASE INHIBITOR (HUMAN)

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

Applicant/License No: CSL BEHRING LLC / 1767

125078 / 0	1	7/8/2003	1000 MG (1000 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125078 / 818	2	4/16/2019	4000 MG (4000 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125078 / 818	3	4/16/2019	5000 MG (5000 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: DENDREON PHARMACEUTICALS LLC / 1749

Trade Name: PROVENGE
Proper Name: SIPULEUCEL-T

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125197 / 0	1	4/29/2010	50 M CD54+ ACTIVATED CELLS/250 ML (50 M CD54+ ACTIVATED CELLS/250 ML) SOLUTION / INTRAVENOUS / PLASTIC CONTAINER

Applicant/License No: DYNAVAX TECHNOLOGIES CORP / 1883

Trade Name: HEPLISAV-B
Proper Name: HEPATITIS B VACCINE (RECOMBINANT), ADJUVANTED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125428 / 0	1	11/9/2017	20 MCG HBSAG/0.5 ML (20 MCG HBSAG/0.5 ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: EMERGENT BIODEFENSE OPERATIONS LANSING LLC / 1755

Trade Name: BIOTHRAX
Proper Name: ANTHRAX VACCINE ADSORBED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103821 / 0	1	11/12/1998	5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL

Applicant/License No: **EMERGENT BIOSOLUTIONS CANADA INC / 2084**

Trade Name: ANTHRASIL
Proper Name: ANTHRAX IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125562 / 0	1	3/24/2015	≥60 UNITS/VIAL (≥60 UNITS/VIAL) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: BAT
Proper Name: BOTULISM ANTITOXIN HEPTAVALENT (A, B, C, D, E, F, G) (EQUINE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125462 / 0	1	3/22/2013	VARIABLE BETWEEN 10-22 ML (VARIABLE BETWEEN 10-22 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: CNJ-016
Proper Name: VACCINIA IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125109 / 0	1	5/2/2005	>50,000 U/15 ML (>50,000 U/15 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC / 2089**

Trade Name: ACAM2000
Proper Name: SMALLPOX (VACCINIA) VACCINE, LIVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125158 / 0	1	8/31/2007	1 – 5 X 10-8TH PFU (1 – 5 X 10-8TH PFU/ML) POWDER / PERCUTANEOUS / MULTI-DOSE VIAL

Trade Name: CYFENDUS
Proper Name: ANTHRAX VACCINE ADSORBED, ADJUVANTED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125761 / 0	1	7/20/2023	5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL

Applicant/License No: ETHICON INC / 1879

Trade Name: EVARREST
Proper Name: FIBRIN SEALANT PATCH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125392 / 0	1	5/27/2014	55.5MG PER SQUARE INCH HUMAN FIBRINOGEN AND 241.9 UNITS PER SQUARE INCH HUMAN THROMBIN (2X4 IN UNIT WITH 55.5 MG/IN HUMAN PATCH / TOPICAL / PACKET

Applicant/License No: FERRING PHARMACEUTICALS AS / 2222

Trade Name: ADSTILADRIN
Proper Name: NADOFARAGENE FIRADENOVEC-VNCG

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125700 / 0	1	12/16/2022	NLT 20ML/VIAL (3 X 10^11 VP/ML) SUSPENSION / INTRAVESICAL / SINGLE-USE VIAL

Applicant/License No: FERRING PHARMACEUTICALS INC / 2112

Trade Name: REBYOTA
Proper Name: FECAL MICROBIOTA, LIVE-JSLM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125739 / 0	1	11/30/2022	150 ML/DOSE (150 ML/DOSE) SUSPENSION / RECTAL / SINGLE DOSE CONTAINER

Applicant/License No: FONDAZIONE TELETHON ETS / 2378

Trade Name: WASKYRA
Proper Name: ETUVETIDIGENE AUTOTEMCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125846 / 0	1	12/9/2025	1 TO 8 INFUSION BAGS OVERALL CONTAINING A SUSPENSION OF 2-11.4 X 106 CELLS/ML (1.9-11.4 X 10^6 CD34+ CELLS/ML) SUSPENSION / INTRAVENOUS / FLEXIBLE CONTAINER CLOSURE SYSTEM

Applicant/License No: GAMIDA CELL LTD / 2223

Trade Name: OMISIRGE
Proper Name: OMIDUBICEL-ONLV

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125738 / 0	1	4/17/2023	8.0X10^8 TOTAL VIABLE CELLS WITH A MINIMUM OF 8.7% CD34+CELLS & A MINIMUM OF 9.2X10^7 CD34+CELLS/BAG (8.0X10^8 TOTAL VIABLE SUSPENSION / INTRAVENOUS / KIT

Applicant/License No: GC BIOPHARMA CORP / 2033

Trade Name: ALYGLO
Proper Name: IMMUNE GLOBULIN INTRAVENOUS, HUMAN-STWK

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125743 / 0	1	12/15/2023	5 GM/50 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125743 / 0	2	12/15/2023	10 GM/100 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125743 / 0	3	12/15/2023	20 GM/200 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: GENETIX BIOTHERAPEUTICS INC / 2425

Trade Name: LYFGENIA
Proper Name: LOVOTIBEGLOGENE AUTOTEMCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125788 / 0	1	12/8/2023	20 ML/BAG (1.7 TO 20 × 10^6 CELLS/ML) SUSPENSION / INTRAVENOUS / FLEXIBLE CONTAINER CLOSURE SYSTEM

Trade Name: SKYSONA
Proper Name: ELIVALDOGENE AUTOTEMCEL

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

Applicant/License No: GENETIX BIOTHERAPEUTICS INC / 2425

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125755 / 0	1	9/16/2022	20 ML/BAG (4 to 30 x 10^6 cells/mL in 20 ML BAG) SUSPENSION / INTRAVENOUS / SINGLE DOSE CONTAINER

Trade Name: ZYNTEGLO
Proper Name: BETIBEGLOGENE AUTOTEMCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125717 / 0	1	8/17/2022	20 ML/BAG (2.0 to 20 x 10^6 CELLS/ML IN 20 ML BAG) SUSPENSION / INTRAVENOUS / SINGLE DOSE CONTAINER

Applicant/License No: GENZYME CORP / 1596

Trade Name: THYMOGLOBULIN
Proper Name: ANTI-THYMOCYTE GLOBULIN (RABBIT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103869 / 0	1	5/19/1999	25 MG (25 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: GLAXOSMITHKLINE BIOLOGICALS SA / 1617

Trade Name: AREXVY
Proper Name: RESPIRATORY SYNCYTIAL VIRUS VACCINE ADJUVANTED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125775 / 0	1	5/3/2023	0.5ML (0.5ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: BEXSERO
Proper Name: MENINGOCOCCAL GROUP B VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125546 / 0	1	1/23/2015	0.5 ML/SYRINGE (0.5 ML/SYRINGE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: BOOSTRIX
Proper Name: TETANUS TOXOID, REDUCED DIPHTHERIA TOXOID AND ACELLULAR PERTUSSIS VACCINE, ADSORBED

Applicant/License No: **GLAXOSMITHKLINE BIOLOGICALS SA / 1617**

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125106 / 0	1	5/3/2005	0.5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: ENGERIX-B
Proper Name: HEPATITIS B VACCINE (RECOMBIANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103239 / 0	2	8/28/1989	20 MCG/ML (20 MCG/ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Proper Name: HEPATITIS B VACCINE (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103239 / 0	1	8/28/1989	10 MCG/0.5 ML (10 MCG/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: FLUARIX
Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125127 / 0	1	8/31/2005	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: HAVRIX
Proper Name: HEPATITIS A VACCINE INACTIVATED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103475 / 0	1	2/22/1995	720 ELISA U/0.5 ML (720 ELISA U/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
103475 / 0	2	2/22/1995	1440 ELISA U/ML (1440 ELISA U/ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: HIBERIX
Proper Name: HAEMOPHILUS B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE)

Applicant/License No: GLAXOSMITHKLINE BIOLOGICALS SA / 1617

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125347 / 0	2	12/20/2023	25 MCG (25 MCG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: INFANRIX
Proper Name: DIPHTHERIA & TETANUS TOXOIDS & ACELLULAR PERTUSSIS VACCINE ABSORBED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103647 / 0	1	1/29/1997	25LF/10LF/25MCG/0.5 ML (25LF/10LF/25MCG/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: KINRIX
Proper Name: DIPHTHERIA & TETANUS TOXOIDS & ACELLULAR PERTUSSIS ADSORBED & INACTIVATED POLIO VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125260 / 0	1	6/24/2008	0.5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: MENVEO
Proper Name: MENINGOCOCCAL (GROUPS A, C, Y, AND W 135) OLIGOSACCHARIDE DIPHTHERIA CRM197 CONJUGATE VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125300 / 0	1	2/19/2010	0.5 ML (0.5 ML/DOSE) POWDER & SOLUTION / INTRAMUSCULAR / TWO-VIAL
125300 / 0	2	10/14/2022	0.5 ML (0.5 ML/DOSE) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: PEDIARIX
Proper Name: DTAP & HEPATITIS B (RECOMBINANT) & INACTIVATED POLIOVIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103907 / 0	1	12/13/2002	0.5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: PENMENVY

Applicant/License No: GLAXOSMITHKLINE BIOLOGICALS SA / 1617

Proper Name: MENINGOCOCCAL GROUPS A, B, C, W, AND Y VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125819 / 0	1	2/14/2025	0.5 ML/DOSE (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: PRIORIX
Proper Name: MEASLES, MUMPS AND RUBELLA VACCINE, LIVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125748 / 0	1	6/3/2022	0.5 ML/DOSE (0.5 ML/DOSE) SUSPENSION / SUBCUTANEOUS / SINGLE-USE VIAL

Trade Name: ROTARIX
Proper Name: ROTAVIRUS VACCINE, LIVE, ORAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125265 / 0	2	11/4/2022	1.5 ML/DOSE (1.5 ML/DOSE) LIQUID / ORAL / PREFILLED SYRINGE

