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 product correspondence to the respective product review office requesting the product be placed on CBER's Discontinued List. CBERPDUFAStaff@fda.hhs.gov should be copied on all discontinuation requests.

The potency information contained in this list is based on current information in CBER's regulatory database. Applicants are responsible for alerting CBER to any discrepancies regarding potency or proprietary name information. Any such discrepancies should be reported to CBER's PDUFA billing staff - **CBERPDUFAStaff@fda.hhs.gov**. This list is updated three times a year.

(Latest Update – November 2021)

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.

Applicant / License #	Proprietary Name	Proper Name	BLA#	Product #	Total Drug Content (Concentration)	Approval Date	Dosage Form/Route/Presentation
ADMA BIOLOGICS INC / 2019	ASCENIV	IMMUNE GLOBULIN INTRAVENOUS, HUMAN-SLRA 10%	125590 / 0	1	5000 MG/50 ML (100 MG/ML)	04/01/2019	SOLUTION / INTRAVENOUS / SINGLE-USE VIAL
ADMA BIOLOGICS INC / 2019	BIVIGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125389 / 0	1	10 GM/100 ML (10 GM/100 ML)	12/19/2012	SOLUTION / INTRAVENOUS / SINGLE-USE VIAL
ADMA BIOLOGICS INC / 2019	BIVIGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125389 / 0	2	5 GM/50 ML (10 GM/100 ML)	12/19/2012	SOLUTION / INTRAVENOUS / SINGLE-USE VIAL
ADMA BIOLOGICS INC / 2019	NABI-HB	HEPATITIS B IMMUNE GLOBULIN (HUMAN)	103945 / 0	1	>312 IU/ML (>312 IU/ML)	10/23/2001	SOLUTION / INTRAMUSCULAR / SINGLE-USE VIAL
ADMA BIOLOGICS INC / 2019	NABI-HB	HEPATITIS B IMMUNE GLOBULIN (HUMAN)	103945 / 0	2	>1560 IU/5 ML (>312 IU/ML)	10/23/2001	SOLUTION / INTRAMUSCULAR / SINGLE-USE VIAL
ALK ABELLO INC / 1256	HISTATROL	POSITIVE SKIN TEST CONTROL - HISTAMINE	103754 / 0	1	1 MG/10 ML (0.1 MG/ML)	02/23/1998	SOLUTION / INTRADERMAL / MULTI-DOSE VIAL
ALK ABELLO INC / 1256	HISTATROL	POSITIVE SKIN TEST CONTROL - HISTAMINE	103754 / 0	2	5 MG/5 ML (1 MG/ML)	02/23/1998	SOLUTION / PERCUTANEOUS / MULTI-DOSE VIAL
AMGEN INC / 1080	IMLYGIC	TALIMOGENE IAHERPAREPVEC	125518 / 0	1	1 MILLION PFU/ML (1 MILLION PFU/ML)	10/27/2015	SUSPENSION / INTRALESIONAL / SINGLE-DOSE VIAL
AMGEN INC / 1080	IMLYGIC	TALIMOGENE IAHERPAREPVEC	125518 / 0	2	100 MILLION PFU/ML (100 MILLION PFU/ML)	10/27/2015	SUSPENSION / INTRALESIONAL / SINGLE-DOSE VIAL
BAVARIAN NORDIC AS / 2096	JYNNEOS	SMALLPOX AND MONKEYPOX VACCINE, LIVE, NONREPLICATING	125678 / 0	1	0.5 ML/DOSE (0.5 ML/DOSE)	09/24/2019	SUSPENSION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAVARIAN NORDIC AS / 2096	RABAVERT	RABIES VACCINE	103334 / 0	1	>2.5 U (>2.5 U/VIAL)	10/20/1997	POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125063 / 0	1	250 IU (250 IU/VIAL)	07/25/2003	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125063 / 0	2	500 IU (500 IU/VIAL)	07/25/2003	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125063 / 0	3	1000 IU (1000 IU/VIAL)	07/25/2003	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125063 / 0	4	1500 IU (1500 IU/VIAL)	07/25/2003	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125063 / 0	5	2000 IU (2000 IU/VIAL)	04/12/2006	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125063 / 0	6	3000 IU (3000 IU/VIAL)	07/03/2007	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125063 / 0	7	4000 IU (4000 IU/VIAL)	07/12/2012	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADYNOVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED	125566 / 0	1	250 IU (250 IU/VIAL)	11/13/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADYNOVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED	125566 / 0	2	500 IU (500 IU/VIAL)	11/13/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADYNOVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED	125566 / 0	3	1000 IU (1000 IU/VIAL)	11/13/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADYNOVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED	125566 / 0	4	2000 IU (2000 IU/VIAL)	11/13/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADYNOVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED	125566 / 104	5	750 IU (750 IU/VIAL)	10/25/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADYNOVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED	125566 / 104	6	1500 IU (1500 IU/VIAL)	10/25/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ADYNOVATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED	125566 / 152	7	3000 IU (3000 IU/VIAL)	03/13/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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BAXALTA US INC / 2020	ARALAST	ALPHA-1-PROTEINASE INHIBITOR (HUMAN)	125039 / 0	1	0.5 GM (0.5 GM/VIAL)	12/23/2002	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	ARALAST	ALPHA-1-PROTEINASE INHIBITOR (HUMAN)	125039 / 0	2	1 GM (1 GM/VIAL)	12/23/2002	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	CEPROTIN	PROTEIN C CONCENTRATE (HUMAN)	125234 / 0	1	500 IU (500 IU/VIAL)	03/30/2007	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	CEPROTIN	PROTEIN C CONCENTRATE (HUMAN)	125234 / 0	2	1000 IU (1000 IU/VIAL)	03/30/2007	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	CUVITRU	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN), 20%	125596 / 0	1	1 G/5 ML (20 G/100 ML)	09/13/2016	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	CUVITRU	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN), 20%	125596 / 0	2	2 GM/10 ML (20 GM/100 ML)	09/13/2016	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	CUVITRU	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN), 20%	125596 / 0	3	4 GM/20 ML (20 GM/100 ML)	09/13/2016	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	CUVITRU	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN), 20%	125596 / 0	4	8 GM/40 ML (20 GM/100 ML)	09/13/2016	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	CUVITRU	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN), 20%	125596 / 272	5	10 GM/50 ML (20 GM/100 ML)	02/07/2019	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	FEIBA NF	ANTI-INHIBITOR COAGULANT COMPLEX	101447 / 5352	1	500 IU (500 IU/VIAL)	12/21/1979	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	FEIBA NF	ANTI-INHIBITOR COAGULANT COMPLEX	101447 / 5352	2	1000 IU (1000 IU/VIAL)	12/21/1979	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	FEIBA NF	ANTI-INHIBITOR COAGULANT COMPLEX	101447 / 5352	5	2500 IU (2500 IU/VIAL)	08/11/2005	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	FLEXBUMIN	ALBUMIN (HUMAN) 20%	101452 / 0	2	10 GM/50 ML (20 GM/100 ML)	03/03/1954	SOLUTION / INTRAVENOUS / PLASTIC CONTAINER
BAXALTA US INC / 2020	FLEXBUMIN	ALBUMIN (HUMAN) 20%	101452 / 0	3	20 GM/100 ML (20 GM/100 ML)	03/03/1954	SOLUTION / INTRAVENOUS / PLASTIC CONTAINER
BAXALTA US INC / 2020	FLEXBUMIN	ALBUMIN (HUMAN) 25%	101452 / 0	4	12.5 GM/50 ML (25 GM/100 ML)	03/03/1954	SOLUTION / INTRAVENOUS / PLASTIC CONTAINER
BAXALTA US INC / 2020	FLEXBUMIN	ALBUMIN (HUMAN) 25%	101452 / 0	5	25 GM/100 ML (25 GM/100 ML)	03/03/1954	SOLUTION / INTRAVENOUS / PLASTIC CONTAINER
BAXALTA US INC / 2020	FLEXBUMIN	ALBUMIN (HUMAN) 5%	101452 / 0	1	12.5 GM/250 ML (5 GM/100 ML)	03/03/1954	SOLUTION / INTRAVENOUS / PLASTIC CONTAINER
BAXALTA US INC / 2020	GAMMAGARD LIQUID 10%	IMMUNE GLOBULIN INFUSION (HUMAN)	125105 / 0	1	1000 MG/10 ML (100 MG/ML)	04/27/2005	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
BAXALTA US INC / 2020	GAMMAGARD LIQUID 10%	IMMUNE GLOBULIN INFUSION (HUMAN)	125105 / 0	2	2500 MG/25 ML (100 MG/ML)	04/27/2005	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
BAXALTA US INC / 2020	GAMMAGARD LIQUID 10%	IMMUNE GLOBULIN INFUSION (HUMAN)	125105 / 0	3	5000 MG/50 ML (100 MG/ML)	04/27/2005	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
BAXALTA US INC / 2020	GAMMAGARD LIQUID 10%	IMMUNE GLOBULIN INFUSION (HUMAN)	125105 / 0	4	10000 MG/100 ML (100 MG/ML)	04/27/2005	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
BAXALTA US INC / 2020	GAMMAGARD LIQUID 10%	IMMUNE GLOBULIN INFUSION (HUMAN)	125105 / 0	5	20000 MG/200 ML (100 MG/ML)	04/27/2005	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
BAXALTA US INC / 2020	GAMMAGARD LIQUID 10%	IMMUNE GLOBULIN INFUSION (HUMAN)	125105 / 0	6	30000 MG/300 ML (100 MG/ML)	04/27/2005	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
BAXALTA US INC / 2020	GAMMAGARD S/D	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103133 / 0	1	5 GM (5 GM/VIAL)	02/18/1986	POWDER / INTRAVENOUS / SINGLE-USE BOTTLE
BAXALTA US INC / 2020	GAMMAGARD S/D	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103133 / 0	2	10 GM (10 GM/VIAL)	02/18/1986	POWDER / INTRAVENOUS / SINGLE-USE BOTTLE
BAXALTA US INC / 2020	HEMOFIL M	ANTIHEMOPHILIC FACTOR (HUMAN)	101448 / 0	1	250 IU (250 IU/VIAL)	03/11/1966	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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BAXALTA US INC / 2020	HEMOFIL M	ANTIHEMOPHILIC FACTOR (HUMAN)	101448 / 0	2	500 IU (500 IU/VIAL)	03/11/1966	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	HEMOFIL M	ANTIHEMOPHILIC FACTOR (HUMAN)	101448 / 0	3	1000 IU (1000 IU/VIAL)	03/11/1966	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	HEMOFIL M	ANTIHEMOPHILIC FACTOR (HUMAN)	101448 / 0	4	1700 IU (1700 IU/VIAL)	03/11/1966	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	HYQVIA	IMMUNE GLOBULIN INFUSION (HUMAN), 10% WITH RECOMBINANT HUMAN HYALURONIDASE	125402 / 0	1	2.5 GM/25 ML (10 GM/100 ML)	09/12/2014	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	HYQVIA	IMMUNE GLOBULIN INFUSION (HUMAN), 10% WITH RECOMBINANT HUMAN HYALURONIDASE	125402 / 0	2	5 GM/50 ML (10 GM/100 ML)	09/12/2014	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	HYQVIA	IMMUNE GLOBULIN INFUSION (HUMAN), 10% WITH RECOMBINANT HUMAN HYALURONIDASE	125402 / 0	3	10 GM/100 ML (10 GM/100 ML)	09/12/2014	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	HYQVIA	IMMUNE GLOBULIN INFUSION (HUMAN), 10% WITH RECOMBINANT HUMAN HYALURONIDASE	125402 / 0	4	20 GM/200 ML (10 GM/100 ML)	09/12/2014	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	HYQVIA	IMMUNE GLOBULIN INFUSION (HUMAN), 10% WITH RECOMBINANT HUMAN HYALURONIDASE	125402 / 0	5	30 GM/300 ML (10 GM/100 ML)	09/12/2014	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	OBIZUR	ANTIHEMOPHILICA FACTOR (RECOMBINANT), PORCINE SEQUENCE	125512 / 0	1	500 U (500 U/VIAL)	10/23/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RECOMBINATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103375 / 0	1	250 IU (250 IU/VIAL)	12/10/1992	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RECOMBINATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103375 / 0	2	500 IU (500 IU/VIAL)	12/10/1992	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RECOMBINATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103375 / 0	3	1000 IU (1000 IU/VIAL)	12/10/1992	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RECOMBINATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103375 / 0	4	1500 IU (1500 IU/VIAL)	12/10/1992	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RECOMBINATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103375 / 0	5	2000 IU (2000 IU/VIAL)	12/10/1992	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RIXUBIS	COAGULATION FACTOR IX (RECOMBINANT)	125446 / 0	1	250 IU (250 IU/VIAL)	06/26/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RIXUBIS	COAGULATION FACTOR IX (RECOMBINANT)	125446 / 0	2	500 IU (500 IU/VIAL)	06/26/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RIXUBIS	COAGULATION FACTOR IX (RECOMBINANT)	125446 / 0	3	1000 IU (1000 IU/VIAL)	06/26/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RIXUBIS	COAGULATION FACTOR IX (RECOMBINANT)	125446 / 0	4	2000 IU (2000 IU/VIAL)	06/26/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	RIXUBIS	COAGULATION FACTOR IX (RECOMBINANT)	125446 / 0	5	3000 IU (3000 IU/VIAL)	06/26/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	VONVENDI	VON WILLEBRAND FACTOR (RECOMBINANT)	125577 / 0	1	650 IU (650 IU/VIAL)	12/08/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXALTA US INC / 2020	VONVENDI	VON WILLEBRAND FACTOR (RECOMBINANT)	125577 / 0	2	1300 IU (1300 IU/VIAL)	12/08/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAXTER HEALTHCARE CORP / 0140	ARTISS	FIBRIN SEALANT (HUMAN)	125266 / 0	1	2 ML (2 ML)	03/19/2008	SOLUTION / TOPICAL / PREFILLED SYRINGE
BAXTER HEALTHCARE CORP / 0140	ARTISS	FIBRIN SEALANT (HUMAN)	125266 / 0	5	4 ML (4 ML)	03/19/2008	SOLUTION / TOPICAL / PREFILLED SYRINGE

