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125296	Adenovirus Type 4 and Type 7 Vaccine, Live, Oral		3/16/2011				
101138	Albumin (Human)	Plasbumin-5; Plasbumin-20; Plasbumin-25; Albuked	10/21/1942				
101452	Albumin (Human)	Buminate; Buminate 25%; Buminate 5%; Buminate 20%; Flexbumin	3/3/1954				
101993	Albumin (Human)		9/7/1979				
102366	Albumin (Human)	AlbuRx	7/23/1976				
102478	Albumin (Human)	Albutein	8/15/1978				
103352	Albumin (Human)		2/17/1995				
103955	Albumin (Human)	Albuminar; Albuminar-5; Albuminar-20; Albuminar-25	5/17/1949				
125154	Albumin (Human)		10/17/2006				
125384	Albumin (Human)	kedbumin	6/3/2011				
125400	Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen	GINTUIT	3/9/2012				
103174	Alpha-1-Proteinase Inhibitor (Human)	Prolastin; Prolastin-C	12/2/1987				
125039	Alpha-1-Proteinase Inhibitor (Human)	Aralast; Aralast NP	12/23/2002				
125078	Alpha-1-Proteinase Inhibitor (Human)	Zemaira	7/8/2003				
125325	Alpha-1-Proteinase Inhibitor (Human)	Glassia	7/1/2010				
103324	Animal Allergens, Standardized Cat Hair		7/11/1930				
103368	Animal Allergens, Standardized Cat Hair		3/22/1974				
103397	Animal Allergens, Standardized Cat Hair		9/15/1958				
103473	Animal Allergens, Standardized Cat Hair		3/12/1974				
103810	Animal Allergens, Standardized Cat Hair		12/16/1971				
103889	Animal Allergens, Standardized Cat Hair		3/13/1924				
103061	Animal Allergens, Standardized Cat Pelt		9/29/1950				
103890	Animal Allergens, Standardized Cat Pelt		3/13/1924				
103821	Anthrax Vaccine Adsorbed	BioThrax	11/4/1970				
101130	Antihemophilic Factor (Human)	Koate; Koate-DVI	1/24/1974				
101448	Antihemophilic Factor (Human)	Hemofil M	3/11/1966				
103953	Antihemophilic Factor (Human)	Monoclate-P; Monoclate	9/18/1972				
103332	Antihemophilic Factor (Recombinant)	Kogenate; Helixate FS; Kogenate FS	2/25/1993				
103375	Antihemophilic Factor (Recombinant)	Recombinate; Bioclate (Armour)	12/10/1992				
103779	Antihemophilic Factor (Recombinant)	ReFacto	3/6/2000				
125466	Antihemophilic Factor (Recombinant)	Novoeight	10/15/2013				
125487	Antihemophilic Factor (Recombinant), Fc Fusion protein	ELOCTATE	6/6/2014				
125264	Antihemophilic Factor (Recombinant), Plasma/Albumin Free	XYNTHA; XYNTHA SOLOFUSE	2/21/2008				
125063	Antihemophilic Factor (Recombinant), Plasma/Albumin Free Method	Advate	7/25/2003				

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102475	Antihemophilic Factor/von Willebrand Factor Complex (Human)	Alphanate	8/15/1978				
103960	Antihemophilic Factor/von Willebrand Factor Complex (Human)	Humate-P	4/1/1999				
101447	Anti-Inhibitor Coagulant Complex	Autoplex; Feiba VH; FEIBA NF	12/21/1979				
125284	Antithrombin (Recombinant)	ATryn	2/6/2009				
103196	Antithrombin III (Human)	Thrombate III	12/30/1991				
103869	Anti-thymocyte Globulin (Rabbit)	Thymoglobulin	12/30/1998				
101098	Antivenin (Crotalidae) Polyvalent		2/8/1954				
101062	Antivenin (Latrodectus mactans)	Lactrodectus Mactans	2/13/1936				
101099	Antivenin (Micrurus fulvius)	Micrurus Fulvius	8/28/1967				
103661	Autologous Cultured Chondrocytes	Carticel SM Service	8/22/1997				
125348	Azficel-T	LaViv	6/21/2011				
102821	BCG Live	Tice BCG	6/21/1989				
103943	BCG Live	TheraCys	5/21/1990				
103050	BCG Vaccine		6/21/1989				
125462	Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) - (Equine)	BAT	3/22/2013				
125034	Botulism Immune Globulin Intravenous (Human)	Baby BIG	10/23/2003				
125267	C1 Esterase Inhibitor (Human)	Cinryze	10/10/2008				
125287	C1 Esterase Inhibitor (Human)	Berinert	10/9/2009				
125495	C1 Esterase Inhibitor (Recombinant)	RUCONEST	7/16/2014				
103257	Candida albicans Skin Test Antigen for Cellular Hypersensitivity	Candin	11/27/1995				
125335	Centruroides (Scorpion) Immune F(ab')2 (Equine) Injection	Anascorp	8/3/2011				
103249	Coagulation Factor IX (Human)	AlphaNine HP; AlphaNine; AlphaNine SD	12/31/1990				