Trade Name: SHINGRIX
Proper Name: ZOSTER VACCINE RECOMBINANT, ADJUVANTED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125614 / 0	1	10/20/2017	0.5 ML (0.5 ML) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
125614 / 0	2	7/16/2025	0.5 ML (0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: TWINRIX
Proper Name: HEPATITIS A INACTIVATED & HEPATITIS B (RECOMBINANT) VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103850 / 0	1	5/11/2001	1 ML (1 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: GRIFOLS BIOLOGICALS LLC / 1694

Trade Name: ALBUTEIN

Proper Name: ALBUMIN (HUMAN) 20%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
102478 / 0	4	8/15/1978	10 GM/50 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM
102478 / 0	5	8/15/1978	20 GM/100 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM

Proper Name: ALBUMIN (HUMAN) 25%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
102478 / 0	6	8/15/1978	5 GM/20 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
102478 / 0	7	8/15/1978	12.5 GM/50 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM
102478 / 0	8	8/15/1978	25 GM/100 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM

Proper Name: ALBUMIN (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
102478 / 0	1	8/15/1978	2.5 GM/50 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
102478 / 0	2	8/15/1978	12.5 GM/250 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM
102478 / 0	3	8/15/1978	25 GM/500 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM

Trade Name: ALPHANATE

Proper Name: ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)

Applicant/License No: GRIFOLS BIOLOGICALS LLC / 1694

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
102475 / 0	1	8/15/1978	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
102475 / 0	2	8/15/1978	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
102475 / 0	3	8/15/1978	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
102475 / 0	4	8/15/1978	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
102475 / 0	5	6/26/2014	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ALPHANINE SD
Proper Name: COAGULATION FACTOR IX (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103249 / 0	1	12/31/1990	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103249 / 0	2	12/31/1990	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103249 / 0	3	12/31/1990	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PROFILNINE
Proper Name: FACTOR IX COMPLEX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
102476 / 0	1	7/20/1981	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: GRIFOLS BIOLOGICALS LLC / 1694

102476 / 0	2	7/20/1981	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
102476 / 0	3	7/20/1981	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: GRIFOLS THERAPEUTICS LLC / 1871

Trade Name: FESILTY
Proper Name: FIBRINOGEN, HUMAN - CHMT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125833 / 0	1	12/16/2025	1 GRAM (1 GRAM) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: GAMASTAN
Proper Name: IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101134 / 0	1	1/11/1944	10 ML (16.5%) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
101134 / 0	2	1/11/1944	2 ML (16.5%) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: GAMUNEX-C
Proper Name: IMMUNE GLOBULIN INJECTION (HUMAN), 10%, CAPRYLATE/CHROMATOGRAPHY PURIFIED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125046 / 0	1	8/27/2003	1 GM/10 ML (1 GM/10 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
125046 / 0	2	8/27/2003	2.5 GM/25 ML (1 GM/10 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE

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125046 / 0	3	8/27/2003	5 GM/50 ML (1 GM/10 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM
125046 / 0	4	8/27/2003	10 GM/100 ML (1 GM/10 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM
125046 / 0	5	8/27/2003	20 GM/200 ML (1 GM/10 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM
125046 / 0	6	8/27/2003	40 GM/400 ML (1 GM/10 ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM

Trade Name: HYPERHEP B

Proper Name: HEPATITIS B IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101146 / 0	1	9/23/1977	110 IU/0.5 ML (110 IU/0.5 ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
101146 / 0	2	9/23/1977	220 IU/ML (220 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
101146 / 0	3	9/23/1977	1100 IU/5 ML (220 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: HYPERRAB

Proper Name: RABIES IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101144 / 0	1	6/12/1974	300 IU/ML (300 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
101144 / 0	2	6/12/1974	1500 IU/5 ML (300 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: GRIFOLS THERAPEUTICS LLC / 1871

101144 / 5817	3	11/6/2019	900 IU/3 ML (300 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: HYPERRHO
Proper Name: RHO(D) IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101141 / 0	1	6/11/1971	250 IU/ML (250 IU/ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
101141 / 0	2	6/11/1971	1500 IU/ML (1500 IU/ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: HYPERTET
Proper Name: TETANUS IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101142 / 0	1	10/17/1957	250 IU/ML (250 IU/ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: KOATE
Proper Name: ANTIHEMOPHILIC FACTOR (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101130 / 0	1	1/24/1974	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
101130 / 0	2	1/24/1974	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
101130 / 0	3	1/24/1974	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PLASBUMIN
Proper Name: ALBUMIN (HUMAN) 20%

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

Applicant/License No: GRIFOLS THERAPEUTICS LLC / 1871

101138 / 0	4	10/21/1942	10 GM/50 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
101138 / 0	5	10/21/1942	20 GM/100 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Proper Name: ALBUMIN (HUMAN) 25%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101138 / 0	6	10/21/1942	5 GM/20 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
101138 / 0	7	10/21/1942	12.5 GM/50 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
101138 / 0	8	10/21/1942	25 GM/100 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Proper Name: ALBUMIN (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101138 / 0	1	10/21/1942	2.5 GM/50 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
101138 / 0	2	10/21/1942	12.5 GM/250 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
101138 / 0	3	10/21/1942	25 GM/500 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PLASMANATE
Proper Name: PLASMA PROTEIN FRACTION (HUMAN), USP

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

Applicant/License No: GRIFOLS THERAPEUTICS LLC / 1871

101140 / 0	2	10/2/1958	12.5 GM/250 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PROLASTIN-C
Proper Name: ALPHA-1-PROTEINASE INHIBITOR (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103174 / 0	1	12/2/1987	1000 MG (1000 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: PROLASTIN-C LIQUID
Proper Name: ALPHA-1-PROTEINASE INHIBITOR (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103174 / 6160	3	9/8/2017	1000 MG/20 ML (500 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
103174 / 6314	4	3/5/2020	500 MG/10 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
103174 / 6314	5	3/5/2020	4000 MG/80 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: THROMBATE III
Proper Name: ANTITHROMBIN III (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103196 / 0	1	12/30/1991	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: XEMBIFY
Proper Name: IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% - KLHW

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125683 / 0	1	7/3/2019	1 GM/5 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: GRIFOLS THERAPEUTICS LLC / 1871

125683 / 0	2	7/3/2019	2 GM/10 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125683 / 0	3	7/3/2019	4 GM/20 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125683 / 0	4	7/3/2019	10 GM/50 ML (200 MG/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: HUMACYTE GLOBAL INC / 2336

Trade Name: SYMVESS
Proper Name: ACELLULAR TISSUE ENGINEERED VESSEL-TYOD

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125812 / 0	1	12/19/2024	6 MM IN INNER DIAMETER AND 42 CM IN LENGTH (APPROXIMATELY 40 CM OF USABLE LENGTH) (6 MM IN INNER DIAMETER AND 42 CM IN IMPLANT / IMPLANTATION / KIT

Applicant/License No: ID BIOMEDICAL CORPORATION QUEBEC / 1739

Trade Name: FLULAVAL
Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125163 / 0	1	10/5/2006	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: INOVIO PHARMACEUTICALS INC / 2358

Trade Name: VOCERYQ
Proper Name: doruxapapogene ralaplasmid and lalikinogene sifuplasmid-gxfd

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125825 / 0	1	10/30/2026	6.25 mg/mL (6.25 mg/mL) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / CARTRIDGE

Applicant/License No: INSTITUTO GRIFOLS SA / 1181

Trade Name: FLEBOGAMMA DIF
Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125077 / 0	1	12/15/2003	20 GM/400 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125077 / 0	7	12/15/2003	5 GM/100 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125077 / 0	8	12/15/2003	10 GM/200 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: HUMAN ALBUMIN GRIFOLS
Proper Name: ALBUMIN (HUMAN) 20%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103352 / 0	2	2/17/1995	20 GM/100 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: VISTASEAL
Proper Name: FIBRIN SEALANT (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125640 / 0	1	11/1/2017	2 ML (2 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE
125640 / 0	2	11/1/2017	4 ML (4 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE
125640 / 0	3	11/1/2017	6 ML (6 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE
125640 / 0	4	11/1/2017	10 ML (10 ML) SOLUTION / TOPICAL / PREFILLED SYRINGE

Applicant/License No: **IOVANCE BIOTHERAPEUTICS INC / 2298**

Trade Name: AMTAGVI
Proper Name: LIFILEUCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125773 / 0	1	2/16/2024	7.5 X 10^9 TO 72 X 10^9 VIABLE CELLS/SPLIT IN 1-4 BAGS (100 ML TO 125 ML/BAG) (7.5 X 10^9 TO 72 X 10^9 VIABLE CELLS/SPLIT IN 1-4 BAGS (100 SUSPENSION / INTRAVENOUS / FLEXIBLE CONTAINER CLOSURE SYSTEM

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

Trade Name: CARVYKTI
Proper Name: CILTACABTAGENE AUTOLEUCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125746 / 0	1	2/28/2022	30ML/BAG (0.5-1.0x10^6 in 30ML BAG) SUSPENSION / INTRAVENOUS / SINGLE DOSE CONTAINER
125746 / 0	2	2/28/2022	70ML/BAG (0.5-1.0x10^6 in 70ML BAG) SUSPENSION / INTRAVENOUS / SINGLE DOSE CONTAINER

Applicant/License No: **JUNO THERAPEUTICS / 2156**

Trade Name: BREYANZI
Proper Name: LISOCABTAGENE MARALEUCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125714 / 0	1	2/5/2021	6.9 × 10E6 to 322 × 10E6/4.6 ML (1.5 × 10E6 to 70 × 10E6/ML) SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **KAMADA LTD / 1826**

Trade Name: CYTOGAM
Proper Name: CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103189 / 0	1	4/17/1990	2500 MG/50 ML (50 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: HEPAGAM B