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BAXTER HEALTHCARE CORP / 0140	ARTISS	FIBRIN SEALANT (HUMAN)	125266 / 0	6	10 ML (10 ML)	03/19/2008	SOLUTION / TOPICAL / PREFILLED SYRINGE
BAXTER HEALTHCARE CORP / 0140	RECOTHROM	THROMBIN TOPICAL (RECOMBINANT)	125248 / 0	1	5000 IU (5000 IU/VIAL)	01/17/2008	POWDER / TOPICAL / SINGLE-DOSE VIAL
BAXTER HEALTHCARE CORP / 0140	RECOTHROM	THROMBIN TOPICAL (RECOMBINANT)	125248 / 0	2	20000 IU (20000 IU/VIAL)	01/17/2008	POWDER / TOPICAL / SINGLE-DOSE VIAL
BAXTER HEALTHCARE CORP / 0140	TISSEEL	FIBRIN SEALANT	103980 / 0	5	2 ML (2 ML)	07/27/2006	SOLUTION / TOPICAL / PREFILLED SYRINGE
BAXTER HEALTHCARE CORP / 0140	TISSEEL	FIBRIN SEALANT	103980 / 0	6	10 ML (10 ML)	07/27/2006	SOLUTION / TOPICAL / PREFILLED SYRINGE
BAXTER HEALTHCARE CORP / 0140	TISSEEL	FIBRIN SEALANT	103980 / 5121	4	4 ML (4 ML)	07/27/2006	SOLUTION / TOPICAL / PREFILLED SYRINGE
BAXTER HEALTHCARE CORP / 0140	TISSEEL KIT	FIBRIN SEALANT	103980 / 1	1	2 ML (2 ML)	02/07/2000	POWDER / TOPICAL / SINGLE-DOSE VIAL
BAXTER HEALTHCARE CORP / 0140	TISSEEL KIT	FIBRIN SEALANT	103980 / 1	2	4 ML (4 ML)	02/07/2000	POWDER / TOPICAL / SINGLE-DOSE VIAL
BAXTER HEALTHCARE CORP / 0140	TISSEEL KIT	FIBRIN SEALANT	103980 / 1	3	10 ML (10 ML)	02/07/2000	POWDER / TOPICAL / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	JIVI	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED-AUCL	125661 / 0	2	500 IU (500 IU/VIAL)	08/29/2018	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	JIVI	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED-AUCL	125661 / 0	3	1000 IU (1000 IU/VIAL)	08/29/2018	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	JIVI	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED-AUCL	125661 / 0	4	2000 IU (2000 IU/VIAL)	08/29/2018	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	JIVI	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED-AUCL	125661 / 0	5	3000 IU (3000 IU/VIAL)	08/29/2018	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOGENATE FS	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103332 / 0	1	250 IU (250 IU/VIAL)	08/20/2002	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOGENATE FS	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103332 / 0	2	500 IU (500 IU/VIAL)	08/20/2002	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOGENATE FS	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103332 / 0	3	1000 IU (1000 IU/VIAL)	08/20/2002	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOGENATE FS	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103332 / 0	4	2000 IU (2000 IU/VIAL)	06/07/2007	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOGENATE FS	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103332 / 0	5	3000 IU (3000 IU/VIAL)	07/31/2009	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOVALTRY	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FULL LENGTH	125574 / 0	1	250 IU (250 IU/VIAL)	03/16/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOVALTRY	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FULL LENGTH	125574 / 0	2	500 IU (500 IU/VIAL)	03/16/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOVALTRY	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FULL LENGTH	125574 / 0	3	1000 IU (1000 IU/VIAL)	03/16/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOVALTRY	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FULL LENGTH	125574 / 0	4	2000 IU (2000 IU/VIAL)	03/16/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BAYER HEALTHCARE LLC / 0008	KOVALTRY	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FULL LENGTH	125574 / 0	5	3000 IU (3000 IU/VIAL)	03/16/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIO PRODUCTS LABORATORY / 1811	ALBUMINEX	ALBUMIN (HUMAN)-KJDA 25%	125644 / 0	3	12.5 GM/50 ML (25 GM/100 ML)	06/19/2018	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
BIO PRODUCTS LABORATORY / 1811	ALBUMINEX	ALBUMIN (HUMAN)-KJDA 25%	125644 / 0	4	25 GM/100 ML (25 GM/100 ML)	06/19/2018	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
BIO PRODUCTS LABORATORY / 1811	ALBUMINEX	ALBUMIN (HUMAN)-KJDA 5%	125644 / 0	1	12.5 GM/250 ML (5 GM/100 ML)	06/19/2018	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
BIO PRODUCTS LABORATORY / 1811	ALBUMINEX	ALBUMIN (HUMAN)-KJDA 5%	125644 / 0	2	25 GM/500 ML (5 GM/100 ML)	06/19/2018	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
BIO PRODUCTS LABORATORY / 1811	COAGADEX	COAGULATION FACTOR X (HUMAN)	125506 / 0	1	250 IU (250 IU/VIAL)	10/20/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIO PRODUCTS LABORATORY / 1811	COAGADEX	COAGULATION FACTOR X (HUMAN)	125506 / 0	2	500 IU (500 IU/VIAL)	10/20/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant / License #	Proprietary Name	Proper Name	BLA#	Product #	Total Drug Content (Concentration)	Approval Date	Dosage Form/Route/Presentation
BIO PRODUCTS LABORATORY / 1811	GAMMAPLEX	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125329 / 0	5	5 GM/50 ML (10 GM/100 ML)	02/06/2017	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
BIO PRODUCTS LABORATORY / 1811	GAMMAPLEX	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125329 / 0	6	10 GM/100 ML (10 GM/100 ML)	02/06/2017	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
BIO PRODUCTS LABORATORY / 1811	GAMMAPLEX	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125329 / 0	7	20 GM/200 ML (10 GM/100 ML)	02/06/2017	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
BIO PRODUCTS LABORATORY / 1811	GAMMAPLEX	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125329 / 0	2	5 GM/100 ML (5 GM/100 ML)	09/17/2009	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
BIO PRODUCTS LABORATORY / 1811	GAMMAPLEX	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125329 / 0	3	10 GM/200 ML (5 GM/100 ML)	09/17/2009	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
BIO PRODUCTS LABORATORY / 1811	GAMMAPLEX	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125329 / 0	4	20 GM/400 ML (5 GM/100 ML)	09/17/2009	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
BIONTECH MANUFACTURING GMBH / 2229	COMIRNATY	COVID-19 VACCINE MRNA	125742 / 0	1	1.8ML/VIAL (0.3ML/DOSE)	08/23/2021	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ALPROLIX	COAGULATION FACTOR IX (RECOMBINANT), FC FUSION PROTEIN	125444 / 0	1	250 IU (250 IU/VIAL)	02/18/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ALPROLIX	COAGULATION FACTOR IX (RECOMBINANT), FC FUSION PROTEIN	125444 / 0	2	500 IU (500 IU/VIAL)	03/28/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ALPROLIX	COAGULATION FACTOR IX (RECOMBINANT), FC FUSION PROTEIN	125444 / 0	3	1000 IU (1000 IU/VIAL)	03/28/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ALPROLIX	COAGULATION FACTOR IX (RECOMBINANT), FC FUSION PROTEIN	125444 / 0	4	2000 IU (2000 IU/VIAL)	03/28/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ALPROLIX	COAGULATION FACTOR IX (RECOMBINANT), FC FUSION PROTEIN	125444 / 0	5	3000 IU (3000 IU/VIAL)	03/28/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ALPROLIX	COAGULATION FACTOR IX (RECOMBINANT), FC FUSION PROTEIN	125444 / 286	6	4000 IU (4000 IU/VIAL)	07/14/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 0	1	250 IU (250 IU/VIAL)	06/06/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 0	2	500 IU (500 IU/VIAL)	06/06/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 0	3	750 IU (750 IU/VIAL)	06/06/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 0	4	1000 IU (1000 IU/VIAL)	06/06/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 0	5	1500 IU (1500 IU/VIAL)	06/06/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 0	6	2000 IU (2000 IU/VIAL)	06/06/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 0	7	3000 IU (3000 IU/VIAL)	06/06/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 450	8	4000 IU (4000 IU/VIAL)	01/27/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 450	9	5000 IU (5000 IU/VIAL)	01/27/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BIOVERATIV THERAPEUTICS INC / 2078	ELOCTATE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), FC FUSION PROTEIN	125487 / 450	10	6000 IU (6000 IU/VIAL)	01/27/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BTG INTERNATIONAL INC / 1861	CROFAB	CROTALIDAE POLYVALENT IMMUNE FAB (OVINE)	103788 / 0	1	1 GM (1 GM/VIAL)	10/02/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
BTG INTERNATIONAL INC / 1861	DIGIFAB	DIGOXIN IMMUNE FAB (OVINE)	103910 / 0	1	40 MG (40 MG/VIAL)	08/31/2001	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CALIFORNIA DEPARTMENT OF PUBLIC HEALTH / 1797	BABYBIG	BOTULISM IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	125034 / 0	1	100 MG (100 MG/VIAL)	10/23/2003	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CELGENE CORPORTION A BRISTOL MYERS SQUIBB COMPANY / 2252	ABECMA	IDECABTAGENE VICLEUCEL	125736 / 0	1	50 ML/BAG (300 TO 460 x10^6 CAR-POSITIVE T CELLS/1 OR MORE BAGS)	03/26/2021	SUSPENSION / INTRAVENOUS / KIT
CELGENE CORPORTION A BRISTOL MYERS SQUIBB COMPANY / 2252	ABECMA	IDECABTAGENE VICLEUCEL	125736 / 0	2	250 ML/BAG (300 TO 460 x10^6 CAR-POSITIVE T CELLS/1 OR MORE BAGS)	03/26/2021	SUSPENSION / INTRAVENOUS / KIT
CELGENE CORPORTION A BRISTOL MYERS SQUIBB COMPANY / 2252	ABECMA	IDECABTAGENE VICLEUCEL	125736 / 0	3	500 ML/BAG (300 TO 460 x10^6 CAR-POSITIVE T CELLS/1 OR MORE BAGS)	03/26/2021	SUSPENSION / INTRAVENOUS / KIT
CSL BEHRING AG / 1766	ALBURX	ALBUMIN (HUMAN) 25%	102366 / 0	3	12.5 GM/50 ML (25 GM/100 ML)	07/23/1976	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	ALBURX	ALBUMIN (HUMAN) 25%	102366 / 0	4	25 GM/100 ML (25 GM/100 ML)	07/23/1976	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	ALBURX	ALBUMIN (HUMAN) 5%	102366 / 0	1	12.5 GM/250 ML (5 GM/100 ML)	07/23/1976	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	ALBURX	ALBUMIN (HUMAN) 5%	102366 / 0	2	25 GM/500 ML (5 GM/100 ML)	07/23/1976	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	HIZENTRA	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% LIQUID	125350 / 0	1	1000 MG/5 ML (200 MG/ML)	03/04/2010	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	HIZENTRA	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% LIQUID	125350 / 0	2	2000 MG/10 ML (200 MG/ML)	03/04/2010	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	HIZENTRA	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% LIQUID	125350 / 0	3	4000 MG/20 ML (200 MG/ML)	03/04/2010	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	HIZENTRA	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% LIQUID	125350 / 0	4	10000 MG/50 ML (200 MG/ML)	03/04/2010	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	HIZENTRA	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% LIQUID	125350 / 913	5	1000 MG/5 ML (200 MG/ML)	03/27/2020	SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
CSL BEHRING AG / 1766	HIZENTRA	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% LIQUID	125350 / 913	6	2000 MG/10 ML (200 MG/ML)	03/27/2020	SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
CSL BEHRING AG / 1766	HIZENTRA	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% LIQUID	125350 / 913	7	4000 MG/20 ML (200 MG/ML)	03/27/2010	SOLUTION / SUBCUTANEOUS / PREFILLED SYRINGE
CSL BEHRING AG / 1766	PRIVIGEN	IMMUNE GLOBULIN INTRAVENOUS (HUMAN), 10% LIQUID	125201 / 0	1	2.5 GM/25 ML (10 GM/100 ML)	10/02/2009	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	PRIVIGEN	IMMUNE GLOBULIN INTRAVENOUS (HUMAN), 10% LIQUID	125201 / 0	2	5 GM/50 ML (10 GM/100 ML)	07/26/2007	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	PRIVIGEN	IMMUNE GLOBULIN INTRAVENOUS (HUMAN), 10% LIQUID	125201 / 0	3	10 GM/100 ML (10 GM/100 ML)	07/26/2007	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	PRIVIGEN	IMMUNE GLOBULIN INTRAVENOUS (HUMAN), 10% LIQUID	125201 / 0	4	20 GM/200 ML (10 GM/100 ML)	07/26/2007	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	PRIVIGEN	IMMUNE GLOBULIN INTRAVENOUS (HUMAN), 10% LIQUID	125201 / 0	5	40 GM/400 ML (10 GM/100 MG)	02/07/2013	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING AG / 1766	RHOPHYLAC	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	125070 / 0	1	300 MCG/2 ML (150 MCG/ML)	02/12/2004	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / PREFILLED SYRINGE
CSL BEHRING GMBH / 1765	BERINERT	C1 ESTERASE INHIBITOR (HUMAN)	125287 / 0	1	500 UNITS (500 UNITS/VIAL)	10/09/2009	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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CSL BEHRING GMBH / 1765	CORIFACT	FACTOR XIII CONCENTRATE (HUMAN)	125385 / 0	1	1000-1600 U (1000-1600 U/VIAL)	02/17/2011	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING GMBH / 1765	HAEGARDA	C1 ESTERASE INHIBITOR SUBCUTANEOUS (HUMAN)	125606 / 0	1	2000 IU (2000 IU/VIAL)	06/22/2017	POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
CSL BEHRING GMBH / 1765	HAEGARDA	C1 ESTERASE INHIBITOR SUBCUTANEOUS (HUMAN)	125606 / 0	2	3000 IU (3000 IU/VIAL)	06/22/2017	POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
CSL BEHRING GMBH / 1765	HUMATE-P	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)	103960 / 0	1	600 IU & 250 IU (600 IU & 250 IU/VIAL)	04/11/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING GMBH / 1765	HUMATE-P	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)	103960 / 0	2	1200 IU & 500 IU (1200 IU & 500 IU/VIAL)	04/11/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING GMBH / 1765	HUMATE-P	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)	103960 / 0	3	2400 IU& 1000 IU (2400 IU & 1000 IU/VIAL)	04/11/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING GMBH / 1765	KCENTRA	PROTHROMBIN COMPLEX CONCENTRATE (HUMAN)	125421 / 0	1	500 IU (500 IU/VIAL)	04/29/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING GMBH / 1765	KCENTRA	PROTHROMBIN COMPLEX CONCENTRATE (HUMAN)	125421 / 0	2	1000 IU (1000 IU/VIAL)	04/29/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING GMBH / 1765	RIASTAP	FIBRINOGEN CONCENTRATE (HUMAN)	125317 / 0	1	900-1300 MG (900-1300 MG/VIAL)	01/16/2009	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	AFSTYLA	ANTIHEMOPHILIC FACTOR (RECOMBINANT), SINGLE CHAIN	125591 / 0	1	250 IU (250 IU/VIAL)	05/25/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	AFSTYLA	ANTIHEMOPHILIC FACTOR (RECOMBINANT), SINGLE CHAIN	125591 / 0	2	500 IU (500 IU/VIAL)	05/25/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	AFSTYLA	ANTIHEMOPHILIC FACTOR (RECOMBINANT), SINGLE CHAIN	125591 / 0	3	1000 IU (1000 IU/VIAL)	05/25/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	AFSTYLA	ANTIHEMOPHILIC FACTOR (RECOMBINANT), SINGLE CHAIN	125591 / 0	4	2000 IU (2000 IU/VIAL)	05/25/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	AFSTYLA	ANTIHEMOPHILIC FACTOR (RECOMBINANT), SINGLE CHAIN	125591 / 0	5	3000 IU (3000 IU/VIAL)	05/25/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	AFSTYLA	ANTIHEMOPHILIC FACTOR (RECOMBINANT), SINGLE CHAIN	125591 / 47	6	1500 IU (1500 IU/VIAL)	03/31/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	AFSTYLA	ANTIHEMOPHILIC FACTOR (RECOMBINANT), SINGLE CHAIN	125591 / 47	7	2500 IU (2500 IU/VIAL)	03/31/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	IDELVION	COAGULATION FACTOR IX (RECOMBINANT), ALBUMIN FUSION PROTEIN	125582 / 0	1	250 IU (250 IU/VIAL)	03/04/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	IDELVION	COAGULATION FACTOR IX (RECOMBINANT), ALBUMIN FUSION PROTEIN	125582 / 0	2	500 IU (500 IU/VIAL)	03/04/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	IDELVION	COAGULATION FACTOR IX (RECOMBINANT), ALBUMIN FUSION PROTEIN	125582 / 0	3	1000 IU (1000 IU/VIAL)	03/04/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	IDELVION	COAGULATION FACTOR IX (RECOMBINANT), ALBUMIN FUSION PROTEIN	125582 / 0	4	2000 IU (2000 IU/VIAL)	03/04/2016	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LENGNAU AG / 2009	IDELVION	COAGULATION FACTOR IX (RECOMBINANT), ALBUMIN FUSION PROTEIN	125582 / 116	5	3500 IU (3500 IU/VIAL)	05/30/2018	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LLC / 1767	ZEMAIRA	ALPHA-1 PROTEINASE INHIBITOR (HUMAN)	125078 / 0	1	1000 MG (1000 MG/VIAL)	07/08/2003	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LLC / 1767	ZEMAIRA	ALPHA-1 PROTEINASE INHIBITOR (HUMAN)	125078 / 818	2	4000 MG (4000 MG/VIAL)	04/16/2019	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
CSL BEHRING LLC / 1767	ZEMAIRA	ALPHA-1 PROTEINASE INHIBITOR (HUMAN)	125078 / 818	3	5000 MG (5000 MG/VIAL)	04/16/2019	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
DENDREON PHARMACEUTICALS LLC / 1749	PROVENGE	SIPULEUCEL-T	125197 / 0	1	50 M CD54+ ACTIVATED CELLS/250 ML (50 M CD54+ ACTIVATED CELLS/250 ML)	04/29/2010	SOLUTION / INTRAVENOUS / PLASTIC CONTAINER