103957	Coagulation Factor IX (Human)	Mononine	8/20/1992				
103677	Coagulation Factor IX (Recombinant)	BeneFIX; BeneFIX RTS	2/11/1997				
125446	Coagulation Factor IX (Recombinant)	RIXUBIS	6/26/2013				
125444	Coagulation Factor IX (Recombinant), Fc Fusion Protein	ALPROLIX	3/28/2014				
103665	Coagulation Factor VIIa (Recombinant)	NovoSeven; NovoSeven RT	3/25/1999				
125398	Coagulation Factor XIII A Subunit (Recombinant)	TRETTEN	12/23/2013				
125354	Coccidioides immitis Spherule-Derived Skin Test Antigen	Spherusol	7/29/2011				
103788	Crotalidae Polyvalent Immune Fab (Ovine)	CroFab	10/2/2000				
103189	Cytomegalovirus Immune Globulin Intravenous (Human)	CytoGam	4/17/1990				
103141	Digoxin Immune Fab (Ovine)	Digibind	4/22/1986				
103910	Digoxin Immune Fab (Ovine)	DigiFab	8/31/2001				
103647	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	Infanrix	1/29/1997				

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103666	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	Daptacel	5/14/2002				
103922	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	Tripedia	5/16/1949				
103919	Diphtheria & Tetanus Toxoids Adsorbed		1/29/2003				
103944	Diphtheria & Tetanus Toxoids Adsorbed		4/11/1997				
125260	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed and Inactivated Poliovirus Vaccine	Kinrix	6/24/2008				
103907	DTaP & Hepatitis B (Recombinant) & Inactivated Polio Virus Vaccine	PEDIARIX	12/13/2002				
102476	Factor IX Complex	Profilnine HP; Profilnine HT; Profilnine SD; Profilnine	7/20/1981				
103112	Factor IX Complex	Bebulin VH; Bebulin	8/21/1970				
125385	Factor XIII Concentrate (Human)	Corifact	2/17/2011				
125010	Fibrin Sealant (Human)	Crosseal; EVICEL	3/21/2003				
125266	Fibrin Sealant (Human)	ARTISS	3/19/2008				
103980	Fibrin Sealant (Tisseel)	TISSEEL	5/1/1998				
125351	Fibrin Sealant Patch	TachoSil	4/5/2010				
125392	Fibrin Sealant Patch	EVARREST	12/5/2012				
125317	Fibrinogen Concentrate (Human)	RiaSTAP	1/16/2009				
103623	Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine	COMVAX	10/2/1996				
103237	Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)	PedvaxHIB	12/20/1989				
103935	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)	ActHIB; OmniHIB	3/30/1993				
125347	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)	Hiberix	8/19/2009				
125145	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) Reconstituted with Diphtheria and Tetanus Toxoids and	Pentacel	6/20/2008				
125397	Hematopoietic Progenitor Cells, Cord (HPC-C)	Hemacord	11/10/2011				
101246	Hemin for Injection	Panhematin	7/20/1983				
103850	Hepatitis A Inactivated & Hepatitis B (Recombinant) Vaccine	Twinrix	5/11/2001				
103475	Hepatitis A Vaccine Inactivated	Havrix	2/22/1995				
103606	Hepatitis A Vaccine Inactivated	VAQTA	3/29/1996				
101146	Hepatitis B Immune Globulin (Human)	BayHep B; HyperHep B S/D	9/23/1977				
103945	Hepatitis B Immune Globulin (Human)	Nabi-HB	10/23/2001				
125035	Hepatitis B Immune Globulin (Human)	HepaGam B	1/27/2006				
125237	Hepatitis B Immune Globulin Intravenous (Human)	HepaGam BT	4/6/2007				
101066	Hepatitis B Vaccine (Recombinant)	Recombivax HB; Recombivax	7/23/1986				
103239	Hepatitis B Vaccine (Recombinant)	Engerix-B	8/28/1989				
125391	HPC, Cord Blood		5/24/2012				
125407	HPC, Cord Blood	DuCord	10/4/2012				
125413	HPC, Cord Blood	ALLOCORD	5/30/2013				

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125432	HPC, Cord Blood		6/13/2013				
125259	Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant	Cervarix	10/16/2009				
125126	Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant	GARDASIL	6/8/2006				
101134	Immune Globulin (Human)	GammaSTAN; BayGam	1/11/1944				
125105	Immune Globulin Infusion (Human)	Polygam LQ; KIOVIG; GAMMAGARD LIQUID	4/27/2005				
125046	Immune Globulin Injection (Human) 10% Caprylate/Chromatography Purified	Gamunex-C; GAMMAKED (Kendrion)	8/27/2003				