Applicant/License No: KAMADA LTD / 1826

Proper Name: HEPATITIS B IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125035 / 0	1	4/6/2007	>312 IU/ML (>312 IU/ML) SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL
125035 / 0	2	4/6/2007	>1560 IU/5 ML (>312 IU/ML) SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: KEDRAB
Proper Name: RABIES IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125613 / 0	1	8/23/2017	300 IU/2 ML (150 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
125613 / 0	2	8/23/2017	1500 IU/10 ML (150 IU/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: VARIZIG
Proper Name: VARICELLA ZOSTER IMMUNE GLOBLIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125430 / 0	1	12/2/2012	125 IU/VIAL (125 IU/VIAL) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: WINRHO SDF
Proper Name: RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103649 / 0	5	4/2/1996	1500 IU/VIAL (1500 IU/VIAL) SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL

Applicant/License No: KEDRION BIOPHARMA INC / 1906

Trade Name: KEDBUMIN
Proper Name: ALBUMIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125384 / 0	1	6/3/2011	12.5 GM/50 ML (25 GM/100 ML, 25%) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125384 / 0	2	9/5/2013	25 GM/100 ML (25 GM/100 ML, 25%) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: RHOGAM
Proper Name: RHO(D) IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103777 / 0	2	4/23/1998	300 MCG/SYRINGE (300 MCG/SYRINGE) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: RYPLAZIM
Proper Name: PLASMINOGEN HUMAN-TVMH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125659 / 0	1	6/4/2021	68.8 MG/12.5 ML (5.5 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: KEDRION SPA / 1851

Trade Name: QIVIGY
Proper Name: IMMUNE GLOBULIN INTRAVENOUS, HUMAN-KTHM, 10% SOLUTION

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125822 / 0	1	9/26/2025	5 G/50 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125822 / 0	2	9/26/2025	10 G/100 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: KITE PHARMA INC / 2064

Trade Name: TECARTUS
Proper Name: BREXUCABTAGENE AUTOLEUCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125703 / 0	1	7/24/2020	~68 ML/BAG (~68 ML/BAG) SUSPENSION / INTRAVENOUS / PLASTIC CONTAINER

Trade Name: YESCARTA
Proper Name: AXICABTAGENE CILOLEUCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125643 / 0	1	10/18/2017	~68 ML/BAG (~68 ML/BAG) SUSPENSION / INTRAVENOUS / PLASTIC CONTAINER

Applicant/License No: KRYSTAL BIOTECH INC / 2301

Trade Name: VYJUVEK
Proper Name: BEREMAGENE GEPERPAVEC-SVDT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125774 / 0	1	5/19/2023	5X10^9 PFU/ML/VIAL (5X10^9 PFU/ML/VIAL) SUSPENSION / TOPICAL / SINGLE-DOSE VIAL

Applicant/License No: LABORATOIRE FRANCAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES SA / 206

Trade Name: SEVENFACT
Proper Name: COAGULATION FACTOR VIIA (RECOMBINANT)-JNCW

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125641 / 0	1	4/1/2020	1 MG (1 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125641 / 0	2	4/1/2020	5 MG (5 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: MEDEXUS PHARMA INC / 2220

Trade Name: IXINITY

Proper Name: COAGULATION FACTOR IX (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125426 / 0	3	4/29/2015	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125426 / 0	4	4/29/2015	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125426 / 0	6	12/21/2015	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: MEDIMMUNE LLC / 1799

Trade Name: FLUMIST

Proper Name: INFLUENZA VIRUS VACCINE LIVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125020 / 0	2	6/17/2003	10 X 6.5-7.5 TCID (10 X 6.5-7.5 TCID) SPRAY / INTRANASAL / PREFILLED SPRAYER

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

Trade Name:

Proper Name: ANTIVENIN (LATRODECTUS MACTANS)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101062 / 0	1	2/13/1936	NLT 6,000 U (NLT 6,000 U/VIAL) POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL

Proper Name: NORMAL HORSE SERUM

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101084 / 0	1	1/2/1959	1 ML (1 ML/VIAL) SOLUTION / INTRADERMAL / SINGLE-DOSE VIAL

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

Trade Name: CAPVAXIVE
Proper Name: PNEUMOCOCCAL 21-VALENT CONJUGATE VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125814 / 0	1	6/17/2024	84 UG/0.5 ML (84 UG/0.5 ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: ERVEBO
Proper Name: EBOLA ZAIRE VACCINE, LIVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125690 / 0	1	12/19/2019	1 ML/DOSE (1 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: GARDASIL 9
Proper Name: HUMAN PAPILLOMAVIRUS 9-VALENT VACCINE RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125508 / 0	1	12/10/2014	0.5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: M-M-R II
Proper Name: MEASLES, MUMPS AND RUBELLA VIRUS VACCINE LIVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101069 / 0	1	4/22/1971	0.5 ML (0.5 ML/DOSE) POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: PEDVAXHIB
Proper Name: HAEMOPHILUS B CONJUGATE VACCINE (MENINGOCOCCAL PROTEIN CONJUGATE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103237 / 0	1	12/20/1989	7.5 MCG/0.5 ML (7.5 MCG/0.5 ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: PNEUMOVAX 23
Proper Name: PNEUMOCOCCAL VACCINE, POLYVALENT

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101094 / 5911	2	11/21/1977	0.5 ML (0.5 ML/DOSE) SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: PROQUAD
Proper Name: MEASLES, MUMPS, RUBELLA, AND VARICELLA VIRUS VACCINE LIVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125108 / 0	1	9/6/2005	0.5 ML (0.5 ML/VIAL) POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: RECOMBIVAX, RECOMBIVAX HB
Proper Name: HEPATITIS B VACCINE (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101066 / 0	1	7/23/1986	10 MCG/ML (10 MCG/ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
101066 / 0	2	7/23/1986	40 MCG/ML (40 MCG/ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
101066 / 0	3	7/23/1986	5 MCG/0.5 ML (5 MCG/0.5 ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: ROTATEQ
Proper Name: ROTAVIRUS VACCINE LIVE, ORAL PENTAVALENT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125122 / 0	1	2/3/2006	2 ML (2 ML) SOLUTION / ORAL / SINGLE-DOSE TUBE
125122 / 0	2	3/20/2026	2 ML (2 ML) SOLUTION / ORAL / AMPULE

Trade Name: VAQTA
Proper Name: HEPATITIS A VACCINE INACTIVATED

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

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103606 / 0	1	3/29/1996	25 U/0.5 ML (25 U/0.5 ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
103606 / 0	2	3/29/1996	50 U/ML (50 U/ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: VARIVAX
Proper Name: VARICELLA VIRUS VACCINE LIVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103552 / 0	1	3/17/1995	NLT 1350 PF U (NLT 1350 PF U/0.5 ML) POWDER / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: VAXNEUVANCE
Proper Name: PNEUMOCOCCAL 15-VALENT CONJUGATE VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125741 / 0	1	7/16/2021	2MCG/0.5ML (2MCG/0.5ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: MERCK TEKNIKA LLC / 1747

Trade Name:
Proper Name: BCG VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103050 / 0	1	6/21/1989	100-800 MIL CFU (100-800 MIL CFU/VIAL) POWDER / PERCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: TICE BCG
Proper Name: BCG LIVE

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

Applicant/License No: MERCK TEKNIKA LLC / 1747

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
102821 / 0	1	6/21/1989	100-800 MIL CFU (100-800 MIL CFU/VIAL) POWDER / INTRAVESICAL / SINGLE-DOSE VIAL

Applicant/License No: MESOBLAST INC / 2140

Trade Name: RYONCIL
Proper Name: REMESTEMCEL-L-RKND

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125706 / 0	1	12/18/2024	25 x 10^6 MSCs/6 ML CRYOVIAL (6.68 X 10^6 MSCS/ML IN 3.8 ML CONTAINED IN A 6 ML CRYOVIAL) SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: MODERNATX INC / 2256

Trade Name: MFLUSIVA
Proper Name: Influenza Vaccine, mRNA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125869 /	1	8/5/2026	(0.38 mL/dose) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: MRESVIA
Proper Name: RESPIRATORY SYNCYTIAL VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125796 / 0	1	5/31/2024	50 MCG/0.5 ML (50 MCG/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: SPIKEVAX
Proper Name: COVID-19 VACCINE, MRNA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125752 / 0	3	9/11/2023	0.5 ML/DOSE (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: MODERNATX INC / 2256

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125752 / 0	6	7/9/2025	0.25 ML (0.25 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
125835 / 0	1	5/30/2025	0.5 ML (0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: MSP VACCINE COMPANY / 2202

Trade Name: VAXELIS

Proper Name: DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS ADSORBED, INACTIVATED POLIOVIRUS, HAEMOPHILUS B CONJUGATE [MENINGOCOCCAL PROTEIN CONJUGATE] AND

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125563 / 0	1	9/25/2020	0.5 ML/DOSE (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: NEUROTECH PHARMACEUTICALS INC / 2321

Trade Name: ENCELTO

Proper Name: REVAKINAGENE TARORETCEL-LWEY

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125798 / 0	1	3/5/2025	200,000 TO 440,000 ALLOGENEIC RETINAL PIGMENT EPITHELIAL CELLS EXPRESSING RHCNTF (200,000 TO 440,000 ALLOGENEIC RETINAL IMPLANTATION / INTRAVITREAL / SINGLE DOSE CONTAINER

Applicant/License No: NOVARTIS GENE THERAPIES INC / 2250

Trade Name: ITVISMA

Proper Name: ONASEMNOGENE ABEPARVOVEC-BRVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125856 / 0	1	11/24/2025	1.2 × 10^14 VG/3 ML (4 × 10^13 VG/ML) SUSPENSION / INTRATHECAL / SINGLE-DOSE VIAL