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DYNAVAX TECHNOLOGIES CORP / 1883	HEPLISAV-B	HEPATITIS B VACCINE (RECOMBINANT), ADJUVANTED	125428 / 0	1	20 MCG HBSAG/0.5 ML (20 MCG HBSAG/0.5 ML)	11/09/2017	SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
EMERGENT BIODEFENSE OPERATIONS LANSING LLC / 1755	BIOTHRAX	ANTHRAX VACCINE ADSORBED	103821 / 0	1	5 ML (0.5 ML/DOSE)	11/12/1998	SUSPENSION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL
EMERGENT BIOSOLUTIONS CANADA INC / 2084	ANTHRASIL	ANTRAX IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	125562 / 0	1	≥60 UNITS/VIAL (≥60 UNITS/VIAL)	03/24/2015	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
EMERGENT BIOSOLUTIONS CANADA INC / 2084	BAT	BOTULISM ANTITOXIN HEPTAVALENT (A, B, C, D, E, F, G) (EQUINE)	125462 / 0	1	VARIABLE BETWEEN 10-22 ML (VARIABLE BETWEEN 10-22 ML)	03/22/2013	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
EMERGENT BIOSOLUTIONS CANADA INC / 2084	CNJ-016	VACCINIA IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	125109 / 0	1	>50,000 U/15 ML (>50,000 U/15 ML)	05/02/2005	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC / 2089	ACAM2000	SMALLPOX (VACCINIA) VACCINE, LIVE	125158 / 0	1	1 – 5 X 10-8TH PFU (1 – 5 X 10-8TH PFU/ML)	08/31/2007	POWDER / PERCUTANEOUS / MULTI-DOSE VIAL
EMERGENT TRAVEL HEALTH INC / 2199	VAXCHORA	CHOLERA VACCINE LIVE, ORAL	125597 / 0	1	4.0x10E8 – 2.0x10E9 CFU (4.0x10E8 – 2.0x10E9 CFU/DOSE)	06/10/2016	POWDER / ORAL / PACKET
EMERGENT TRAVEL HEALTH INC / 2199	VIVOTIF	TYPHOID VACCINE LIVE ORAL TY21A	103123 / 0	1	2.0-10.0x10E+9 CFU (2.0-10.0x10E+9 CFU)	12/15/1989	CAPSULE / ORAL
ENZYVANT THERAPEUTICS GMBH / 2100	RETHYMIC	ALLOGENEIC PROCESSED THYMUS TISSUE–AGDC	125685 / 0	1	UP TO 42 SLICES (SLICE)	10/08/2021	IMPLANTATION / IMPLANTATION / KIT
ETHICON INC / 1879	EVARREST	FIBRIN SEALANT PATCH	125392 / 0	1	(2X4 OR 4X4 IN UNIT WITH 55.5 MG/IN HUMAN FIBRINOGEN AND 241.9 IU/IN HUMAN THROMBIN)	12/05/2012	PATCH / TOPICAL
GENZYME CORP / 1596	THYMOGLOBULIN	ANTI-THYMOCYTE GLOBULIN (RABBIT)	103869 / 0	1	25 MG (25 MG/VIAL)	05/19/1999	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GLAXOSMITHKLINE BIOLOGICALS / 1617	BEXSERO	MENINGOCOCCAL GROUP B VACCINE	125546 / 0	1	0.5 ML/SYRINGE (0.5 ML/SYRINGE)	01/23/2015	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	BOOSTRIX	TETANUS TOXOID, REDUCED DIPHTHERIA TOXOID AND ACELLULAR PERTUSSIS VACCINE, ADSORBED	125106 / 0	1	0.5 ML (0.5 ML/DOSE)	05/03/2005	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	CERVARIX	HUMAN PAPILLOMAVIRUS BIVALENT (TYPES 16 AND 18) VACCINE, RECOMBINANT	125259 / 0	1	0.5 ML (0.5 ML/DOSE)	10/16/2009	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	ENGERIX-B	HEPATITIS B VACCINE (RECOMBIANT)	103239 / 0	2	20 MCG/ML (20 MCG/ML)	08/28/1989	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	ENGERIX-B	HEPATITIS B VACCINE (RECOMBINANT)	103239 / 0	1	10 MCG/0.5 ML (20 MCG/ML)	08/28/1989	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	FLUARIX QUADRIVALENT	INFLUENZA VIRUS VACCINE	125127 / 513	2	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML)	12/14/2012	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	HAVRIX	HEPATITIS A VACCINE INACTIVATED	103475 / 0	1	720 ELISA U/0.5 ML (1440 ELISA U/ML)	02/22/1995	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	HAVRIX	HEPATITIS A VACCINE INACTIVATED	103475 / 0	2	1440 ELISA U/ML (1440 ELISA U/ML)	02/22/1995	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	HIBERIX	HAEMOPHILUS B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE)	125347 / 0	1	25 MCG (25 MCG/VIAL)	08/19/2009	POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
GLAXOSMITHKLINE BIOLOGICALS / 1617	INFANRIX	DIPHTHERIA & TETANUS TOXOIDS & ACELLULAR PERTUSSIS VACCINE	103647 / 0	1	25LF/10LF/25MCG/0.5 ML (25LF/10LF/25MCG/0.5 ML)	01/29/1997	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	KINRIX	DIPHTHERIA & TETANUS TOXOIDS & ACELLULAR PERTUSSIS ADSORBED & INACTIVATED POLIO VIRUS VACCINE	125260 / 0	1	0.5 ML (0.5 ML/DOSE)	06/24/2008	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE

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GLAXOSMITHKLINE BIOLOGICALS / 1617	MENVEO	MENINGOCOCCAL (GROUPS A, C, Y, AND W 135) OLIGOSACCHARIDE DIPHTHERIA CRM197 CONJUGATE VACCINE	125300 / 0	1	0.5 ML (0.5 ML/DOSE)	02/19/2010	POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
GLAXOSMITHKLINE BIOLOGICALS / 1617	PEDIARIX	DTAP & HEPATITIS B (RECOMBINANT) & INACTIVATED POLIOVIRUS VACCINE	103907 / 0	1	0.5 ML (0.5 ML/DOSE)	12/13/2002	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
GLAXOSMITHKLINE BIOLOGICALS / 1617	ROTARIX	ROTAVIRUS VACCINE, LIVE, ORAL	125265 / 0	1	1 ML (1 ML/DOSE)	04/03/2008	POWDER / ORAL / SINGLE-DOSE VIAL
GLAXOSMITHKLINE BIOLOGICALS / 1617	SHINGRIX	ZOSTER VACCINE RECOMBINANT, ADJUVANTED	125614 / 0	1	0.5 ML (0.5 ML/VIAL)	10/20/2017	POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
GLAXOSMITHKLINE BIOLOGICALS / 1617	TWINRIX	HEPATITIS A INACTIVATED & HEPATITIS B (RECOMBINANT) VACCINE	103850 / 0	1	1 ML (1 ML/DOSE)	05/11/2001	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
GRIFOLS BIOLOGICALS LLC / 1694	ALBUTEIN	ALBUMIN (HUMAN) 20%	102478 / 0	4	10 GM/50 ML (20 GM/100 ML)	08/15/1978	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALBUTEIN	ALBUMIN (HUMAN) 20%	102478 / 0	5	20 GM/100 ML (20 GM/100 ML)	08/15/1978	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALBUTEIN	ALBUMIN (HUMAN) 25%	102478 / 0	6	5 GM/20 ML (25 GM/100 ML)	08/15/1978	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALBUTEIN	ALBUMIN (HUMAN) 25%	102478 / 0	7	12.5 GM/50 ML (25 GM/100 ML)	08/15/1978	SOLUTION / INTRAVENOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM
GRIFOLS BIOLOGICALS LLC / 1694	ALBUTEIN	ALBUMIN (HUMAN) 25%	102478 / 0	8	25 GM/100 ML (25 GM/100 ML)	08/15/1978	SOLUTION / INTRAVENOUS / SINGLE DOSE VIAL AND FLEXIBLE CONTAINER CLOSURE SYSTEM
GRIFOLS BIOLOGICALS LLC / 1694	ALBUTEIN	ALBUMIN (HUMAN) 5%	102478 / 0	1	2.5 GM/50 ML (5 GM/100 ML)	08/15/1978	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALBUTEIN	ALBUMIN (HUMAN) 5%	102478 / 0	2	12.5 GM/250 ML (5 GM/100 ML)	08/15/1978	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALBUTEIN	ALBUMIN (HUMAN) 5%	102478 / 0	3	25 GM/500 ML (5 GM/100 ML)	08/15/1978	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALPHANATE	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)	102475 / 0	1	250 IU (250 IU/VIAL)	08/15/1978	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALPHANATE	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)	102475 / 0	2	500 IU (500 IU/VIAL)	08/15/1978	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALPHANATE	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)	102475 / 0	3	1000 IU (1000 IU/VIAL)	08/15/1978	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALPHANATE	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)	102475 / 0	4	1500 IU (1500 IU/VIAL)	08/15/1978	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALPHANATE	ANTIHEMOPHILIC FACTOR/VON WILLEBRAND FACTOR COMPLEX (HUMAN)	102475 / 0	5	2000 IU (2000 IU/VIAL)	06/26/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALPHANINE SD	COAGULATION FACTOR IX (HUMAN)	103249 / 0	1	500 IU (500 IU/VIAL)	12/31/1990	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALPHANINE SD	COAGULATION FACTOR IX (HUMAN)	103249 / 0	2	1000 IU (1000 IU/VIAL)	12/31/1990	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	ALPHANINE SD	COAGULATION FACTOR IX (HUMAN)	103249 / 0	3	1500 IU (1500 IU/VIAL)	12/31/1990	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	PROFILNINE	FACTOR IX COMPLEX	102476 / 0	1	500 IU (500 IU/VIAL)	07/20/1981	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS BIOLOGICALS LLC / 1694	PROFILNINE	FACTOR IX COMPLEX	102476 / 0	2	1000 IU (1000 IU/VIAL)	07/20/1981	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