102367	Immune Globulin Intravenous (Human)	Sandoglobulin; Panglobulin; Carimune; Carimune NF	6/7/1984				
103133	Immune Globulin Intravenous (Human)	Gammagard; Gammagard S/D; Iveegam	2/18/1986				
125062	Immune Globulin Intravenous (Human)	OCTAGAM	5/21/2004				
125077	Immune Globulin Intravenous (Human)	Flebogamma 5%; Flebogamma; Flebogamma 5% DIF	12/15/2003				
125389	Immune Globulin Intravenous (Human)	Bivigam	12/19/2012				
125201	Immune Globulin Intravenous (Human), 10% Liquid	Privigen	7/26/2007				
125329	Immune Globulin Intravenous (Human), 5% Liquid	Gammaplex	9/17/2009				
125350	Immune Globulin Subcutaneous (Human), 20% Liquid	Hizentra	3/4/2010				
125419	Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted		11/22/2013				
125285	Influenza Vaccine	FluBlok	1/16/2013				
125297	Influenza Vaccine	Agriflu	11/27/2009				
125020	Influenza Vaccine Live, Intranasal	FluMist; FluMist Quad	6/17/2003				
103837	Influenza Virus Vaccine	FluVirin	8/12/1988				
103914	Influenza Virus Vaccine	Fluzone; Fluzone High Dose; Fluzone Intradermal; Fluzone Quadrivalent	12/9/1999				
125127	Influenza Virus Vaccine	FLUARIX; FLUARIX Quadrivalent	8/31/2005				
125163	Influenza Virus Vaccine	FluLaval; FluLaval Quadrivalent	10/5/2006				
125254	Influenza Virus Vaccine	AFLURIA	9/28/2007				
125408	Influenza Virus Vaccine	Flucelvax	11/20/2012				
125244	Influenza Virus Vaccine, H5N1		4/17/2007				
101377	Insects (Whole Body), Mite Dermatophagoides farinae		7/11/1930				
101834	Insects (Whole Body), Mite Dermatophagoides farinae		9/15/1958				
102212	Insects (Whole Body), Mite Dermatophagoides farinae		3/12/1974				
102224	Insects (Whole Body), Mite Dermatophagoides farinae		3/12/1974				
103060	Insects (Whole Body), Mite Dermatophagoides farinae		9/29/1950				
103870	Insects (Whole Body), Mite Dermatophagoides farinae		3/13/1924				
101378	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		7/11/1930				
101835	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		9/15/1958				
102213	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		3/12/1974				

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102225	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		3/12/1974				
103752	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		9/29/1950				
103871	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		3/13/1924				
125280	Japanese Encephalitis Vaccine, Inactivated, Adsorbed	Ixiaro	3/30/2009				
103676	Lymphocyte Immune Globulin, Anti-thymocyte Globulin (Equine)	Atgam	11/17/1981				
101069	Measles, Mumps and Rubella Virus Vaccine Live	M-M-R II	4/22/1971				
125108	Measles, Mumps, Rubella and Varicella Virus Vaccine Live	ProQuad	9/6/2005				
125300	Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine	Menveo	2/19/2010				
125089	Meningococcal Groups (A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine	Menactra	1/14/2005				
125363	Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine	MENHIBRIX	6/14/2012				
103924	Meningococcal Polysaccharide Vaccine, Group A	Menomune-A	9/19/1975				
103923	Meningococcal Polysaccharide Vaccine, Group C	Menomune-C	7/11/1975				
103925	Meningococcal Polysaccharide Vaccine, Groups A and C Combined	Menomune-A/C	12/13/1976				
103926	Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W135 Combined	Menomune	11/23/1981				
102932	Multiple Products: Allergen Patch Test Kit		4/20/1988				
101376	Multiple Products: Non-standardized Allergenics		7/11/1930				
102223	Multiple Products: Non-standardized Allergenics		7/11/1930				
103753	Multiple Products: Non-standardized Allergenics		9/29/1950				
103888	Multiple Products: Non-standardized Allergenics		3/13/1924				
101833	Multiple Products: Non-standardized Allergenics		7/11/1930				
102211	Multiple Products: Non-standardized Allergenics		3/12/1974				
101084	Normal Horse Serum		1/2/1959				
103569	Plague Vaccine		10/5/1994				