Trade Name: ZOLGENSMA

Proper Name: ONASEMNOGENE ABEPARVOVEC-XIOI

Applicant/License No: NOVARTIS GENE THERAPIES INC / 2250

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125694 / 0	1	5/24/2019	11 LOG 13VG/5.5 ML (2.0 LOG 13VG/ML) SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL
125694 / 0	2	5/24/2019	16.6 LOG 13VG/8.3 ML (2.0 LOG 13VG/ML) SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: NOVARTIS PHARMACEUTICALS CORP / 1244

Trade Name: KYMRIAH
Proper Name: TISAGENLECLEUCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125646 / 0	1	8/30/2017	INFUSION BAG (INFUSION BAG) SUSPENSION / INTRAVENOUS / PLASTIC CONTAINER

Applicant/License No: NOVO NORDISK INC / 1261

Trade Name: ESPEROCT
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT), GLYCOPEGYLATED-EXEI

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125671 / 0	1	2/19/2019	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125671 / 0	2	2/19/2019	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125671 / 0	3	2/19/2019	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125671 / 0	4	2/19/2019	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: NOVO NORDISK INC / 1261

125671 / 0	5	2/19/2019	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125671 / 0	6	7/3/2024	4000 IU (4000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: NOVOEIGHT
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125466 / 0	1	10/15/2013	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125466 / 0	2	10/15/2013	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125466 / 0	3	10/15/2013	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125466 / 0	4	10/15/2013	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125466 / 0	5	10/15/2013	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125466 / 0	6	10/15/2013	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: NOVOSEVEN RT
Proper Name: COAGULATION FACTOR VIIA (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103665 / 1	1	5/9/2008	1 MG (1 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: NOVO NORDISK INC / 1261

103665 / 5605	2	5/9/2008	2 MG (2 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103665 / 5605	3	5/9/2008	5 MG (5 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103665 / 5605	4	8/6/2010	8 MG (8 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: REBINYN
Proper Name: COAGULATION FACTOR IX (RECOMBINANT), GLYCOPEGYLATED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125611 / 0	1	5/31/2017	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125611 / 0	2	5/31/2017	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125611 / 0	3	5/31/2017	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125611 / 0	4	8/11/2022	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: TRETTEN
Proper Name: COAGULATION FACTOR XIII A-SUBUNIT (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125398 / 0	1	12/23/2013	2000 - 3125 IU (2000 - 3125 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646**

Trade Name:

Proper Name: ALBUMIN (HUMAN) 20%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125154 / 0	4	10/17/2006	10 GM/50 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125154 / 0	5	10/17/2006	20 GM/100 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE

Proper Name: ALBUMIN (HUMAN) 25%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125154 / 0	6	10/17/2006	12.5 GM/50 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125154 / 0	7	10/17/2006	25 GM/100 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE

Proper Name: ALBUMIN (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125154 / 0	1	10/17/2006	5 GM/100 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125154 / 0	2	10/17/2006	12.5 GM/250 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125154 / 0	3	10/17/2006	25 GM/500 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE

Trade Name: BALFAXAR

Proper Name: PROTHROMBIN COMPLEX CONCENTRATE, HUMAN-LANS

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

Applicant/License No: OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646

125776 / 0	1	7/21/2023	500 IU/ 20 ML (25 IU/ML) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125776 / 0	2	7/21/2023	1000 IU/ 40 ML (25 IU/ML) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: CUTAQUIG
Proper Name: IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN)-HIPP 16.5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125668 / 0	1	12/12/2018	1 GM/6 ML (0.165 GM/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125668 / 0	2	12/12/2018	1.65 GM/10 ML (0.165 GM/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125668 / 0	3	12/12/2018	2 GM/12 ML (0.165 GM/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125668 / 0	4	12/12/2018	3.3 GM/20 ML (0.165 GM/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125668 / 0	5	12/12/2018	4 GM/24 ML (0.165 GM/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125668 / 0	6	12/12/2018	8 GM/48 ML (0.165 GM/ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: FIBRYGA
Proper Name: FIBRINOGEN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125612 / 0	1	6/7/2017	1 GM (1 GM/BOTTLE) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE

Applicant/License No: OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646

125612 / 0	2	6/23/2025	2 GM (2 GM/BOTTLE) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE

Trade Name: NUWIQ
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125555 / 0	1	9/4/2015	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125555 / 0	2	9/4/2015	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125555 / 0	3	9/4/2015	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125555 / 0	4	9/4/2015	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125555 / 55	5	7/7/2017	2500 IU (2500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125555 / 55	6	7/7/2017	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125555 / 55	7	7/7/2017	4000 IU (4000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125555 / 0	8	12/7/2021	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: OCTAGAM
Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%

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

Applicant/License No: OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646

125062 / 0	6	7/11/2014	2 GM/20 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125062 / 0	7	7/11/2014	5 GM/50 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125062 / 0	8	7/11/2014	10 GM/100 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125062 / 0	9	7/11/2014	20 GM/200 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125062 / 572	10	11/30/2018	30 GM/300 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE

Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125062 / 0	1	5/21/2004	1 GM/20 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125062 / 0	2	5/21/2004	2.5 GM/50 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125062 / 0	3	5/21/2004	5 GM/100 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125062 / 0	4	5/21/2004	10 GM/200 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125062 / 0	5	5/21/2004	25 GM/500 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE

Trade Name: OCTAPLAS
Proper Name: POOLED PLASMA (HUMAN), SOLVENT/DETERGENT TREATED

Applicant/License No: OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125416 / 0	1	1/17/2013	9000-14000 MG/200 ML (45-70 MG/ML) SOLUTION / INTRAVENOUS / PLASTIC CONTAINER

Trade Name: PANZYGA
Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN)-IFAS

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125587 / 0	1	8/2/2018	1 GM/10 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125587 / 0	2	8/2/2018	2.5 GM/25 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125587 / 0	3	8/2/2018	5 GM/50 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125587 / 0	4	8/2/2018	10 GM/100 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125587 / 0	5	8/2/2018	20 GM/200 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
125587 / 0	6	8/2/2018	30 GM/300 ML (100 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE

Trade Name: WILATE
Proper Name: VON WILLEBRAND FACTOR/COAGULATION FACTOR VIII COMPLEX (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125251 / 22	1	12/4/2009	500 IU/500 IU (500 IU/500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125251 / 22	2	12/4/2009	1000 IU/1000 IU (1000 IU/1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: **OMRIX BIOPHARMACEUTICALS LTD / 1603**

Trade Name: EVITHROM
Proper Name: THROMBIN, TOPICAL (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125247 / 89	4	9/17/2009	1600-2400 IU (1600-2400 IU/VIAL) POWDER / TOPICAL / SINGLE-DOSE VIAL

Applicant/License No: **ORCA BIOSYSTEMS INC / 2404**

Trade Name: TREGZI
Proper Name: ALLOGENEIC REGULATORY T CELL IMMUNOTHERAPY WITH HSPC AND T CELLS-VLDQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125868 / 0	1	6/30/2026	1.0 X 10^6 HSPC CELLS, 0.9-3.5 X 10^6 TREG CELLS, 0.9-6.9 X 10^6 TCON CELLS /PATIENT KG (1.0 X 10^6 HSPC CELLS, 0.9-3.5 X 10^6 TREG SUSPENSION / INTRAVENOUS / PLASTIC CONTAINER

Applicant/License No: **ORCHARD THERAPEUTICS EUROPE LTD / 2263**

Trade Name: LENMELDY
Proper Name: ATIDARSAGENE AUTOTEMCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125758 / 0	1	3/18/2024	10-20 ML/BAG (2 TO 11.8 X 10^6 CELLS/ML (1.8 TO 11.8 X 10^6CD34+ CELLS/ML)) SUSPENSION / INTRAVENOUS / FLEXIBLE CONTAINER CLOSURE SYSTEM

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

Trade Name:
Proper Name: ANTIVENIN (MICRURUS FULVIUS)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101099 / 0	1	8/28/1967	10 ML (10 ML/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ABRYSVO
Proper Name: RESPIRATORY SYNCYTIAL VIRUS VACCINE

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

Applicant/License No: PFIZER INC / 2001

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125769 / 0	1	5/31/2023	0.5 ML/VIAL (0.5 ML/VIAL) SOLUTION / INTRAMUSCULAR / KIT

Applicant/License No: PFIZER IRELAND PHARMACEUTICALS / 2060

Trade Name: PENBRAYA
Proper Name: MENINGOCOCCAL GROUPS A B C W AND Y VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125770 / 0	1	10/20/2023	0.5 ML/DOSE (0.5 ML/DOSE) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: TICOVAC
Proper Name: TICK-BORNE ENCEPHALITIS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125740 / 0	1	8/13/2021	1.2MCG/0.25ML (1.2MCG/0.25ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
125740 / 0	2	8/13/2021	2.4MCG/0.5ML (2.4MCG/0.5ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: PHARMACIA AND UPJOHN CO / 1216

Trade Name: ATGAM
Proper Name: LYMPHOCYTE IMMUNE GLOBULIN, ANTI-THYMOCYTE GLOBULIN (EQUINE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103676 / 0	1	12/4/1996	250 MG/5 ML (50 MG/ML) SOLUTION / INTRAVENOUS / AMPULE

Applicant/License No: PHARMING AMERICAS BV / 2079

Trade Name: RUCONEST
Proper Name: C1 ESTERASE INHIBITOR (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125495 / 0	1	7/16/2014	2100 IU (2100 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: PRECIGEN INC / 2364

Trade Name: PAPZIMEOS
Proper Name: ZOPAPOGENE IMADENOVEC-DRBA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125832 / 0	1	8/14/2025	5 X 10^11 PARTICLE UNITS (PU)/1 ML DOSE (5 X 10^11 PARTICLE UNITS (PU)/1 ML DOSE) SUSPENSION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: PROTEIN SCIENCES CORP / 1795