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GRIFOLS BIOLOGICALS LLC / 1694	PROFILNINE	FACTOR IX COMPLEX	102476 / 0	3	1500 IU (1500 IU/VIAL)	07/20/1981	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	GAMMASTAN	IMMUNE GLOBULIN (HUMAN)	101134 / 0	1	10 ML (16.5%)	01/11/1944	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	GAMMASTAN	IMMUNE GLOBULIN (HUMAN)	101134 / 0	2	2 ML (16.5%)	01/11/1944	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	GAMUNEX-C	IMMUNE GLOBULIN INJECTION (HUMAN), 10%, CAPRYLATE/CHROMATOGRAPHY PURIFIED	125046 / 0	1	1 GM/10 ML (1 GM/10 ML)	08/27/2003	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
GRIFOLS THERAPEUTICS LLC / 1871	GAMUNEX-C	IMMUNE GLOBULIN INJECTION (HUMAN), 10%, CAPRYLATE/CHROMATOGRAPHY PURIFIED	125046 / 0	2	2.5 GM/25 ML (1 GM/10 ML)	08/27/2003	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
GRIFOLS THERAPEUTICS LLC / 1871	GAMUNEX-C	IMMUNE GLOBULIN INJECTION (HUMAN), 10%, CAPRYLATE/CHROMATOGRAPHY PURIFIED	125046 / 0	3	5 GM/50 ML (1 GM/10 ML)	08/27/2003	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
GRIFOLS THERAPEUTICS LLC / 1871	GAMUNEX-C	IMMUNE GLOBULIN INJECTION (HUMAN), 10%, CAPRYLATE/CHROMATOGRAPHY PURIFIED	125046 / 0	4	10 GM/100 ML (1 GM/10 ML)	08/27/2003	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
GRIFOLS THERAPEUTICS LLC / 1871	GAMUNEX-C	IMMUNE GLOBULIN INJECTION (HUMAN), 10%, CAPRYLATE/CHROMATOGRAPHY PURIFIED	125046 / 0	5	20 GM/200 ML (1 GM/10 ML)	08/27/2003	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
GRIFOLS THERAPEUTICS LLC / 1871	GAMUNEX-C	IMMUNE GLOBULIN INJECTION (HUMAN), 10%, CAPRYLATE/CHROMATOGRAPHY PURIFIED	125046 / 0	6	40 GM/400 ML (1 GM/10 ML)	08/27/2003	SOLUTION / INTRAVENOUS, SUBCUTANEOUS / SINGLE-USE BOTTLE
GRIFOLS THERAPEUTICS LLC / 1871	HYPERHEP B S/D	HEPATITIS B IMMUNE GLOBULIN (HUMAN)	101146 / 0	1	110 IU/0.5 ML (220 IU/ML)	09/23/1977	SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
GRIFOLS THERAPEUTICS LLC / 1871	HYPERHEP B S/D	HEPATITIS B IMMUNE GLOBULIN (HUMAN)	101146 / 0	2	220 IU/ML (220 IU/ML)	09/23/1977	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
GRIFOLS THERAPEUTICS LLC / 1871	HYPERHEP B S/D	HEPATITIS B IMMUNE GLOBULIN (HUMAN)	101146 / 0	3	1100 IU/5 ML (220 IU/ML)	09/23/1977	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	HYPERRAB	RABIES IMMUNE GLOBULIN (HUMAN)	101144 / 0	1	300 IU/ML (300 IU/ML)	06/12/1974	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	HYPERRAB	RABIES IMMUNE GLOBULIN (HUMAN)	101144 / 0	2	1500 IU/5 ML (300 IU/ML)	06/12/1974	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	HYPERRAB	RABIES IMMUNE GLOBULIN (HUMAN)	101144 / 5817	3	900 IU/3 ML (300 IU/ML)	11/06/2019	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	HYPERRHO S/D	RHO(D) IMMUNE GLOBULIN (HUMAN)	101141 / 0	1	250 IU/VIAL (250 IU/VIAL)	06/11/1971	SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
GRIFOLS THERAPEUTICS LLC / 1871	HYPERRHO S/D	RHO(D) IMMUNE GLOBULIN (HUMAN)	101141 / 0	2	1500 IU/VIAL (1500 IU/VIAL)	06/11/1971	SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
GRIFOLS THERAPEUTICS LLC / 1871	HYPERTET S/D	TETANUS IMMUNE GLOBULIN (HUMAN)	101142 / 0	1	250 U/SYRINGE (250 U/SYRINGE)	10/17/1957	SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
GRIFOLS THERAPEUTICS LLC / 1871	KOATE-DVI	ANTIHEMOPHILIC FACTOR (HUMAN)	101130 / 0	1	250 IU (250 IU/VIAL)	01/24/1974	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	KOATE-DVI	ANTIHEMOPHILIC FACTOR (HUMAN)	101130 / 0	2	500 IU (500 IU/VIAL)	01/24/1974	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	KOATE-DVI	ANTIHEMOPHILIC FACTOR (HUMAN)	101130 / 0	3	1000 IU (1000 IU/VIAL)	01/24/1974	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASBUMIN	ALBUMIN (HUMAN) 20%	101138 / 0	4	10 GM/50 ML (20 GM/100 ML)	10/21/1942	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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GRIFOLS THERAPEUTICS LLC / 1871	PLASBUMIN	ALBUMIN (HUMAN) 20%	101138 / 0	5	20 GM/100 ML (20 GM/100 ML)	10/21/1942	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASBUMIN	ALBUMIN (HUMAN) 25%	101138 / 0	6	5 GM/20 ML (25 GM/100 ML)	10/21/1942	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASBUMIN	ALBUMIN (HUMAN) 25%	101138 / 0	7	12.5 GM/50 ML (25 GM/100 ML)	10/21/1942	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASBUMIN	ALBUMIN (HUMAN) 25%	101138 / 0	8	25 GM/100 ML (25 GM/100 ML)	10/21/1942	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASBUMIN	ALBUMIN (HUMAN) 5%	101138 / 0	1	2.5 GM/50 ML (5 GM/100 ML)	10/21/1942	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASBUMIN	ALBUMIN (HUMAN) 5%	101138 / 0	2	12.5 GM/250 ML (5 GM/100 ML)	10/21/1942	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASBUMIN	ALBUMIN (HUMAN) 5%	101138 / 0	3	25 GM/500 ML (5 GM/100 ML)	10/21/1942	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASMANATE	PLASMA PROTEIN FRACTION (HUMAN), USP	101140 / 0	1	2.5 GM/50 ML (5 GM/100 ML)	10/02/1958	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASMANATE	PLASMA PROTEIN FRACTION (HUMAN), USP	101140 / 0	2	12.5 GM/250 ML (5 GM/100 ML)	10/02/1958	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PLASMANATE	PLASMA PROTEIN FRACTION (HUMAN), USP	101140 / 0	3	25 GM/500 ML (5 GM/100 ML)	10/02/1958	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PROLASTIN-C	ALPHA-1-PROTEINASE INHIBITOR (HUMAN)	103174 / 0	1	1000 MG (1000 MG/VIAL)	12/02/1987	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PROLASTIN-C LIQUID	ALPHA-1-PROTEINASE INHIBITOR (HUMAN)	103174 / 6160	3	1000 MG/20 ML (500 MG/ML)	09/08/2017	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PROLASTIN-C LIQUID	ALPHA-1-PROTEINASE INHIBITOR (HUMAN)	103174 / 6314	4	500 MG/10 ML (50 MG/ML)	03/05/2020	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	PROLASTIN-C LIQUID	ALPHA-1-PROTEINASE INHIBITOR (HUMAN)	103174 / 6314	5	4000 MG/80 ML (50 MG/ML)	03/05/2020	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	THROMBATE III	ANTITHROMBIN III (HUMAN)	103196 / 0	1	500 IU (500 IU/VIAL)	12/30/1991	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	XEMBIFY	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% - KLHW	125683 / 0	1	1 GM/5 ML (200 MG/ML)	07/03/2019	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	XEMBIFY	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% - KLHW	125683 / 0	2	2 GM/10 ML (200 MG/ML)	07/03/2019	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	XEMBIFY	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% - KLHW	125683 / 0	3	4 GM/20 ML (200 MG/ML)	07/03/2019	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
GRIFOLS THERAPEUTICS LLC / 1871	XEMBIFY	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN) 20% - KLHW	125683 / 0	4	10 GM/50 ML (200 MG/ML)	07/03/2019	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
ID BIOMEDICAL CORPORATION QUEBEC / 1739	FLULAVAL QUADRIVALENT	INFLUENZA VIRUS VACCINE	125163 / 253	4	600 MCG HA/5 ML (60 MCG HA/0.5 ML)	08/15/2013	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL
ID BIOMEDICAL CORPORATION QUEBEC / 1739	FLULAVAL QUADRIVALENT	INFLUENZA VIRUS VACCINE	125163 / 279	2	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML)	09/27/2013	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
INSTITUTO GRIFOLS SA / 1181	FLEBOGAMMA DIF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125077 / 146	2	5 GM/50 ML (10 GM/100 ML)	12/15/2003	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	FLEBOGAMMA DIF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125077 / 146	3	10 GM/100 ML (10 GM/100 ML)	12/15/2003	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	FLEBOGAMMA DIF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125077 / 146	4	20 GM/200 ML (10 GM/100 ML)	12/15/2003	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	FLEBOGAMMA DIF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125077 / 0	1	20 GM/400 ML (5 GM/100 ML)	12/15/2003	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	FLEBOGAMMA DIF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125077 / 0	5	0.5 GM/10 ML (5 GM/100 ML)	12/15/2003	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	FLEBOGAMMA DIF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125077 / 0	6	2.5 GM/50 ML (5 GM/100 ML)	12/15/2003	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	FLEBOGAMMA DIF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125077 / 0	7	5 GM/100 ML (5 GM/100 ML)	12/15/2003	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	FLEBOGAMMA DIF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125077 / 0	8	10 GM/200 ML (5 GM/100 ML)	12/15/2003	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL

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INSTITUTO GRIFOLS SA / 1181	HUMAN ALBUMIN GRIFOLS	ALBUMIN (HUMAN) 20%	103352 / 0	1	10 GM/50 ML (20 GM/100 ML)	02/17/1995	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	HUMAN ALBUMIN GRIFOLS	ALBUMIN (HUMAN) 20%	103352 / 0	2	20 GM/100 ML (20 GM/100 ML)	02/17/1995	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	HUMAN ALBUMIN GRIFOLS	ALBUMIN (HUMAN) 25%	103352 / 0	3	12.5 GM/50 ML (25 GM/100 ML)	02/17/1995	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	HUMAN ALBUMIN GRIFOLS	ALBUMIN (HUMAN) 25%	103352 / 0	4	25 GM/100 ML (25 GM/100 ML)	02/17/1995	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
INSTITUTO GRIFOLS SA / 1181	VISTASEAL	FIBRIN SEALANT (HUMAN)	125640 / 0	1	2 ML (2 ML)	11/01/2017	SOLUTION / TOPICAL / PREFILLED SYRINGE
INSTITUTO GRIFOLS SA / 1181	VISTASEAL	FIBRIN SEALANT (HUMAN)	125640 / 0	2	4 ML (4 ML)	11/01/2017	SOLUTION / TOPICAL / PREFILLED SYRINGE
INSTITUTO GRIFOLS SA / 1181	VISTASEAL	FIBRIN SEALANT (HUMAN)	125640 / 0	3	6 ML (6 ML)	11/01/2017	SOLUTION / TOPICAL / PREFILLED SYRINGE
INSTITUTO GRIFOLS SA / 1181	VISTASEAL	FIBRIN SEALANT (HUMAN)	125640 / 0	4	10 ML (10 ML)	11/01/2017	SOLUTION / TOPICAL / PREFILLED SYRINGE
JUBILANT HOLLISTERSTIER LLC / 1272		POSITIVE SKIN TEST CONTROL-HISTAMINE	103891 / 0	1	6 MG/ML (6 MG/ML)	06/02/1999	SOLUTION / TOPICAL / MULTI-DOSE VIAL
JUNO THERAPEUTICS / 2156	BREYANZI	LISOCABTAGENE MARALEUCEL	125714 / 0	1	6.9 × 10E6 to 322 × 10E6/4.6 ML (1.5 × 10E6 to 70 × 10E6/ML)	02/05/2021	SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL
KAMADA LTD / 1826	GLASSIA	ALPHA-1-PROTEINASE INHIBITOR (HUMAN)	125325 / 0	1	1 G/50 ML (20 MG/ML)	07/01/2010	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
KAMADA LTD / 1826	KEDRAB	RABIES IMMUNE GLOBULIN (HUMAN)	125613 / 0	1	300 IU/2 ML (150 IU/ML)	08/23/2017	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
KAMADA LTD / 1826	KEDRAB	RABIES IMMUNE GLOBULIN (HUMAN)	125613 / 0	2	1500 IU/10 ML (150 IU/ML)	08/23/2017	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
KEDRION BIOPHARMA INC / 1906	MICRHOGAM	RHO(D) IMMUNE GLOBULIN (HUMAN)	103777 / 0	1	50 MCG/SYRINGE (50 MCG/SYRINGE)	04/23/1998	SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
KEDRION BIOPHARMA INC / 1906	RHOGAM	RHO(D) IMMUNE GLOBULIN (HUMAN)	103777 / 0	2	300 MCG/SYRINGE (300 MCG/SYRINGE)	04/23/1998	SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
KEDRION SPA / 1851	KEDBUMIN	ALBUMIN (HUMAN)	125384 / 0	1	12.5 GM/50 ML (25 GM/100 ML, 25%)	06/03/2011	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
KEDRION SPA / 1851	KEDBUMIN	ALBUMIN (HUMAN)	125384 / 0	2	25 GM/100 ML (25 GM/100 ML, 25%)	09/05/2013	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
KITE PHARMA INC / 2064	TECARTUS	BREXUCABTAGENE AUTOLEUCEL	125703 / 0	1	~68 ML/BAG (~68 ML/BAG)	07/24/2020	SUSPENSION / INTRAVENOUS / PLASTIC CONTAINER
KITE PHARMA INC / 2064	YESCARTA	AXICABTAGENE CILOLEUCEL	125643 / 0	1	~68 ML/BAG (~68 ML/BAG)	10/18/2017	SUSPENSION / INTRAVENOUS / PLASTIC CONTAINER
LABORATOIRE FRANCAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES SA / 2061	SEVENFACT	COAGULATION FACTOR VIIA (RECOMBINANT)-JNCW	125641 / 0	1	1 MG (1 MG/VIAL)	04/01/2020	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
LABORATOIRE FRANCAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES SA / 2061	SEVENFACT	COAGULATION FACTOR VIIA (RECOMBINANT)-JNCW	125641 / 0	2	5 MG (5 MG/VIAL)	04/01/2020	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
MASSBIOLOGICS / 1779	TDVAX	TETANUS AND DIPHTHERIA TOXOIDS ADSORBED	101322 / 0	1	0.5 ML/DOSE (0.5 ML/DOSE)	07/27/1970	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
MEDEXUS PHARMA INC / 2220	IXINITY	COAGULATION FACTOR IX (RECOMBINANT)	125426 / 0	1	250 IU (250 IU/VIAL)	12/21/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
MEDEXUS PHARMA INC / 2220	IXINITY	COAGULATION FACTOR IX (RECOMBINANT)	125426 / 0	2	500 IU (500 IU/VIAL)	04/29/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
MEDEXUS PHARMA INC / 2220	IXINITY	COAGULATION FACTOR IX (RECOMBINANT)	125426 / 0	3	1000 IU (1000 IU/VIAL)	04/29/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
MEDEXUS PHARMA INC / 2220	IXINITY	COAGULATION FACTOR IX (RECOMBINANT)	125426 / 0	4	1500 IU (1500 IU/VIAL)	04/29/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL

Applicant / License #	Proprietary Name	Proper Name	BLA#	Product #	Total Drug Content (Concentration)	Approval Date	Dosage Form/Route/Presentation
MEDEXUS PHARMA INC / 2220	IXINITY	COAGULATION FACTOR IX (RECOMBINANT)	125426 / 0	5	2000 IU (2000 IU/VIAL)	12/21/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
MEDEXUS PHARMA INC / 2220	IXINITY	COAGULATION FACTOR IX (RECOMBINANT)	125426 / 0	6	3000 IU (3000 IU/VIAL)	12/21/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
MEDIMMUNE LLC / 1799	FLUMIST QUAD	INFLUENZA VIRUS VACCINE LIVE, INTRANASAL	125020 / 1668	1	0.2 ML (0.2 ML/SPRAY)	02/29/2012	SUSPENSION / INTRANASAL / PREFILLED SPRAYER
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002		ANTIVENIN (LATRODECTUS MACTANS)	101062 / 0	1	NLT 6,000 U (NLT 6,000 U/VIAL)	02/13/1936	POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002		NORMAL HORSE SERUM	101084 / 0	1	1 ML (1 ML/VIAL)	01/02/1959	/ SINGLE-DOSE VIAL
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	ERVEBO	EBOLA ZAIRE VACCINE, LIVE	125690 / 0	1	1 ML/DOSE (1 ML/DOSE)	12/19/2019	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	GARDASIL 9	HUMAN PAPILLOMAVIRUS 9-VALENT VACCINE RECOMBINANT	125508 / 0	1	0.5 ML (0.5 ML/DOSE)	12/10/2014	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	M-M-R II	MEASLES, MUMPS AND RUBELLA VIRUS VACCINE LIVE	101069 / 0	1	0.5 ML (0.5 ML/DOSE)	04/22/1971	POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	PEDVAXHIB	HAEMOPHILUS B CONJUGATE VACCINE (MENINGOCOCCAL PROTEIN CONJUGATE)	103237 / 0	1	7.5 MCG/0.5 ML (7.5 MCG/0.5 ML)	12/20/1989	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	PNEUMOVAX 23	PNEUMOCOCCAL VACCINE, POLYVALENT	101094 / 5911	2	0.5 ML (0.5 ML/DOSE)	11/21/1977	SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	PROQUAD	MEASLES, MUMPS, RUBELLA, AND VARICELLA VIRUS VACCINE LIVE	125108 / 0	1	0.5 ML (0.5 ML/VIAL)	09/06/2005	POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	RECOMBIVAX, RECOMBIVAX HB	HEPATITIS B VACCINE (RECOMBINANT)	101066 / 0	1	10 MCG/ML (10 MCG/ML)	07/23/1986	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	RECOMBIVAX, RECOMBIVAX HB	HEPATITIS B VACCINE (RECOMBINANT)	101066 / 0	2	40 MCG/ML (40 MCG/ML)	07/23/1986	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	RECOMBIVAX, RECOMBIVAX HB	HEPATITIS B VACCINE (RECOMBINANT)	101066 / 0	3	5 MCG/0.5 ML (10 MCG/ML)	07/23/1986	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	ROTATEQ	ROTAVIRUS VACCINE LIVE, ORAL PENTAVALENT	125122 / 0	1	2 ML (2 ML/TUBE)	02/03/2006	SOLUTION / ORAL / SINGLE-DOSE TUBE
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	VAQTA	HEPATITIS A VACCINE INACTIVATED	103606 / 0	1	25 U/0.5 ML (50 U/ML)	03/29/1996	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	VAQTA	HEPATITIS A VACCINE INACTIVATED	103606 / 0	2	50 U/ML (50 U/ML)	03/29/1996	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	VARIVAX	VARICELLA VIRUS VACCINE LIVE	103552 / 0	1	NLT 1350 PF U (NLT 1350 PF U/0.5 ML)	03/17/1995	POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	VAXNEUVANCE	PNEUMOCOCCAL 15-VALENT CONJUGATE VACCINE	125741 / 0	1	2MCG/0.5ML (2MCG/0.5ML)	07/16/2021	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
MSP VACCINE COMPANY / 2202	VAXELIS	DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS ADSORBED, INACTIVATED POLIOVIRUS, HAEMOPHILUS B CONJUGATE [MENINGOCOCCAL PROTEIN CONJUGATE] AND HEPATITIS B [RECOMBINANT] VACCINE	125563 / 0	1	0.5 ML/DOSE (0.5 ML/DOSE)	12/21/2018	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
NIELSEN BIOSCIENCES INC / 1903	SPHERUSOL	COCCIDIOIDES IMMITIS SPHERULE-DERIVED SKIN TEST ANTIGEN	125354 / 0	1	1.27 MCG/ML (1.27 MCG/ML)	07/29/2011	SOLUTION / INTRADERMAL / MULTI-DOSE VIAL
NOVARTIS GENE THERAPIES INC / 2250	ZOLGENSMA	ONASEMNOGENE ABEPARVOVEC-XIOI	125694 / 0	1	11 LOG 13VG/5.5 ML (2.0 LOG 13VG/ML)	05/24/2019	SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL
NOVARTIS GENE THERAPIES INC / 2250	ZOLGENSMA	ONASEMNOGENE ABEPARVOVEC-XIOI	125694 / 0	2	16.6 LOG 13VG/8.3 ML (2.0 LOG 13VG/ML)	05/24/2019	SUSPENSION / INTRAVENOUS / SINGLE-DOSE VIAL
NOVARTIS PHARMACEUTICALS CORP / 1244	KYMRIAH	TISAGENLECLEUCEL	125646 / 0	1	INFUSION BAG (INFUSION BAG)	08/30/2017	SUSPENSION / INTRAVENOUS / PLASTIC CONTAINER

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NOVO NORDISK INC / 1261	ESPEROCT	ANTIHEMOPHILIC FACTOR (RECOMBINANT), GLYCOPEGYLATED-EXEI	125671 / 0	1	500 IU (500 IU/VIAL)	02/19/2019	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	ESPEROCT	ANTIHEMOPHILIC FACTOR (RECOMBINANT), GLYCOPEGYLATED-EXEI	125671 / 0	2	1000 IU (1000 IU/VIAL)	02/19/2019	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	ESPEROCT	ANTIHEMOPHILIC FACTOR (RECOMBINANT), GLYCOPEGYLATED-EXEI	125671 / 0	3	1500 IU (1500 IU/VIAL)	02/19/2019	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	ESPEROCT	ANTIHEMOPHILIC FACTOR (RECOMBINANT), GLYCOPEGYLATED-EXEI	125671 / 0	4	2000 IU (2000 IU/VIAL)	02/19/2019	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	ESPEROCT	ANTIHEMOPHILIC FACTOR (RECOMBINANT), GLYCOPEGYLATED-EXEI	125671 / 0	5	3000 IU (3000 IU/VIAL)	02/19/2019	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOEIGHT	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125466 / 0	1	250 IU (250 IU/VIAL)	10/15/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOEIGHT	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125466 / 0	2	500 IU (500 IU/VIAL)	10/15/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOEIGHT	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125466 / 0	3	1000 IU (1000 IU/VIAL)	10/15/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOEIGHT	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125466 / 0	4	1500 IU (1500 IU/VIAL)	10/15/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOEIGHT	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125466 / 0	5	2000 IU (2000 IU/VIAL)	10/15/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOEIGHT	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125466 / 0	6	3000 IU (3000 IU/VIAL)	10/15/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOSEVEN RT	COAGULATION FACTOR VIIA (RECOMBINANT)	103665 / 1	1	1 MG (1 MG/VIAL)	05/09/2008	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOSEVEN RT	COAGULATION FACTOR VIIA (RECOMBINANT)	103665 / 5605	2	2 MG (2 MG/VIAL)	05/09/2008	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOSEVEN RT	COAGULATION FACTOR VIIA (RECOMBINANT)	103665 / 5605	3	5 MG (5 MG/VIAL)	05/09/2008	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	NOVOSEVEN RT	COAGULATION FACTOR VIIA (RECOMBINANT)	103665 / 5605	4	8 MG (8 MG/VIAL)	08/06/2010	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	REBINYN	COAGULATION FACTOR IX (RECOMBINANT), GLYCOPEGYLATED	125611 / 0	1	500 IU (500 IU/VIAL)	05/31/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	REBINYN	COAGULATION FACTOR IX (RECOMBINANT), GLYCOPEGYLATED	125611 / 0	2	1000 IU (1000 IU/VIAL)	05/31/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	REBINYN	COAGULATION FACTOR IX (RECOMBINANT), GLYCOPEGYLATED	125611 / 0	3	2000 IU (2000 IU/VIAL)	05/31/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
NOVO NORDISK INC / 1261	TRETTEN	COAGULATION FACTOR XIII A-SUBUNIT (RECOMBINANT)	125398 / 0	1	2000 - 3125 IU (2000 - 3125 IU/VIAL)	12/23/2013	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646		ALBUMIN (HUMAN) 20%	125154 / 0	4	10 GM/50 ML (20 GM/100 ML)	10/17/2006	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646		ALBUMIN (HUMAN) 20%	125154 / 0	5	20 GM/100 ML (20 GM/100 ML)	10/17/2006	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646		ALBUMIN (HUMAN) 25%	125154 / 0	6	12.5 GM/50 ML (25 GM/100 ML)	10/17/2006	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646		ALBUMIN (HUMAN) 25%	125154 / 0	7	25 GM/100 ML (25 GM/100 ML)	10/17/2006	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646		ALBUMIN (HUMAN) 5%	125154 / 0	1	5 GM/100 ML (5 GM/100 ML)	10/17/2006	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646		ALBUMIN (HUMAN) 5%	125154 / 0	2	12.5 GM/250 ML (5 GM/100 ML)	10/17/2006	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646		ALBUMIN (HUMAN) 5%	125154 / 0	3	25 GM/500 ML (5 GM/100 ML)	10/17/2006	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE

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OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	CUTAQUIG	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN)-HIPP 16.5%	125668 / 0	1	1 GM/6 ML (0.165 GM/ML)	12/12/2018	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	CUTAQUIG	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN)-HIPP 16.5%	125668 / 0	2	1.65 GM/10 ML (0.165 GM/ML)	12/12/2018	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	CUTAQUIG	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN)-HIPP 16.5%	125668 / 0	3	2 GM/12 ML (0.165 GM/ML)	12/12/2018	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	CUTAQUIG	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN)-HIPP 16.5%	125668 / 0	4	3.3 GM/20 ML (0.165 GM/ML)	12/12/2018	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	CUTAQUIG	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN)-HIPP 16.5%	125668 / 0	5	4 GM/24 ML (0.165 GM/ML)	12/12/2018	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	CUTAQUIG	IMMUNE GLOBULIN SUBCUTANEOUS (HUMAN)-HIPP 16.5%	125668 / 0	6	8 GM/48 ML (0.165 GM/ML)	12/12/2018	SOLUTION / SUBCUTANEOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	FIBRYNA	FIBRINOGEN (HUMAN)	125612 / 0	1	1 GM (1 GM/BOTTLE)	06/07/2017	POWDER / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	NUWIQ	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125555 / 0	1	250 IU (250 IU/VIAL)	09/04/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	NUWIQ	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125555 / 0	2	500 IU (500 IU/VIAL)	09/04/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	NUWIQ	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125555 / 0	3	2000 IU (2000 IU/VIAL)	09/04/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	NUWIQ	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125555 / 0	4	1000 IU (1000 IU/VIAL)	09/04/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	NUWIQ	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125555 / 55	5	2500 IU (2500 IU/VIAL)	07/07/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	NUWIQ	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125555 / 55	6	3000 IU (3000 IU/VIAL)	07/07/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	NUWIQ	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	125555 / 55	7	4000 IU (4000 IU/VIAL)	07/07/2017	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125062 / 0	6	2 GM/20 ML (10 GM/100 ML)	07/11/2014	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125062 / 0	7	5 GM/50 ML (10 GM/100 ML)	07/11/2014	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125062 / 0	8	10 GM/100 ML (10 GM/100 ML)	07/11/2014	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125062 / 0	9	20 GM/200 ML (10 GM/100 ML)	07/11/2014	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10%	125062 / 572	10	30 GM/300 ML (10 GM/100 ML)	11/30/2018	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125062 / 0	1	1 GM/20 ML (5 GM/100 ML)	05/21/2004	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125062 / 0	2	2.5 GM/50 ML (5 GM/100 ML)	05/21/2004	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125062 / 0	3	5 GM/100 ML (5 GM/100 ML)	05/21/2004	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125062 / 0	4	10 GM/200 ML (5 GM/100 ML)	05/21/2004	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAGAM	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125062 / 0	5	25 GM/500 ML (5 GM/100 ML)	05/21/2004	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	OCTAPLAS	POOLED PLASMA (HUMAN), SOLVENT/DETERGENT TREATED	125416 / 0	1	9000-14000 MG/200 ML (45-70 MG/ML)	01/17/2013	SOLUTION / INTRAVENOUS / PLASTIC CONTAINER
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	PANZYGA	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)-IFAS	125587 / 0	1	1 GM/10 ML (100 MG/ML)	08/02/2018	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	PANZYGA	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)-IFAS	125587 / 0	2	2.5 GM/25 ML (100 MG/ML)	08/02/2018	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	PANZYGA	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)-IFAS	125587 / 0	3	5 GM/50 ML (100 MG/ML)	08/02/2018	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	PANZYGA	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)-IFAS	125587 / 0	4	10 GM/100 ML (100 MG/ML)	08/02/2018	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE

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OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	PANZYGA	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)-IFAS	125587 / 0	5	20 GM/200 ML (100 MG/ML)	08/02/2018	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	PANZYGA	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)-IFAS	125587 / 0	6	30 GM/300 ML (100 MG/ML)	08/02/2018	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	WILATE	VON WILLEBRAND FACTOR/COAGULATION FACTOR VIII COMPLEX (HUMAN)	125251 / 22	1	500 IU/500 IU (500 IU/500 IU/VIAL)	12/04/2009	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OCTAPHARMA PHARMAZEUTIKA PRODUKTIONS GESMBH / 1646	WILATE	VON WILLEBRAND FACTOR/COAGULATION FACTOR VIII COMPLEX (HUMAN)	125251 / 22	2	1000 IU/1000 IU (1000 IU/1000 IU/VIAL)	12/04/2009	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
OMRIX BIOPHARMACEUTICALS LTD / 1603	EVICEL	FIBRIN SEALANT (HUMAN)	125010 / 0	1	1 ML (1 ML KIT)	03/21/2003	SOLUTION / TOPICAL / SINGLE-DOSE VIAL
OMRIX BIOPHARMACEUTICALS LTD / 1603	EVICEL	FIBRIN SEALANT (HUMAN)	125010 / 0	2	2 ML (2 ML KIT)	03/21/2003	SOLUTION / TOPICAL / SINGLE-DOSE VIAL
OMRIX BIOPHARMACEUTICALS LTD / 1603	EVICEL	FIBRIN SEALANT (HUMAN)	125010 / 0	3	5 ML (5 ML KIT)	03/21/2003	SOLUTION / TOPICAL / SINGLE-DOSE VIAL
OMRIX BIOPHARMACEUTICALS LTD / 1603	EVITHROM	THROMBIN, TOPICAL (HUMAN)	125247 / 0	1	1600-2400 IU/2 ML (800-1,200 IU/ML)	08/27/2007	SOLUTION / TOPICAL / SINGLE-DOSE VIAL
OMRIX BIOPHARMACEUTICALS LTD / 1603	EVITHROM	THROMBIN, TOPICAL (HUMAN)	125247 / 89	4	1600-2400 IU (1600-2400 IU/VIAL)	09/17/2009	POWDER / TOPICAL / SINGLE-DOSE VIAL
ORGANON TEKNIKA CORP / 1747		BCG VACCINE	103050 / 0	1	100-800 MIL CFU (100-800 MIL CFU/VIAL)	06/21/1989	POWDER / PERCUTANEOUS / SINGLE-DOSE VIAL
ORGANON TEKNIKA CORP / 1747	TICE BCG	BCG LIVE	102821 / 0	1	100-800 MIL CFU (100-800 MIL CFU/VIAL)	06/21/1989	POWDER / INTRAVESICAL / SINGLE-DOSE VIAL
PAR PHARMACEUTICALS COMPANIES INC / 1997	APLISOL	TUBERCULIN, PURIFIED PROTEIN DERIVATIVE	103782 / 0	1	50 TU/ML (5 TU/0.1 ML)	04/20/1998	SOLUTION / INTRADERMAL / MULTI-DOSE VIAL
PAR PHARMACEUTICALS COMPANIES INC / 1997	APLISOL	TUBERCULIN, PURIFIED PROTEIN DERIVATIVE	103782 / 0	2	250 TU/5 ML (5 TU/0.1 ML)	04/20/1998	SOLUTION / INTRADERMAL / MULTI-DOSE VIAL
PFIZER IRELAND PHARMACEUTICALS / 2060	TICOVAC	TICK-BORNE ENCEPHALITIS VACCINE	125740 / 0	1	1.2MCG/0.25ML (1.2MCG/0.25ML)	08/13/2021	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
PFIZER IRELAND PHARMACEUTICALS / 2060	TICOVAC	TICK-BORNE ENCEPHALITIS VACCINE	125740 / 0	2	2.4MCG/0.5ML (2.4MCG/0.5ML)	08/13/2021	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
PHARMACIA AND UPJOHN CO / 1216	ATGAM	LYMPHOCYTE IMMUNE GLOBULIN, ANTI-THYMOCYTE GLOBULIN (EQUINE)	103676 / 0	1	250 MG/5 ML (50 MG/ML)	12/04/1996	SOLUTION / INTRAVENOUS / AMPULE
PHARMING AMERICAS BV / 2079	RUCONEST	C1 ESTERASE INHIBITOR (RECOMBINANT)	125495 / 0	1	2100 IU (2100 IU/VIAL)	07/16/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
PORTOLA PHARMACEUTICALS INC / 2017	ANDEXXA	COAGULATION FACTOR XA (RECOMBINANT), INACTIVATED - ZHZO	125586 / 27	2	200 MG (200 MG/VIAL)	12/31/2018	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
PROMETIC BIOTHERAPEUTICS INC / 2065	RYPLAZIM	PLASMINOGEN HUMAN-TVMH	125659 / 0	1	68.8 MG/12.5 ML (5.5 MG/ML)	06/04/2021	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
PROTEIN SCIENCES CORP / 1795	FLUBLOK QUADRIVALENT	INFLUENZA VACCINE	125285 / 194	2	180 MCG HA/0.5 ML (180 MCG HA/0.5 ML)	10/07/2016	SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
RARE DISEASE THERAPEUTICS INC / 1860	ANASCORP	CENTRUROIDES (SCORPION) IMMUNE F (AB') 2(EQUINE) INJECTION	125335 / 0	1	120MG (120MG/VIAL)	08/03/2011	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
RARE DISEASE THERAPEUTICS INC / 1860	ANAVIP	CROTALIDAE IMMUNE F(AB')2 (EQUINE)	125488 / 0	1	120 MG (120 MG/VIAL)	05/06/2015	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
RECORDATI RARE DISEASES INC / 1899	PANHEMATIN	HEMIN FOR INJECTION	101246 / 0	1	350 MG (350 MG/VIAL)	07/20/1983	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
REVO BIOLOGICS INC / 1904	ATRYN	ANTITHROMBIN (RECOMBINANT)	125284 / 0	1	1750 IU (1750 IU/VIAL)	02/06/2009	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
REVO BIOLOGICS INC / 1904	ATRYN	ANTITHROMBIN (RECOMBINANT)	125284 / 134	2	525 IU (525 IU/VIAL)	04/11/2014	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
SANOFI PASTEUR INC / 1725	DENGVAXIA	DENGUE TETRAVALENT VACCINE, LIVE	125682 / 0	1	0.5 ML (0.5 ML/VIAL)	05/01/2019	POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL

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SANOFI PASTEUR INC / 1725	FLUZONE HD QUADRIVALENT	INFLUENZA VIRUS VACCINE	103914 / 6290	9	240 MCG HA/0.7 ML (240 MCG HA/0.7 ML)	11/04/2019	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
SANOFI PASTEUR INC / 1725	FLUZONE HIGH DOSE	INFLUENZA VIRUS VACCINE	103914 / 5240	1	180 MCG HA/0.5 ML (180 MCG HA/0.5ML)	12/23/2009	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
SANOFI PASTEUR INC / 1725	FLUZONE QUADRIVALENT	INFLUENZA VIRUS VACCINE	103914 / 5574	2	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML)	06/07/2013	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
SANOFI PASTEUR INC / 1725	FLUZONE QUADRIVALENT	INFLUENZA VIRUS VACCINE	103914 / 5574	8	600 MCG HA/5 ML (60 MCG HA/0.5 ML)	06/07/2013	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL
SANOFI PASTEUR INC / 1725	MENACTRA	MENINGOCOCCAL (GROUPS A, C, Y, AND W135) POLYSACCHARIDE DIPHTHERIA TOXOID CONJUGATE VACCINE	125089 / 0	1	48 MCG/0.5ML (48 MCG/0.5ML)	01/14/2005	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
SANOFI PASTEUR INC / 1725	MENQUADFI	MENINGOCOCCAL (GROUPS A, C, Y, W) CONJUGATE VACCINE	125701 / 0	1	0.5 ML (0.5 ML/DOSE)	04/23/2020	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
SANOFI PASTEUR INC / 1725	YF-VAX	YELLOW FEVER VACCINE	103915 / 0	1	NLT 4.74 LOG10 PFU (NLT 4.74 LOG10 PFU/0.5 ML)	12/09/1999	POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL
SANOFI PASTEUR LTD / 1726		DIPHTHERIA & TETANUS TOXOIDS ADSORBED	103944 / 0	1	0.5 ML (0.5 ML/DOSE)	02/24/2000	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
SANOFI PASTEUR LTD / 1726	ADACEL	TETANUS TOXOID & REDUCED DIPHTHERIA TOXOID & ACELLULAR PERTUSSIS VACCINE, ADSORBED	125111 / 0	1	0.5 ML (0.5 ML/DOSE)	06/10/2005	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
SANOFI PASTEUR LTD / 1726	DAPTACEL	DIPHTHERIA & TETANUS TOXOIDS & ACELLULAR PERTUSSIS VACCINE	103666 / 0	1	0.5 ML/DOSE (0.5 ML/DOSE)	05/14/2002	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
SANOFI PASTEUR LTD / 1726	PENTACEL	DTAP INACTIVATED POLIOVIRUS & HAEMOPHILUS B CONJUGATE VACCINE	125145 / 0	1	0.5 ML (0.5 ML/DOSE)	06/20/2008	POWDER & SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
SANOFI PASTEUR LTD / 1726	QUADRACEL	DIPHTHERIA & TETANUS TOXOIDS & ACELLULAR PERTUSSIS ADSORBED & INACTIVATED POLIOVIRUS VACCINE	125525 / 0	1	0.5 ML (0.5 ML/DOSE)	03/24/2015	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL
SANOFI PASTEUR LTD / 1726	TENIVAC	TETANUS & DIPHTHERIA TOXOIDS ADSORBED FOR ADULT USE	103171 / 0	1	5LF/2LF/0.5 ML (5LF/2LF/0.5 ML)	11/03/2003	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE
SANOFI PASTEUR LTD / 1726	TUBERSOL	TUBERCULIN, PURIFIED PROTEIN DERIVATIVE	103941 / 0	1	50 TU/ML (5 TU/0.1 ML)	02/24/2000	SOLUTION / INTRADERMAL / MULTI-DOSE VIAL
SANOFI PASTEUR LTD / 1726	TUBERSOL	TUBERCULIN, PURIFIED PROTEIN DERIVATIVE	103941 / 0	2	250 TU/5 ML (5 TU/0.1 ML)	02/24/2000	SOLUTION / INTRADERMAL / MULTI-DOSE VIAL
SANOFI PASTEUR SA / 1724	ACTHIB	HAEMOPHILUS B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE)	103935 / 0	1	24 MCG (24 MCG/VIAL)	02/04/2000	POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
SANOFI PASTEUR SA / 1724	IMOGAM RABIES HT	RABIES IMMUNE GLOBULIN (HUMAN)	103932 / 0	1	>300 IU/2 ML (>150 IU/ML)	02/04/2000	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
SANOFI PASTEUR SA / 1724	IMOVAX RABIES	RABIES VACCINE	103931 / 0	1	(IM) 2.5 IU ((IM) 2.5 IU/ML)	02/04/2000	POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL
SANOFI PASTEUR SA / 1724	IPOL	POLIOVIRUS VACCINE INACTIVATED (MONKEY KIDNEY CELL)	103930 / 0	1	5 ML (0.5 ML/DOSE)	02/04/2000	SUSPENSION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL
SANOFI PASTEUR SA / 1724	TYPHIM VI	TYPHOID VI POLYSACCHARIDE VACCINE	103936 / 0	1	25 MCG/0.5 ML (50 MCG/ML)	02/04/2000	SOLUTION / INTRAMUSCULAR / PREFILLED SYRINGE
SANOFI PASTEUR SA / 1724	TYPHIM VI	TYPHOID VI POLYSACCHARIDE VACCINE	103936 / 0	2	500 MCG/10 ML (50 MCG/ML)	02/04/2000	SOLUTION / INTRAMUSCULAR / MULTI-DOSE VIAL
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	CYTOGAM	CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103189 / 0	1	2500 MG/50 ML (50 MG/ML)	04/17/1990	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	HEPAGAM B	HEPATITIS B IMMUNE GLOBULIN (HUMAN)	125035 / 0	1	>312 IU/ML (>312 IU/ML)	04/06/2007	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	HEPAGAM B	HEPATITIS B IMMUNE GLOBULIN (HUMAN)	125035 / 0	2	>1560 IU/5 ML (>312 IU/ML)	04/06/2007	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL

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SAOL THERAPEUTICS RESEARCH LIMITED / 2098	VARIZIG	VARICELLA ZOSTER IMMUNE GLOBLIN INTRAVENOUS (HUMAN)	125430 / 0	1	125 IU/1.25 ML (100 IU/ML)	12/02/2012	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	WINRHO SDF	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103649 / 0	4	600 IU/ML (600 IU/ML)	04/02/1996	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	WINRHO SDF	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103649 / 0	7	5000 IU/ML (5000 IU/ML)	04/02/1996	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	WINRHO SDF	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103649 / 0	8	15000 IU/ML (15000 IU/ML)	04/02/1996	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL
SEQIRUS INC / 2049	FLUAD QUADRIVALENT	INFLUENZA VACCINE, ADJUVANTED	125510 / 143	2	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML)	02/21/2020	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
SEQIRUS INC / 2049	FLUCELVAX QUADRIVALENT	INFLUENZA VIRUS VACCINE	125408 / 0	1	600 MCG HA/5 ML (60 MCG HA/0.5 ML)	03/03/2017	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL
SEQIRUS INC / 2049	FLUCELVAX QUADRIVALENT	INFLUENZA VIRUS VACCINE	125408 / 181	2	60 MCG HA/0.5 ML (60 MCG HA/0.5 ML)	05/23/2016	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
SEQIRUS PTY LTD / 2044	AFLURIA QUADRIVALENT	INFLUENZA VACCINE	125254 / 565	2	60 MCG HA/0.5 ML (60 MCG HA/0.5ML)	08/26/2016	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
SEQIRUS PTY LTD / 2044	AFLURIA QUADRIVALENT	INFLUENZA VACCINE	125254 / 565	4	600 MCG HA/5 ML (60 MCG HA/0.5 ML)	08/26/2016	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL
SEQIRUS PTY LTD / 2044	AFLURIA QUADRIVALENT	INFLUENZA VACCINE	125254 / 692	6	30 MCG HA/0.25 ML (30 MCG HA/0.25ML)	10/04/2018	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
SEQIRUS PTY LTD / 2044	AFLURIA TRIVALENT	INFLUENZA VACCINE	125254 / 0	3	450 MCG HA/5 ML (45 MCG HA/0.5 ML)	09/28/2007	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL
SPARK THERAPEUTICS INC / 2056	LUXTURNA	VORETIGENE NEPARVOVEC	125610 / 0	1	2.5 TRILLION VG/0.5 ML (5 TRILLION VG/ML)	12/19/2017	SUSPENSION / INTRAOCULAR / SINGLE-DOSE VIAL
STRATATECH CORPORATION / 2144	STRATAGRAFT	ALLOGENEIC KERATINOCYTE CELL LINE (NIKS), SEEDED ON RAT COLLAGEN (b) (4) CONDITIONED WITH HUMAN DERMAL FIBROBLASTS (b) (4)	125730 / 0	1	100 CM2 (APPROXIMATELY 8 CM BY 12.5 CM) (100 CM2 (APPROXIMATELY 8 CM BY 12.5 CM))	06/15/2021	CELLULAR SHEET / TOPICAL / KIT
TAKEDA PHARMA AS / 1894	TACHOSIL	FIBRIN SEALANT PATCH	125351 / 0	2	4.8 CM X 4.8 CM (170.5 MG/62.2 UNITS) ( )	04/05/2010	PATCH / TOPICAL
TAKEDA PHARMA AS / 1894	TACHOSIL	FIBRIN SEALANT PATCH	125351 / 0	3	9.5 CM X 4.8 CM (337.4 MG/123.1 UNITS) ( )	04/05/2010	PATCH / TOPICAL
TEVA WOMENS HEALTH INC / 1804		ADENOVIRUS TYPE 4 AND TYPE 7, LIVE, ORAL	125296 / 0	1	TYPE 4 AND TYPE 7, NFT 32000 TCI DOSES ( )	03/16/2011	TABLET / ORAL
VALNEVA AUSTRIA GMBH / 1909	IXIARO	JAPANESE ENCEPHALITIS VIRUS VACCINE INACTIVATED	125280 / 1	1	0.5 ML (0.25 OR 0.5 ML/DOSE (SINGLE USE))	03/30/2009	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
VERICEL CORPORATION / 2010	MACI	AUTOLOGOUS CULTURED CHONDROCYTES ON PORCINE COLLAGEN	125603 / 0	1	500,000 CM2OT (500,000 CM2OT)	12/13/2016	CELLULAR SHEET / IMPLANTATION / SINGLE-USE BOTTLE
VIROPHARMA BIOLOGICS INC / 1833	CINRYZE	C1 ESTERASE INHIBITOR (HUMAN)	125267 / 0	1	500 U (500 U/VIAL)	10/10/2008	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
WYETH PHARMACEUTICALS INC / 0003	BENEFIX	COAGULATION FACTOR IX (RECOMBINANT)	103677 / 0	1	250 IU (250 IU/VIAL)	02/11/1997	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
WYETH PHARMACEUTICALS INC / 0003	BENEFIX	COAGULATION FACTOR IX (RECOMBINANT)	103677 / 0	2	500 IU (500 IU/VIAL)	02/11/1997	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
WYETH PHARMACEUTICALS INC / 0003	BENEFIX	COAGULATION FACTOR IX (RECOMBINANT)	103677 / 0	3	1000 IU (1000 IU/VIAL)	02/11/1997	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
WYETH PHARMACEUTICALS INC / 0003	BENEFIX	COAGULATION FACTOR IX (RECOMBINANT)	103677 / 0	4	2000 IU (2000 IU/VIAL)	02/11/1997	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
WYETH PHARMACEUTICALS INC / 0003	BENEFIX	COAGULATION FACTOR IX (RECOMBINANT)	103677 / 0	5	3000 IU (3000 IU/VIAL)	11/23/2011	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL
WYETH PHARMACEUTICALS INC / 0003	PREVNAR 13	PNEUMOCOCCAL 13-VALENT CONJUGATE VACCINE (DIPHTHERIA CRM197 PROTEIN)	125324 / 0	1	0.5 ML (0.5 ML/DOSE)	02/24/2010	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
WYETH PHARMACEUTICALS INC / 0003	PREVNAR 20	20 VALENT PNEUMOCOCCAL CONJUGATE VACCINE	125731 / 0	1	0.5 ML/SYRINGE (0.5 ML/SYRINGE)	06/08/2021	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE

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WYETH PHARMACEUTICALS INC / 0003	TRUMENBA	MENINGOCOCCAL GROUP B VACCINE	125549 / 0	1	0.5 ML (0.5 ML/DOSE)	10/29/2014	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE
WYETH PHARMACEUTICALS INC / 0003	XYNTHA, XYNTHA SOLOFUSE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125264 / 0	1	250 IU (250 IU/VIAL)	02/21/2008	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
WYETH PHARMACEUTICALS INC / 0003	XYNTHA, XYNTHA SOLOFUSE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125264 / 0	2	1000 IU (1000 IU/VIAL)	02/21/2008	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
WYETH PHARMACEUTICALS INC / 0003	XYNTHA, XYNTHA SOLOFUSE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125264 / 0	3	500 IU (500 IU/VIAL)	02/21/2008	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
WYETH PHARMACEUTICALS INC / 0003	XYNTHA, XYNTHA SOLOFUSE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125264 / 492	4	2000 IU (2000 IU/VIAL)	02/21/2008	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL & PREFILLED SYRINGE
WYETH PHARMACEUTICALS INC / 0003	XYNTHA, XYNTHA SOLOFUSE	ANTIHEMOPHILIC FACTOR (RECOMBINANT), PLASMA/ALBUMIN FREE	125264 / 492	5	3000 IU (3000 IU/SYRINGE)	08/06/2010	POWDER / INTRAVENOUS / PREFILLED SYRINGE

CBER Discontinued Products List

Applicant / License #	Proprietary Name	Proper Name	BLA#	Product #	Total Drug Content (Concentration)	Approval Date	Dosage Form/Route/Presentation	Discontinued Date
BAXALTA US INC / 2020	FEIBA VH	ANTI-INHIBITOR COAGULANT COMPLEX	101447 / 5352	3	500 IU (500 IU/VIAL)	12/21/1979	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	3/15/2012
BAXALTA US INC / 2020	FEIBA VH	ANTI-INHIBITOR COAGULANT COMPLEX	101447 / 5352	4	1000 IU (1000 IU/VIAL)	12/21/1979	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	3/15/2012
BAXALTA US INC / 2020	GAMMAGARD S/D	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103133 / 0	3	0.5 GM (0.5 GM VIAL)	02/18/1986	POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/3/2014
BAXALTA US INC / 2020	GAMMAGARD S/D	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103133 / 0	4	2.5 GM (2.5 GM VIAL)	02/18/1986	POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/3/2014
BAXALTA US INC / 2020	IVEEGAM EN	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103133 / 0	5	500 MG (500 MG/VIAL)	02/18/1986	POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/24/2008
BAXALTA US INC / 2020	IVEEGAM EN	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103133 / 0	6	1000 MG (1000 MG/VIAL)	02/18/1986	POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/24/2008
BAXALTA US INC / 2020	IVEEGAM EN	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103133 / 0	7	2500 MG (2500 MG/VIAL)	02/18/1986	POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/24/2008
BAXALTA US INC / 2020	IVEEGAM EN	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103133 / 0	8	5000 MG (5000 MG/VIAL)	02/18/1986	POWDER / INTRAVENOUS / SINGLE-USE BOTTLE	9/24/2008
BAXTER HEALTHCARE CORP / 0140	ARTISS	FIBRIN SEALANT (HUMAN)	125266 / 0	2	2 ML (2 ML KIT)	03/19/2008	POWDER / TOPICAL / SINGLE-DOSE VIAL	9/3/2014
BAXTER HEALTHCARE CORP / 0140	ARTISS	FIBRIN SEALANT (HUMAN)	125266 / 0	3	4 ML (4 ML KIT)	03/19/2008	POWDER / TOPICAL / SINGLE-DOSE VIAL	9/3/2014
BAXTER HEALTHCARE CORP / 0140	ARTISS	FIBRIN SEALANT (HUMAN)	125266 / 0	4	10 ML (10 ML KIT)	03/19/2008	POWDER / TOPICAL / SINGLE-DOSE VIAL	9/3/2014
BIO PRODUCTS LABORATORY / 1811	GAMMAPLEX	IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 5%	125329 / 0	1	2.5 GM/50 ML (5 GM/100 ML)	09/17/2009	SOLUTION / INTRAVENOUS / SINGLE-USE BOTTLE	10/30/2018
CSL BEHRING AG / 1766	CARIMUNE NF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	102367 / 0	1	6 GM (6 GM/VIAL)	06/07/1984	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	6/10/2020
CSL BEHRING AG / 1766	CARIMUNE NF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	102367 / 0	2	12 GM (12 GM/VIAL)	06/07/1984	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	6/10/2020
CSL BEHRING AG / 1766	CARIMUNE NF	IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	102367 / 0	3	3 GM (3 GM/VIAL)	06/07/1984	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	8/17/2017
CSL BEHRING LLC / 1767	ALBUMINAR	ALBUMIN (HUMAN) 20%	103955 / 0	4	10 GM/50 ML (20 GM/100 ML)	03/17/2000	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	12/19/2019
CSL BEHRING LLC / 1767	ALBUMINAR	ALBUMIN (HUMAN) 20%	103955 / 0	5	20 GM/100 ML (20 GM/100 ML)	03/17/2000	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	12/19/2019
CSL BEHRING LLC / 1767	ALBUMINAR	ALBUMIN (HUMAN) 25%	103955 / 0	6	5 GM/20 ML (25 GM/100 ML)	03/17/2000	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	12/19/2019
CSL BEHRING LLC / 1767	ALBUMINAR	ALBUMIN (HUMAN) 25%	103955 / 0	7	12.5 GM/50 ML (25 GM/100 ML)	03/17/2000	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	12/19/2019
CSL BEHRING LLC / 1767	ALBUMINAR	ALBUMIN (HUMAN) 25%	103955 / 0	8	25 GM/100 ML (25 GM/100 ML)	03/17/2000	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	12/19/2019
CSL BEHRING LLC / 1767	ALBUMINAR	ALBUMIN (HUMAN) 5%	103955 / 0	1	2.5 GM/50 ML (5 GM/100 ML)	07/17/2000	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	12/19/2019
CSL BEHRING LLC / 1767	ALBUMINAR	ALBUMIN (HUMAN) 5%	103955 / 0	2	12.5 GM/250 ML (5 GM/100 ML)	07/17/2000	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	12/19/2019
CSL BEHRING LLC / 1767	ALBUMINAR	ALBUMIN (HUMAN) 5%	103955 / 0	3	25 GM/500 ML (5 GM/100 ML)	07/17/2000	SOLUTION / INTRAVENOUS / SINGLE-DOSE VIAL	12/19/2019
CSL BEHRING LLC / 1767	MONONINE	COAGULATION FACTOR IX (HUMAN)	103957 / 0	1	500 IU (500 IU/VIAL)	03/17/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	5/15/2020
CSL BEHRING LLC / 1767	MONONINE	COAGULATION FACTOR IX (HUMAN)	103957 / 0	2	1000 IU (1000 IU/VIAL)	03/17/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	5/15/2020
EMERGENT BIODEFENSE OPERATIONS LANSING LLC / 1755	BIORAB	RABIES VACCINE ADSORBED	103820 / 0	1	1.0 ML (1.0 ML/VIAL)	11/12/1998	POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
FIBROCELL TECHNOLOGIES INC / 1818	LAVIV	AZFICEL-T	125348 / 0	1	18 MU/1.2 ML (18 MU/1.2 ML)	11/12/1998	SUSPENSION / INTRADERMAL / SINGLE-DOSE VIAL	10/1/2007
GLAXOSMITHKLINE BIOLOGICALS / 1617	FLUARIX	INFLUENZA VIRUS VACCINE	125127 / 0	1	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML)	08/31/2005	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL	9/26/2017

Applicant / License #	Proprietary Name	Proper Name	BLA#	Product #	Total Drug Content (Concentration)	Approval Date	Dosage Form/Route/Presentation	Discontinued Date
GREER LABORATORIES INC / 0308		PLAGUE VACCINE	103569 / 0	1	2 BIL. CELL/ML (2 BIL. CELL/ML)	10/05/1994	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
GRIFOLS BIOLOGICALS LLC / 1694	ALPHANINE SD	COAGULATION FACTOR IX (HUMAN)	103249 / 0	4	250 IU (250 IU/VIAL)	12/31/1990	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/24/2008
GRIFOLS THERAPEUTICS LLC / 1871	PROLASTIN-C	ALPHA-1-PROTEINASE INHIBITOR (HUMAN)	103174 / 0	2	500 MG (500 MG/VIAL)	12/02/1987	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	3/23/2011
ID BIOMEDICAL CORPORATION QUEBEC / 1739		INFLUENZA A (H5N1) VIRUS MONOVALENT VACCINE, ADJUVANTED	125419 / 0	1	0.5 ML/VIAL (0.5 ML/VIAL)	11/22/2013	EMULSION / INTRAMUSCULAR / SINGLE-DOSE VIAL	7/8/2015
ID BIOMEDICAL CORPORATION QUEBEC / 1739	FLULAVAL TRIVALENT	INFLUENZA VIRUS VACCINE	125163 / 0	1	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML)	10/05/2006	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	4/2/2018
ID BIOMEDICAL CORPORATION QUEBEC / 1739	INFLUENZA A (H1N1) 2009 MONOVALENT	INFLUENZA VIRUS VACCINE	125163 / 135	3	15 MCG/0.5 ML (15 MCG/0.5 ML)	10/05/2006	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	12/15/2010
MEDIMMUNE LLC / 1799		INFLUENZA A (H1N1) 2009 MONOVALENT	125020 / 1215	3	(1 X 10 (6.5-7.5) FU/0.2ML)	09/15/2009	SPRAY / INTRANASAL / PREFILLED SPRAYER	9/24/2010
MEDIMMUNE LLC / 1799	FLUMIST	INFLUENZA VIRUS VACCINE LIVE	125020 / 0	2	(10 X 6.5-7.5 TCID)	06/17/2003	SPRAY / INTRANASAL / PREFILLED SPRAYER	9/12/2013
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	GARDASIL	HUMAN PAPILLOMAVIRUS QUADRIVALENT (TYPES 6, 11, 16, 18) VACCINE (RECOMBINANT)	125126 / 0	1	0.5 ML (0.5 ML/DOSE)	06/08/2006	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE	4/6/2016
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	PNEUMOVAX 23	PNEUMOCOCCAL VACCINE, POLYVALENT	101094 / 0	1	2.5 ML (0.5 ML/DOSE)	11/21/1977	SOLUTION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL	6/19/2020
MERCK AND CO INC DIV MERCK SHARP AND DOHME / 0002	ZOSTAVAX	ZOSTER VACCINE LIVE	125123 / 0	1	0.65 ML (0.65 ML/VIAL)	05/25/2006	POWDER / SUBCUTANEOUS / SINGLE-DOSE VIAL	6/24/2020
NIELSEN BIOSCIENCES INC / 1903		POSITIVE SKIN TEST CONTROL-HISTAMINE	103317 / 0	1	1.8 MG/ML (1.8 MG/ML)	02/14/1992	/ INTRAEPIDERMAL	10/1/2007
NOVO NORDISK INC / 1261	NOVOSEVEN	COAGULATION FACTOR VIIA (RECOMBINANT)	103665 / 0	5	1.2 MG (1.2 MG/VIAL)	03/25/1999	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/14/2011
NOVO NORDISK INC / 1261	NOVOSEVEN	COAGULATION FACTOR VIIA (RECOMBINANT)	103665 / 0	6	2.4 MG (2.4 MG/VIAL)	03/25/1999	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/14/2011
NOVO NORDISK INC / 1261	NOVOSEVEN	COAGULATION FACTOR VIIA (RECOMBINANT)	103665 / 0	7	4.8 MG (4.8 MG/VIAL)	03/25/1999	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/14/2011
OMRIX BIOPHARMACEUTICALS LTD / 1603	EVITHROM	THROMBIN, TOPICAL (HUMAN)	125247 / 0	2	4000-6000 IU/5 ML (800-1200 IU/ML)	08/27/2007	SOLUTION / TOPICAL / SINGLE-DOSE VIAL	9/29/2020
OMRIX BIOPHARMACEUTICALS LTD / 1603	EVITHROM	THROMBIN, TOPICAL (HUMAN)	125247 / 0	3	16,000-24,000 IU/20 ML (800-1200 IU/ML)	08/27/2007	SOLUTION / TOPICAL / SINGLE-DOSE VIAL	9/29/2020
ORGANOGENESIS INC / 1863	GINTUIT	ALLOGENEIC CULTURED KERATINOCYTES AND FIBROBLASTS IN BOVINE COLLAGEN	125400 / 0	1	>0.000001 MCG/ML (>0.000001 MCG/ML)	03/09/2012	CELLULAR SHEET / TOPICAL	9/3/2014
PORTOLA PHARMACEUTICALS INC / 2017	ANDEXXA	COAGULATION FACTOR XA (RECOMBINANT), INACTIVATED - ZHZO	125586 / 0	1	100 MG (100 MG/VIAL)	05/03/2018	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	7/6/2021
PROTEIN SCIENCES CORP / 1795	FLUBLOK	INFLUENZA VACCINE	125285 / 0	1	135 MCG HA/0.5 ML (135 MCG HA/0.5 ML)	01/16/2013	SOLUTION / INTRAMUSCULAR / SINGLE-DOSE VIAL	9/27/2017
SANOFI PASTEUR INC / 1725		INFLUENZA A (H1N1) 2009 MONOVALENT	103914 / 5260	6	15 MCG/0.5 ML (15 MCG/0.5 ML)	09/15/2009	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL, MULTI-DOSE VIAL & PREFILLED SYRINGE	9/24/2010
SANOFI PASTEUR INC / 1725		INFLUENZA VIRUS VACCINE, H5N1	125244 / 0	1	90 MCG/0.5ML (90 MCG/0.5ML)	04/17/2007	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	9/14/2011
SANOFI PASTEUR INC / 1725	DECAVAC	TETANUS AND DIPHTHERIA TOXOIDS ABSORBED FOR ADULT USE	103921 / 0	1	5LF/2LF/0.5ML (5LF/2LF/0.5ML)	12/09/1999	SUSPENSION / INTRAMUSCULAR / SINGLE-DOSE VIAL & PREFILLED SYRINGE	7/9/2015
SANOFI PASTEUR INC / 1725	FLUZONE	INFLUENZA VIRUS VACCINE	103914 / 5240	4	45 MCG/0.5ML (45 MCG/0.5ML)	12/09/1999	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	9/26/2016

Applicant / License #	Proprietary Name	Proper Name	BLA#	Product #	Total Drug Content (Concentration)	Approval Date	Dosage Form/Route/Presentation	Discontinued Date
SANOFI PASTEUR INC / 1725	FLUZONE INTRADERMAL	INFLUENZA VIRUS VACCINE	103914 / 5369	5	27 MCG/0.1ML (27 MCG/0.1ML)	05/09/2011	SUSPENSION / INTRADERMAL / PREFILLED PEN	9/26/2016
SANOFI PASTEUR INC / 1725	FLUZONE QUADRIVALENT	INFLUENZA VIRUS VACCINE	103914 / 5733	7	30 MCG HA/0.25 ML (30 MCG HA/0.25 ML)	12/11/2014	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	7/15/2021
SANOFI PASTEUR INC / 1725	FLUZONE QUADRIVALENT INTRADERMAL	INFLUENZA VIRUS VACCINE	103914 / 5733	3	36 MCG HA/0.1 ML (36 MCG HA/0.1 ML)	12/11/2014	SUSPENSION / INTRADERMAL / PREFILLED SYRINGE	9/29/2017
SANOFI PASTEUR INC / 1725	MENOMUNE	MENINGOCOCCAL POLYSACCHARIDE VACCINE, GROUPS A, C,Y AND W-135 COMBINED	103926 / 0	1	50 MCG (50 MCG/0.5ML)	12/09/1999	POWDER / SUBCUTANEOUS / SINGLE & MULTI-DOSE VIAL	6/28/2017
SANOFI PASTEUR INC / 1725	MENOMUNE-A/C	MENINGOCCAL POLYSACCHARIDE VACCINE, GROUPS A AND C COMBINED	103925 / 0	1	50 MCG (50 MCG/0.5ML)	12/09/1999	POWDER / SUBCUTANEOUS / SINGLE & MULTI-DOSE VIAL	9/14/2011
SANOFI PASTEUR INC / 1725	YF-VAX	YELLOW FEVER VACCINE	103915 / 0	2	NLT 23.7 LOG10 PFU (NLT 23.7 LOG10 PFU/0.5 ML)	12/09/1999	POWDER / SUBCUTANEOUS / MULTI-DOSE VIAL	8/13/2019
SANOFI PASTEUR LTD / 1726	POLIOVAX	POLIOVIRUS VACCINE INACTIVATED (HUMAN DIPLOID CELL)	103940 / 0	1	0.5ML/VIAL (0.5ML/VIAL)	02/24/2000	SUSPENSION / INTRAMUSCULAR, SUBCUTANEOUS / MULTI-DOSE VIAL	9/14/2011
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	VARIZIG	VARICELLA ZOSTER IMMUNE GLOBLIN INTRAVENOUS (HUMAN)	125430 / 0	2	125 IU (125 IU/VIAL)	12/02/2012	POWDER / INTRAMUSCULAR / SINGLE-DOSE VIAL	10/5/2015
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	WINRHO SDF	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103649 / 0	1	600 IU (600 IU/VIAL)	04/02/1996	POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	WINRHO SDF	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103649 / 0	2	1500 IU (1500 IU/VIAL)	04/02/1996	POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	WINRHO SDF	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103649 / 0	3	5000 IU (5000 IU/VIAL)	04/02/1996	POWDER / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	WINRHO SDF	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103649 / 0	5	1500 IU/ML (1500 IU/ML)	04/02/1996	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	WINRHO SDF	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103649 / 0	6	2500 IU/ML (2500 IU/ML)	04/02/1996	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
SAOL THERAPEUTICS RESEARCH LIMITED / 2098	WINRHO SDF	RHO(D) IMMUNE GLOBULIN INTRAVENOUS (HUMAN)	103649 / 5690	9	3000 IU/ML (3000 IU/ML)	12/18/2015	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	4/3/2019
SEQIRUS INC / 2049	AGRIFLU	INFLUENZA VACCINE	125297 / 0	1	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML)	11/27/2009	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	6/14/2018
SEQIRUS INC / 2049	AUDENZ	INFLUENZA A (H5N1) MONOVALENT VACCINE, ADJUVANTED	125692 / 0	1	0.5 ML/DOSE (0.5 ML/DOSE)	01/31/2020	EMULSION / INTRAMUSCULAR / PREFILLED SYRINGE	5/11/2020
SEQIRUS INC / 2049	FLUAD	INFLUENZA VACCINE, ADJUVANTED	125510 / 0	1	45 MCG HA/0.5 ML (45 MCG HA/0.5 ML)	11/24/2015	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	5/12/2021
SEQIRUS PTY LTD / 2044		INFLUENZA A (H1N1) 2009 MONOVALENT	125254 / 0	5	75 MCG (15 MCG /0.5 ML)	09/15/2009	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	9/24/2010
SEQIRUS PTY LTD / 2044	AFLURIA	INFLUENZA VACCINE	125254 / 0	1	45 MCG HA/0.5 ML (45 MCG HA/0.5ML)	09/28/2007	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	6/28/2019
SEQIRUS VACCINES LIMITED / 2055		INFLUENZA A (H1N1) 2009 MONOVALENT	103837 / 0	2	15 MCG/0.5 ML (15 MCG/0.5 ML)	09/15/2009	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL & PREFILLED SYRINGE	9/24/2010
SEQIRUS VACCINES LIMITED / 2055	FLUVIRIN	INFLUENZA VIRUS VACCINE	103837 / 0	1	45 MCG HA/0.5 ML (45 MCG HA/0.5ML)	11/03/1998	SUSPENSION / INTRAMUSCULAR / PREFILLED SYRINGE	6/14/2018
SEQIRUS VACCINES LIMITED / 2055	FLUVIRIN	INFLUENZA VIRUS VACCINE	103837 / 0	3	450 MCG HA/5 ML (45 MCG HA/0.5 ML)	09/15/2009	SUSPENSION / INTRAMUSCULAR / MULTI-DOSE VIAL	6/14/2018

CBER Discontinued Products List

Applicant / License #	Proprietary Name	Proper Name	BLA#	Product #	Total Drug Content (Concentration)	Approval Date	Dosage Form/Route/Presentation	Discontinued Date
TAKEDA PHARMA AS / 1894	TACHOSIL	FIBRIN SEALANT PATCH	125351 / 0	1	3.0 CM X 2.5 CM (55.5 MG/20.3 UNITS) ( )	04/05/2010	PATCH / TOPICAL	6/14/2018
VERICEL CORPORATION / 2010	CARTICEL SM SERVICE	AUTOLOGOUS CULTURED CHONDROCYTES	103661 / 0	1	12 MIL CELLS (12 MIL CELLS/VIAL)	08/22/1997	IMPLANTATION / INTRAARTICULAR / SINGLE-DOSE VIAL	9/26/2017
WELLCOME FOUNDATION LIMITED WELLCOME RESEARCH LABORATORIES / 0129	DIGIBIND	DIGOXIN IMMUNE FAB (OVINE)	103141 / 0	1	38 MG (38 MG/VIAL)	04/22/1986	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	9/14/2011
WYETH PHARMACEUTICALS INC / 0003		ANTIVENIN (CROTALIDAE) POLYVALENT	101098 / 0	1	10 ML/VIAL (10 ML/VIAL)	02/08/1954	SOLUTION / INTRAVENOUS, INTRAMUSCULAR / SINGLE-DOSE VIAL	10/1/2007
WYETH PHARMACEUTICALS INC / 0003		ANTIVENIN (MICRURUS FULVIUS)	101099 / 0	1	10 ML (10 ML/VIAL)	08/28/1967	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	10/1/2007
WYETH PHARMACEUTICALS INC / 0003	REFACTO	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103779 / 0	1	250 IU (250 IU/VIAL)	03/06/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	7/24/2012
WYETH PHARMACEUTICALS INC / 0003	REFACTO	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103779 / 0	2	500 IU (500 IU/VIAL)	03/06/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	7/24/2012
WYETH PHARMACEUTICALS INC / 0003	REFACTO	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103779 / 0	3	1000 IU (1000 IU/VIAL)	03/06/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	7/24/2012
WYETH PHARMACEUTICALS INC / 0003	REFACTO	ANTIHEMOPHILIC FACTOR (RECOMBINANT)	103779 / 0	4	2000 IU (2000 IU/VIAL)	03/06/2000	POWDER / INTRAVENOUS / SINGLE-DOSE VIAL	7/24/2012