Trade Name: FLUBLOK
Proper Name: INFLUENZA VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125285 / 0	1	1/16/2013	135 MCG HA/0.5 ML (135 MCG HA/0.5 ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: FLUBLOK QUADRIVALENT
Proper Name: INFLUENZA VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125285 / 194	2	10/7/2016	180 MCG HA/0.5 ML (180 MCG HA/0.5 ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: **PTC THERAPEUTICS INC / 2168**

Trade Name: KEBILIDI
Proper Name: ELADOCAGENE EXUPARVOVEC-TNEQ

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125722 / 0	1	11/13/2024	5.6 x 10^11 VG/ML (5.6 x 10^11 VG/ML) SUSPENSION / INTRAPUTAMINAL / SINGLE-DOSE VIAL

Applicant/License No: **RARE DISEASE THERAPEUTICS INC / 1860**

Trade Name: ANASCORP
Proper Name: CENTRUROIDES (SCORPION) IMMUNE F (AB') 2(EQUINE) INJECTION

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125335 / 0	1	8/3/2011	35MG (NO MORE THAN 35MG TOTAL PROTEIN PER VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ANAVIP
Proper Name: CROTALIDAE IMMUNE F(AB')2 (EQUINE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125488 / 0	1	5/6/2015	120 MG (120 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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

Trade Name: PANHEMATIN
Proper Name: HEMIN FOR INJECTION

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101246 / 0	1	7/29/2016	313 MG-350 MG/VIAL (313 MG-350 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: REGENERON PHARMACEUTICALS INC / 1760

Trade Name: OTARMENI
Proper Name: LUNSOTOGENE PARVEC-CWHA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125874 / 0	1	4/23/2026	3.0 X 10^13 VG/ML (3.0 X 10^13 VG/ML) SUSPENSION / INTRACOCHLEAR / SINGLE-DOSE VIAL

Applicant/License No: REPLIMUNE INC / 2360

Trade Name: TUDRIQEV
Proper Name: vusolimogene oderparepvec-wtpg

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125827 /	1	8/6/2026	10^6 PFU/mL and 10^7 PFU/mL (10^6 PFU/mL and 10^7 PFU/mL) SUSPENSION / INTRATUMOR / SINGLE-DOSE VIAL

Applicant/License No: ROCKET PHARMACEUTICALS INC / 2328

Trade Name: KRESLADI
Proper Name: MARNETEGRAGENE AUTOTEMCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125806 / 0	1	3/26/2026	30 ML/BAG (0.34 TO 6.1 × 10^6 CELLS/ML (INCLUDING 0.32 TO 6.1 × 10^6 CD34+ CELLS/ML)) SUSPENSION / INTRAVENOUS / PLASTIC CONTAINER

Applicant/License No: SALVAGENIX INC / 2424

Trade Name: DIGIFAB
Proper Name: DIGOXIN IMMUNE FAB (OVINE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103910 / 0	1	8/31/2001	40 MG (40 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: SANOFI VACCINES CANADA LTD / 1726

Trade Name: ADACEL

Proper Name: TETANUS TOXOID & REDUCED DIPHTHERIA TOXOID & ACELLULAR PERTUSSIS VACCINE, ADSORBED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125111 / 0	1	6/10/2005	0.5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: DAPTACEL

Proper Name: DIPHTHERIA & TETANUS TOXOIDS & ACELLULAR PERTUSSIS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103666 / 0	1	5/14/2002	0.5 ML/DOSE (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: PENTACEL

Proper Name: DTAP INACTIVATED POLIOVIRUS & HAEMOPHILUS B CONJUGATE VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125145 / 0	1	6/20/2008	0.5 ML (0.5 ML/DOSE) POWDER & SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: QUADRACEL

Proper Name: DIPHTHERIA &TETANUS TOXOIDS & ACELLULAR PERTUSSIS ADSORBED & INACTIVATED POLIOVIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125525 / 0	1	1/25/2022	0.5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Trade Name: TENIVAC

Proper Name: TETANUS & DIPHTHERIA TOXOIDS ADSORBED FOR ADULT USE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103171 / 0	1	11/3/2003	5LF/2LF/0.5 ML (5LF/2LF/0.5 ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

Applicant/License No: SANOFI VACCINES US INC / 1725

Trade Name: DENGVAXIA
Proper Name: DENGUE TETRAVALENT VACCINE, LIVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125682 / 0	1	5/1/2019	0.5 ML (0.5 ML/VIAL) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: FLUZONE
Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103914 / 5240	4	12/9/1999	45 MCG/0.5ML (45 MCG/0.5ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL & PREFILLED SYRINGE

Trade Name: FLUZONE HD QUADRIVALENT
Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103914 / 6290	9	11/4/2019	240 MCG HA/0.7 ML (240 MCG HA/0.7 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: FLUZONE HIGH DOSE
Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103914 / 5240	1	12/23/2009	180 MCG HA/0.5 ML (180 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: FLUZONE QUADRIVALENT
Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103914 / 5574	8	6/7/2013	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL & PREFILLED SYRINGE

Trade Name: MENACTRA
Proper Name: MENINGOCOCCAL (GROUPS A, C, Y, AND W135) POLYSACCHARIDE DIPHTHERIA TOXOID CONJUGATE VACCINE

Applicant/License No: SANOFI VACCINES US INC / 1725

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125089 / 0	1	1/14/2005	48 MCG/0.5ML (48 MCG/0.5ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: MENQUADFI
Proper Name: MENINGOCOCCAL (GROUPS A, C, Y, W) CONJUGATE VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125701 / 0	1	4/23/2020	0.5 ML (0.5 ML/DOSE) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: NUVAXOVID
Proper Name: COVID-19 VACCINE, ADJUVANTED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125817 / 0	1	5/16/2025	0.5 ML (0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: YF-VAX
Proper Name: YELLOW FEVER VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103915 / 0	1	12/9/1999	NLT 4.74 LOG10 PFU (NLT 4.74 LOG10 PFU/0.5 ML) POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: SANOFI WINTHROP INDUSTRIE / 1724

Trade Name: ACTHIB
Proper Name: HAEMOPHILUS B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103935 / 0	1	2/4/2000	24 MCG (24 MCG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: IMOVAX RABIES
Proper Name: RABIES VACCINE

Applicant/License No: SANOFI WINTHROP INDUSTRIE / 1724

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103931 / 0	1	2/4/2000	(IM) 2.5 IU ((IM) 2.5 IU/ML) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL

Trade Name: IPOL
Proper Name: POLIOVIRUS VACCINE INACTIVATED (MONKEY KIDNEY CELL)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103930 / 0	1	2/4/2000	5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL

Trade Name: TYPHIM VI
Proper Name: TYPHOID VI POLYSACCHARIDE VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103936 / 0	1	2/4/2000	25 MCG/0.5 ML (25 MCG/0.5 ML) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: SAREPTA THERAPEUTICS INC / 2308

Trade Name: ELEVIDYS
Proper Name: DELANDISTROGENE MOXEPARVOVEC-ROKL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125781 / 0	1	6/22/2023	1.33 X 10^13 VG/ML (NLT 10 ML/VIAL) - 100 ML - 700 ML KIT (1.33 X 10^13 VG/ML (NLT 10 ML/VIAL)) SUSPENSION / INTRAVENOUS / KIT

Applicant/License No: SEQIRUS INC / 2049

Trade Name: FLUAD
Proper Name: INFLUENZA VACCINE, ADJUVANTED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125510 / 0	1	11/24/2015	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: FLUCELVAX

Applicant/License No: **SEQIRUS INC / 2049**

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125408 / 0	3	11/20/2012	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: **SPARK THERAPEUTICS INC / 2056**

Trade Name: LUXTURNA

Proper Name: VORETIGENE NEPARVOVEC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125610 / 0	1	12/19/2017	2.5 TRILLION VG/0.5 ML (2.5 TRILLION VG/0.5 ML) SUSPENSION / INTRAOCULAR / SINGLE-DOSE VIAL

Applicant/License No: **SUMITOMO PHARMA AMERICA INC / 2368**

Trade Name: RETHYMIC

Proper Name: ALLOGENEIC PROCESSED THYMUS TISSUE–AGDC

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125685 / 0	1	10/8/2021	UP TO 42 SLICES (4 SLICES/5ML BOVINE SERUM) IMPLANTATION / IMPLANTATION / KIT

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

Trade Name: ADVATE

Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125063 / 0	1	7/25/2003	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125063 / 0	2	7/25/2003	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: TAKEDA PHARMACEUTICALS USA INC / 1898

125063 / 0	3	7/25/2003	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125063 / 0	4	7/25/2003	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125063 / 0	5	4/12/2006	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125063 / 0	6	7/3/2007	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125063 / 0	7	7/12/2012	4000 IU (4000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ADYNOVATE
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125566 / 0	1	11/13/2015	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125566 / 0	2	11/13/2015	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125566 / 0	3	11/13/2015	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125566 / 0	4	11/13/2015	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125566 / 0	5	10/25/2016	750 IU (750 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: TAKEDA PHARMACEUTICALS USA INC / 1898

125566 / 0	6	10/25/2016	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125566 / 0	7	3/13/2017	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ADZYNMA
Proper Name: ADAMTS13 RECOMBINANT KRHN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125795 / 0	1	11/9/2023	500 IU/VIAL (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125795 / 0	2	11/9/2023	1500 IU/VIAL (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: ARALAST
Proper Name: ALPHA-1-PROTEINASE INHIBITOR (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125039 / 0	1	12/23/2002	0.5 GM (0.5 GM/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125039 / 0	2	12/23/2002	1 GM (1 GM/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: CEPROTIN
Proper Name: PROTEIN C CONCENTRATE (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125234 / 0	1	3/30/2007	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125234 / 0	2	3/30/2007	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: CINRYZE

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

Proper Name: C1 ESTERASE INHIBITOR (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125267 / 0	1	10/10/2008	500 U (500 U/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: CUVITRU
Proper Name: IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN), 20%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125596 / 0	1	9/13/2016	1 GM/5 ML (20 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125596 / 0	2	9/13/2016	2 GM/10 ML (20 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125596 / 0	3	9/13/2016	4 GM/20 ML (20 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125596 / 0	4	9/13/2016	8 GM/40 ML (20 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125596 / 0	5	2/7/2019	10 GM/50 ML (20 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: FEIBA NF
Proper Name: ANTI-INHIBITOR COAGULANT COMPLEX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101447 / 5352	1	12/21/1979	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
101447 / 5352	2	12/21/1979	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: TAKEDA PHARMACEUTICALS USA INC / 1898

101447 / 5352	5	8/11/2005	2500 IU (2500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: FLEXBUMIN
Proper Name: ALBUMIN (HUMAN) 20%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101452 / 0	2	3/3/1954	10 GM/50 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / PLASTIC CONTAINER
101452 / 0	3	3/3/1954	20 GM/100 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / PLASTIC CONTAINER

Proper Name: ALBUMIN (HUMAN) 25%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101452 / 0	4	3/3/1954	12.5 GM/50 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / PLASTIC CONTAINER
101452 / 0	5	3/3/1954	25 GM/100 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / PLASTIC CONTAINER

Proper Name: ALBUMIN (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101452 / 0	1	3/3/1954	12.5 GM/250 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / PLASTIC CONTAINER

Trade Name: GAMMAGARD LIQUID 10%
Proper Name: IMMUNE GLOBULIN INFUSION (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125105 / 0	1	4/27/2005	1000 MG/10 ML (100 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE

Applicant/License No: TAKEDA PHARMACEUTICALS USA INC / 1898

125105 / 0	2	4/27/2005	2500 MG/25 ML (100 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
125105 / 0	3	4/27/2005	5000 MG/50 ML (100 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
125105 / 0	4	4/27/2005	10000 MG/100 ML (100 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
125105 / 0	5	4/27/2005	20000 MG/200 ML (100 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
125105 / 0	6	4/27/2005	30000 MG/300 ML (100 MG/ML) SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE

Trade Name: GAMMAGARD S/D
Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103133 / 0	1	2/18/1986	5 GM (5 GM/VIAL) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE
103133 / 0	2	2/18/1986	10 GM (10 GM/VIAL) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE

Trade Name: GLASSIA
Proper Name: ALPHA-1-PROTEINASE INHIBITOR (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125325 / 0	1	7/1/2010	1 G/50 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
125325 / 0	2	2/27/2025	4 G/200 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: TAKEDA PHARMACEUTICALS USA INC / 1898

125325 / 0	3	2/27/2025	5 G/250 ML (20 MG/ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: HEMOFIL M
Proper Name: ANTIHEMOPHILIC FACTOR (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
101448 / 0	1	3/11/1966	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
101448 / 0	2	3/11/1966	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
101448 / 0	3	3/11/1966	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
101448 / 0	4	3/11/1966	1700 IU (1700 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: HYQVIA
Proper Name: IMMUNE GLOBULIN INFUSION (HUMAN), 10% WITH RECOMBINANT HUMAN HYALURONIDASE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125402 / 0	1	9/12/2014	2.5 GM/25 ML (10 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125402 / 0	2	9/12/2014	5 GM/50 ML (10 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125402 / 0	3	9/12/2014	10 GM/100 ML (10 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
125402 / 0	4	9/12/2014	20 GM/200 ML (10 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Applicant/License No: TAKEDA PHARMACEUTICALS USA INC / 1898

125402 / 0	5	9/12/2014	30 GM/300 ML (10 GM/100 ML) SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL

Trade Name: OBIZUR
Proper Name: ANTIHEMOPHILICA FACTOR (RECOMBINANT), PORCINE SEQUENCE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125512 / 0	1	10/23/2014	500 U (500 U/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: RECOMBINATE
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103375 / 0	1	12/10/1992	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103375 / 0	2	12/10/1992	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103375 / 0	3	12/10/1992	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103375 / 0	4	3/10/2010	1500 IU (1500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103375 / 0	5	3/10/2010	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: RIXUBIS
Proper Name: COAGULATION FACTOR IX (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125446 / 0	1	6/26/2013	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: TAKEDA PHARMACEUTICALS USA INC / 1898

125446 / 0	2	6/26/2013	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125446 / 0	3	6/26/2013	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125446 / 0	4	6/26/2013	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125446 / 0	5	6/26/2013	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: VONVENDI
Proper Name: VON WILLEBRAND FACTOR (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125577 / 0	1	12/8/2015	650 IU (650 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
125577 / 0	2	12/8/2015	1300 IU (1300 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: TEVA WOMENS HEALTH INC / 1804

Trade Name:
Proper Name: ADENOVIRUS TYPE 4 AND TYPE 7, LIVE, ORAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125296 / 0	1	3/16/2011	TYPE 4 AND TYPE 7, NFT 32000 TCI DOSES ( ) TABLET / ORAL / SINGLE-USE BOTTLE

Applicant/License No: ULTRAGENYX PHARMACEUTICAL INC / 2040

Trade Name: FAYUVI
Proper Name: rebisufligene etisparvovec-hopf

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125845 / 0	1	9/17/2026	1.0 x 10^13 vc/mL (1.0 x 10^13 vg/mL) SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL

Trade Name: GENGLYCOS
Proper Name: pariglasgene brecaparvovec-opnr

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125858 /	1	8/19/2026	(3.0 x 10^13 gc/mL) SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: US WORLDMEDS (USWM CT LLC) / 2416

Trade Name: TECELRA
Proper Name: AFAMITRESGENE AUTOLEUCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125789 / 0	1	8/1/2024	2.68 x 10^9 to 10 x 10^9 MAGE-A4 TCR positive T cells (2.68 x 10^9 to 10 x 10^9 MAGE-A4 TCR positive T cells) SUSPENSION / INTRAVENOUS / KIT

Applicant/License No: VALNEVA AUSTRIA GMBH / 1909

Trade Name: IXIARO
Proper Name: JAPANESE ENCEPHALITIS VIRUS VACCINE INACTIVATED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125280 / 1	1	3/30/2009	0.5 ML (0.25 OR 0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Applicant/License No: VERICEL CORPORATION / 2010

Trade Name: MACI

Proper Name: AUTOLOGOUS CULTURED CHONDROCYTES ON PORCINE COLLAGEN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125603 / 0	1	12/13/2016	500,000 CM2OT (500,000 CM2OT) CELLULAR SHEET / IMPLANTATION / SINGLE-USE BOTTLE

Applicant/License No: VERTEX PHARMACEUTICALS INC / 2279

Trade Name: CASGEVY

Proper Name: EXAGAMGLOGENE AUTOTEMCEL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125787 / 0	1	12/8/2023	4 to 13 × 10^6CD34+ CELLS/ML PER VIAL (4 to 13 × 10^6CD34+ CELLS/ML PER VIAL) SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: WYETH PHARMACEUTICALS INC / 0003

Trade Name: BENEFIX

Proper Name: COAGULATION FACTOR IX (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
103677 / 0	1	2/11/1997	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103677 / 0	2	2/11/1997	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103677 / 0	3	2/11/1997	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103677 / 0	4	3/21/2007	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
103677 / 0	5	11/23/2011	3000 IU (3000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant/License No: WYETH PHARMACEUTICALS INC / 0003

Trade Name: PREVNAR 20
Proper Name: 20 VALENT PNEUMOCOCCAL CONJUGATE VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125731 / 0	1	6/8/2021	0.5 ML/SYRINGE (0.5 ML/SYRINGE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: TRUMENBA
Proper Name: MENINGOCOCCAL GROUP B VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125549 / 0	1	10/29/2014	0.5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

Trade Name: XYNTHA, XYNTHA SOLOFUSE
Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation
125264 / 0	1	2/21/2008	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125264 / 0	2	2/21/2008	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125264 / 0	3	2/21/2008	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125264 / 492	4	2/21/2008	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
125264 / 492	5	8/6/2010	3000 IU (3000 IU/SYRINGE) POWDER / INTRAVENOUS / PREFILLED SYRINGE

Applicant/License No: **ADMA BIOLOGICS INC / 2019**

Trade Name: NABI-HB

Proper Name: HEPATITIS B IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103945 / 0	1	10/23/2001	>312 IU/ML (>312 IU/ML) LIQUID / INTRAMUSCULAR / SINGLE-USE VIAL	8/30/2024

Applicant/License No: **BAXTER HEALTHCARE CORP / 0140**

Trade Name: ARTISS

Proper Name: FIBRIN SEALANT (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125266 / 0	2	3/19/2008	2 ML (2 ML KIT) POWDER / TOPICAL / SINGLE-DOSE VIAL	9/3/2014
125266 / 0	3	3/19/2008	4 ML (4 ML KIT) POWDER / TOPICAL / SINGLE-DOSE VIAL	9/3/2014
125266 / 0	4	3/19/2008	10 ML (10 ML KIT) POWDER / TOPICAL / SINGLE-DOSE VIAL	9/3/2014

Applicant/License No: **BIO PRODUCTS LABORATORY LIMITED / 1811**

Trade Name: GAMMAPLEX

Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125329 / 0	1	9/17/2009	2.5 GM/50 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE	10/30/2018
125329 / 0	2	9/17/2009	5 GM/100 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE	11/22/2024
125329 / 0	3	9/17/2009	10 GM/200 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE	11/22/2024

125329 / 0	4	9/17/2009	20 GM/400 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE	11/22/2024

Applicant/License No: BIONTECH MANUFACTURING GMBH / 2229

Trade Name: COMIRNATY

Proper Name: COVID-19 VACCINE, MRNA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125742 / 0	1	8/23/2021	0.45 ML/VIAL (0.3ML/DOSE) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	7/21/2025
125742 / 0	2	8/23/2023	0.432 ML/SYRINGE (0.3ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	7/21/2025
125742 / 0	3	12/16/2021	2.25 ML/VIAL (0.3ML/DOSE) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	1/22/2026
125742 / 0	4	8/22/2022	0.48 ML/VIAL (0.3 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL	1/22/2026

Applicant/License No: CASTLE CREEK BIOSCIENCES LLC / 1818

Trade Name: LAVIV

Proper Name: AZFICEL-T

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125348 / 0	1	6/21/2011	18 MU/1.2 ML (18 MU/1.2 ML) SUSPENSION / INTRADERMAL / SINGLE-DOSE VIAL	5/9/2017

Applicant/License No: CORZA MEDICAL GMBH / 2294

Trade Name: TACHOSIL

Proper Name: FIBRIN SEALANT PATCH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125351 / 0	1	4/5/2010	3.0 CM X 2.5 CM (55.5 MG/20.3 UNITS) (3.0 CM X 2.5 CM (55.5 MG/20.3 UNITS)) PATCH / TOPICAL / PACKET	6/14/2018

Applicant/License No: **EMERGENT BIODEFENSE OPERATIONS LANSING LLC / 1755**

Trade Name: BIORAB

Proper Name: RABIES VACCINE ADSORBED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103820 / 0	1	11/12/1998	1.0 ML (1.0 ML/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007

Applicant/License No: **ETHICON INC / 1879**

Trade Name: EVARREST

Proper Name: FIBRIN SEALANT PATCH

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125392 / 0	2	5/16/2013	55.5MG PER SQUARE INCH HUMAN FIBRINOGEN AND 241.9 UNITS PER SQUARE PATCH / TOPICAL / PACKET	5/14/2024
125392 / 0	3	12/5/2012	50.3MG PER SQUARE INCH HUMAN FIBRINOGEN AND 203.2 UNITS PER SQUARE PATCH / TOPICAL / PACKET	5/14/2024

Applicant/License No: **GLAXOSMITHKLINE BIOLOGICALS SA / 1617**

Trade Name: CERVARIX

Proper Name: HUMAN PAPILLOMAVIRUS BIVALENT (TYPES 16 AND 18) VACCINE, RECOMBINANT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125259 / 0	1	10/16/2009	0.5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	5/29/2025

Trade Name: FLUARIX QUADRIVALENT

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125127 / 513	2	12/14/2012	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	6/30/2025

Trade Name: HIBERIX

Proper Name: HAEMOPHILUS B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125347 / 0	1	8/19/2009	25 MCG (25 MCG/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	9/24/2025

Trade Name: ROTARIX

Proper Name: ROTAVIRUS VACCINE, LIVE, ORAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125265 / 0	1	4/3/2008	1 ML (1 ML/DOSE) POWDER / ORAL / SINGLE-DOSE VIAL	9/29/2023
125265 / 0	3	11/4/2022	1.5 ML/DOSE (1.5 ML/DOSE) LIQUID / ORAL / SINGLE-DOSE TUBE	9/29/2023

Applicant/License No: GREER LABORATORIES INC / 0308

Trade Name:

Proper Name: PLAGUE VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103569 / 0	1	10/5/1994	2 BIL. CELL/ML (2 BIL. CELL/ML) SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007

Applicant/License No: GRIFOLS BIOLOGICALS LLC / 1694

Trade Name: ALBUTEIN

Proper Name: ALBUMIN (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
102478 / 0	9	11/29/2022	5 GM/100 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / FLEXIBLE CONTAINER CLOSURE SYSTEM	12/2/2024

Trade Name: ALPHANINE SD

Proper Name: COAGULATION FACTOR IX (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103249 / 0	4	12/31/1990	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/24/2008

Applicant/License No: GRIFOLS THERAPEUTICS LLC / 1871

Trade Name: PLASMANATE

Proper Name: PLASMA PROTEIN FRACTION (HUMAN), USP

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
101140 / 0	1	10/2/1958	2.5 GM/50 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	5/15/2025
101140 / 0	3	10/2/1958	25 GM/500 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	5/15/2025

Trade Name: PROLASTIN-C

Proper Name: ALPHA-1-PROTEINASE INHIBITOR (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103174 / 0	2	12/2/1987	500 MG (500 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	3/23/2011

Applicant/License No: ID BIOMEDICAL CORPORATION QUEBEC / 1739

Trade Name:

Proper Name: INFLUENZA A (H5N1) VIRUS MONOVALENT VACCINE, ADJUVANTED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125419 / 0	1	11/22/2013	0.5 ML/VIAL (0.5 ML/VIAL) EMULSION / INTRAMUSCULAR / SINGLE-DOSE VIAL	7/8/2015

Trade Name: FLULAVAL QUADRIVALENT

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125163 / 279	2	9/27/2013	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	6/30/2025
125163 / 253	4	8/15/2013	600 MCG HA/5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	6/9/2023

Trade Name: INFLUENZA A (H1N1) 2009 MONOVALENT

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125163 / 135	3	10/5/2006	15 MCG/0.5 ML (15 MCG/0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	12/15/2010

Applicant/License No: **INSTITUTO GRIFOLS SA / 1181**

Trade Name: FLEBOGAMMA DIF

Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125077 / 146	2	12/15/2003	5 GM/50 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	7/9/2024
125077 / 146	3	12/15/2003	10 GM/100 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	7/9/2024
125077 / 146	4	12/15/2003	20 GM/200 ML (10 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	7/9/2024

Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125077 / 0	5	12/15/2003	0.5 GM/10 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	7/9/2024
125077 / 0	6	12/15/2003	2.5 GM/50 ML (5 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	7/9/2024

Trade Name: HUMAN ALBUMIN GRIFOLS

Proper Name: ALBUMIN (HUMAN) 20%

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103352 / 0	1	2/17/1995	10 GM/50 ML (20 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	2/12/2024

Proper Name: ALBUMIN (HUMAN) 25%

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

103352 / 0	3	2/17/1995	12.5 GM/50 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	2/12/2024
103352 / 0	4	2/17/1995	25 GM/100 ML (25 GM/100 ML) SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	2/12/2024

Applicant/License No: KAMADA LTD / 1826

Trade Name: VARIZIG

Proper Name: VARICELLA ZOSTER IMMUNE GLOBLIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125430 / 0	2	12/2/2012	125 IU/VIAL (125 IU/VIAL) POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/5/2015

Trade Name: WINRHO SDF

Proper Name: RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103649 / 0	1	4/2/1996	600 IU/VIAL (600 IU/VIAL) POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
103649 / 0	2	4/2/1996	1500 IU/VIAL (1500 IU/VIAL) POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
103649 / 0	3	4/2/1996	5000 IU/VIAL (5000 IU/VIAL) POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007

Proper Name: RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103649 / 0	4	4/2/1996	600 IU/VIAL (600 IU/VIAL) SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	9/14/2023
103649 / 0	6	4/2/1996	2500 IU/VIAL (2500 IU/VIAL) SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	4/3/2024

103649 / 0	7	4/2/1996	5000 IU/VIAL (5000 IU/VIAL) SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	6/1/2025
103649 / 0	8	4/2/1996	15000 IU/VIAL (15000 IU/VIAL) SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	5/16/2024

Applicant/License No: KEDRION BIOPHARMA INC / 1906

Trade Name: MICRHOGAM

Proper Name: RHO(D) IMMUNE GLOBULIN (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103777 / 0	1	4/23/1998	50 MCG/SYRINGE (50 MCG/SYRINGE) SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE	9/5/2023

Applicant/License No: LABORATOIRE FRANCAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES SA / 206

Trade Name: SEVENFACT

Proper Name: COAGULATION FACTOR VIIA (RECOMBINANT)-JNCW

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125641 / 0	3	6/20/2024	2 MG (2 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/30/2026

Applicant/License No: MASSBIOLOGICS / 1779

Trade Name: TDVAX

Proper Name: TETANUS AND DIPHTHERIA TOXOIDS ADSORBED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
101322 / 0	1	7/27/1970	0.5 ML/DOSE (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL	2/15/2024

Applicant/License No: MEDEXUS PHARMA INC / 2220

Trade Name: IXINITY

Proper Name: COAGULATION FACTOR IX (RECOMBINANT)

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

125426 / 0	1	12/21/2015	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	6/13/2024
125426 / 0	2	4/29/2015	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	5/5/2026
125426 / 0	5	12/21/2015	2000 IU (2000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	6/13/2024

Applicant/License No: MEDIMMUNE LLC / 1799

Trade Name:

Proper Name: INFLUENZA A (H1N1) 2009 MONOVALENT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125020 / 1215	3	9/15/2009	1 X 10 (6.5-7.5) FU/0.2ML (1 X 10 (6.5-7.5) FU/0.2ML) SPRAY / INTRANASAL / PREFILLED SPRAYER	9/24/2010

Trade Name: FLUMIST QUAD

Proper Name: INFLUENZA VIRUS VACCINE LIVE, INTRANASAL

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125020 / 1668	1	2/29/2012	0.2 ML (0.2 ML/SPRAY) SUSPENSION / INTRANASAL / PREFILLED SPRAYER	8/27/2025

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

Trade Name: GARDASIL

Proper Name: HUMAN PAPILLOMAVIRUS QUADRIVALENT (TYPES 6, 11, 16, 18) VACCINE (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125126 / 0	1	6/8/2006	0.5 ML (0.5 ML/DOSE) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE	4/6/2016

Trade Name: PNEUMOVAX 23

Proper Name: PNEUMOCOCCAL VACCINE, POLYVALENT

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

101094 / 0	1	11/21/1977	2.5 ML (0.5 ML/DOSE)	6/19/2020
			SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL	

Trade Name: ZOSTAVAX

Proper Name: ZOSTER VACCINE LIVE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125123 / 0	1	5/25/2006	0.65 ML (0.65 ML/VIAL)	6/24/2020
			POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	

Applicant/License No: **MODERNATX INC / 2256**

Trade Name: SPIKEVAX

Proper Name: COVID-19 VACCINE, MRNA

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125752 / 0	1	1/31/2022	5.5 ML (0.5 ML/DOSE)	9/21/2023
			SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	
125752 / 0	2	1/31/2022	7.5 ML (0.5 ML/DOSE)	9/21/2023
			SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	
125752 / 0	4	9/11/2023	0.5 ML/DOSE (0.5 ML/DOSE)	12/2/2024
			SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL	
125752 / 0	5	9/11/2023	2.5 ML (0.5 ML/DOSE)	12/2/2024
			SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	

Applicant/License No: **NIELSEN BIOSCIENCES INC / 1903**

Trade Name:

Proper Name: POSITIVE SKIN TEST CONTROL-HISTAMINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103317 / 0	1	2/14/1992	1.8 MG/ML (1.8 MG/ML)	10/1/2007
			/ INTRAEPIDERMAL /	

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

Trade Name: NOVOSEVEN

Proper Name: COAGULATION FACTOR VIIA (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103665 / 0	5	3/25/1999	1.2 MG (1.2 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/14/2011
103665 / 0	6	3/25/1999	2.4 MG (2.4 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/14/2011
103665 / 0	7	3/25/1999	4.8 MG (4.8 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/14/2011

Applicant/License No: OMRIX BIOPHARMACEUTICALS LTD / 1603

Trade Name: EVITHROM

Proper Name: THROMBIN, TOPICAL (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125247 / 0	1	8/27/2007	1600-2400 IU/2 ML (800-1,200 IU/ML) SOLUTION / TOPICAL / SINGLE-DOSE VIAL	12/22/2021
125247 / 0	2	8/27/2007	4000-6000 IU/5 ML (800-1200 IU/ML) SOLUTION / TOPICAL / SINGLE-DOSE VIAL	9/29/2020
125247 / 0	3	8/27/2007	16,000-24,000 IU/20 ML (800-1200 IU/ML) SOLUTION / TOPICAL / SINGLE-DOSE VIAL	9/29/2020

Applicant/License No: ORGANOGENESIS INC / 1863

Trade Name: GINTUIT

Proper Name: ALLOGENEIC CULTURED KERATINOCYTES AND FIBROBLASTS IN BOVINE COLLAGEN

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125400 / 0	1	3/9/2012	>0.000001 MCG/ML (>0.000001 MCG/ML) CELLULAR SHEET / TOPICAL /	9/3/2014

Applicant/License No: SANOFI VACCINES CANADA LTD / 1726

Trade Name: POLIOVAX

Proper Name: POLIOVIRUS VACCINE INACTIVATED (HUMAN DIPLOID CELL)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103940 / 0	1	2/24/2000	0.5ML/VIAL (0.5ML/VIAL) SUSPENSION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL	9/14/2011

Applicant/License No: **SANOFI VACCINES US INC / 1725**

Trade Name:

Proper Name: INFLUENZA A (H1N1) 2009 MONOVALENT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103914 / 5260	6	9/15/2009	15 MCG/0.5 ML (15 MCG/0.5 ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL, MULTI-DOSE VIAL & PREFILLED SYRINGE	9/24/2010

Proper Name: INFLUENZA VIRUS VACCINE, H5N1

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125244 / 0	1	4/17/2007	90 MCG/0.5ML (90 MCG/0.5ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	9/14/2011

Trade Name: FLUZONE INTRADERMAL

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103914 / 5369	5	5/9/2011	27 MCG/0.1ML (27 MCG/0.1ML) SUSPENSION / INTRADERMAL / PREFILLED PEN	9/26/2016

Trade Name: FLUZONE QUADRIVALENT

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103914 / 5574	2	6/7/2013	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE	6/12/2023
103914 / 5733	7	12/11/2014	30 MCG HA/0.25 ML (30 MCG HA/0.25 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	7/15/2021

Trade Name: FLUZONE QUADRIVALENT INTRADERMAL

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103914 / 5733	3	12/11/2014	36 MCG HA/0.1 ML (36 MCG HA/0.1 ML) SUSPENSION / INTRADERMAL / PREFILLED SYRINGE	9/29/2017

Trade Name: YF-VAX

Proper Name: YELLOW FEVER VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103915 / 0	2	12/9/1999	NLT 23.7 LOG10 PFU (NLT 23.7 LOG10 PFU/0.5 ML) POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL	8/13/2019

Applicant/License No: SANOFI WINTHROP INDUSTRIE / 1724

Trade Name: TYPHIM VI

Proper Name: TYPHOID VI POLYSACCHARIDE VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103936 / 0	2	2/4/2000	500 MCG/10 ML (25 MCG/0.5 ML) SOLUTION / INTRAMUSCULAR / MULTI-DOSE VIAL	4/1/2026

Applicant/License No: SEQIRUS INC / 2049

Trade Name: AGRIFLU

Proper Name: INFLUENZA VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125297 / 0	1	11/27/2009	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	6/14/2018

Trade Name: AUDENZ

Proper Name: INFLUENZA A (H5N1) MONOVALENT VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125692 / 0	2	1/31/2020	0.5ML/DOSE (0.5ML/DOSE) EMULSION / INTRAMUSCULAR / MULTI-DOSE VIAL	5/11/2020

Proper Name: INFLUENZA A (H5N1) MONOVALENT VACCINE, ADJUVANTED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125692 / 0	1	1/31/2020	0.5 ML/DOSE (0.5 ML/DOSE) EMULSION / INTRAMUSCULAR / PREFILLED SYRINGE	5/11/2020

Trade Name: FLUAD QUADRIVALENT

Proper Name: INFLUENZA VACCINE, ADJUVANTED

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125510 / 143	2	2/21/2020	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	7/16/2024

Trade Name: FLUCELVAX

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125408 / 0	4	3/4/2024	450 MCG HA/5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	6/30/2026

Trade Name: FLUCELVAX QUADRIVALENT

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125408 / 0	1	3/3/2017	600 MCG HA/5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	6/30/2024
125408 / 0	2	5/23/2016	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	6/30/2024

Applicant/License No: SEQIRUS PTY LTD / 2044

Trade Name:

Proper Name: INFLUENZA A (H1N1) 2009 MONOVALENT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125254 / 0	5	9/15/2009	75 MCG (15 MCG /0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	9/24/2010

Trade Name: AFLURIA

Proper Name: INFLUENZA VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125254 / 0	1	9/28/2007	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	6/30/2026
125254 / 0	7	9/28/2007	225 MCG (225 MCG) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	6/30/2026

Trade Name: AFLURIA QUADRIVALENT

Proper Name: INFLUENZA VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125254 / 565	2	8/26/2016	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	7/16/2024
125254 / 565	4	8/26/2016	600 MCG HA/5 ML (60 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	7/16/2024
125254 / 692	6	10/4/2018	30 MCG HA/0.25 ML (30 MCG HA/0.25 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	5/11/2023

Trade Name: AFLURIA TRIVALENT

Proper Name: INFLUENZA VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125254 / 0	3	9/28/2007	450 MCG HA/5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	6/30/2026

Applicant/License No: **SEQIRUS VACCINES LIMITED / 2055**

Trade Name:

Proper Name: INFLUENZA A (H1N1) 2009 MONOVALENT

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103837 / 0	2	9/15/2009	15 MCG/0.5 ML (15 MCG/0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL & PREFILLED SYRINGE	9/24/2010

Trade Name: FLUVIRIN

Proper Name: INFLUENZA VIRUS VACCINE

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103837 / 0	1	11/3/1998	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	6/14/2018
103837 / 0	3	9/15/2009	450 MCG HA/5 ML (45 MCG HA/0.5 ML) SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	6/14/2018

Applicant/License No: TAKEDA PHARMACEUTICALS USA INC / 1898

Trade Name: FEIBA VH

Proper Name: ANTI-INHIBITOR COAGULANT COMPLEX

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
101447 / 5352	3	12/21/1979	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	3/15/2012
101447 / 5352	4	12/21/1979	1000 IU (1000 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	3/15/2012

Trade Name: GAMMAGARD S/D

Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103133 / 0	3	2/18/1986	0.5 GM (0.5 GM VIAL) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/3/2014
103133 / 0	4	2/18/1986	2.5 GM (2.5 GM VIAL) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/3/2014

Trade Name: IVEEGAM EN

Proper Name: IMMUNE GLOBULIN INTRAVENOUS (HUMAN)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103133 / 0	5	2/18/1986	500 MG (500 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/24/2008

103133 / 0	6	2/18/1986	1000 MG (1000 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/24/2008
103133 / 0	7	2/18/1986	2500 MG (2500 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/24/2008
103133 / 0	8	2/18/1986	5000 MG (5000 MG/VIAL) POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/24/2008

Applicant/License No: **VBI VACCINES DELAWARE INC / 2219**

Trade Name: PREHEVBRIO

Proper Name: HEPATITIS B VACCINE (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
125737 / 0	1	11/30/2021	1ML/VIAL (1ML/VIAL) SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/28/2024

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

Trade Name: CARTICEL SM SERVICE

Proper Name: AUTOLOGOUS CULTURED CHONDROCYTES

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103661 / 0	1	8/22/1997	12 MIL CELLS (12 MIL CELLS/VIAL) IMPLANTATION / INTRAARTICULAR / SINGLE-DOSE VIAL	9/26/2017

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

Trade Name: REFACTO

Proper Name: ANTIHEMOPHILIC FACTOR (RECOMBINANT)

BLA#/STN	Product#	Approval Date	Total Drug Content (Concentration) Dosage Form/Route/Presentation	Date added to Discontinued List
103779 / 0	1	3/6/2000	250 IU (250 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	7/24/2012
103779 / 0	2	3/6/2000	500 IU (500 IU/VIAL) POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	7/24/2012

103779 / 0	3	3/6/2000	1000 IU (1000 IU/VIAL)	7/24/2012
			POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	
103779 / 0	4	3/6/2000	2000 IU (2000 IU/VIAL)	7/24/2012
			POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	