101140	Plasma Protein Fraction (Human)	Plasmanate	10/2/1958				
101454	Plasma Protein Fraction (Human)	Protenate; Protenate 5%	6/16/1960				
125324	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Prevnar 13	2/24/2010				
103905	Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Prevnar	2/17/2000				
101094	Pneumococcal Vaccine, Polyvalent	Pneumovax 23	11/21/1977				
103930	Poliovirus Vaccine Inactivated	IPOL	12/21/1990				
103940	Poliovirus Vaccine Inactivated (Human Diploid Cell)	Poliovax	11/20/1987				
101379	Pollens - Grasses, Bermuda Grass Cynodon dactylon		6/14/1930				
101836	Pollens - Grasses, Bermuda Grass Cynodon dactylon		6/14/1930				
102214	Pollens - Grasses, Bermuda Grass Cynodon dactylon		6/14/1930				
102226	Pollens - Grasses, Bermuda Grass Cynodon dactylon		3/22/1974				

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103051	Pollens - Grasses, Bermuda Grass Cynodon dactylon		9/29/1950				
103872	Pollens - Grasses, Bermuda Grass Cynodon dactylon		3/13/1924				
101380	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		6/14/1930				
101837	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		6/14/1930				
102215	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		6/14/1930				
103052	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		9/29/1950				
103421	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		3/22/1974				
103873	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		3/13/1924				
101381	Pollens - Grasses, Fescue, Meadow Festuca elatior		6/14/1930				
101838	Pollens - Grasses, Fescue, Meadow Festuca elatior		6/14/1930				
102216	Pollens - Grasses, Fescue, Meadow Festuca elatior		3/12/1974				
102227	Pollens - Grasses, Fescue, Meadow Festuca elatior		3/22/1974				
103053	Pollens - Grasses, Fescue, Meadow Festuca elatior		9/29/1950				
103874	Pollens - Grasses, Fescue, Meadow Festuca elatior		3/13/1924				
101382	Pollens - Grasses, Orchard Grass Dactylis glomerata		6/14/1930				
101839	Pollens - Grasses, Orchard Grass Dactylis glomerata		6/14/1930				
102217	Pollens - Grasses, Orchard Grass Dactylis glomerata		3/12/1974				
102228	Pollens - Grasses, Orchard Grass Dactylis glomerata		3/22/1974				
103054	Pollens - Grasses, Orchard Grass Dactylis glomerata		9/29/1950				
103875	Pollens - Grasses, Orchard Grass Dactylis glomerata		3/13/1924				
101383	Pollens - Grasses, Redtop Agrostis alba		6/14/1930				
101840	Pollens - Grasses, Redtop Agrostis alba		6/14/1930				
102218	Pollens - Grasses, Redtop Agrostis alba		3/12/1974				
102229	Pollens - Grasses, Redtop Agrostis alba		3/22/1974				
103055	Pollens - Grasses, Redtop Agrostis alba		9/29/1950				
103876	Pollens - Grasses, Redtop Agrostis alba		3/13/1924				
101384	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		6/14/1930				
101841	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		6/14/1930				
102219	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		6/14/1930				
102230	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		3/22/1974				
103056	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		9/29/1950				
103877	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		3/13/1924				
101385	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		6/14/1930				
101842	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		6/14/1930				

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102220	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		3/12/1974				
103057	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		9/29/1950				
103624	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		3/22/1974				
103878	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		3/13/1924				
101386	Pollens - Grasses, Timothy Phleum pratense		6/14/1930				
101843	Pollens - Grasses, Timothy Phleum pratense		6/14/1930				
102221	Pollens - Grasses, Timothy Phleum pratense		6/14/1930				
102231	Pollens - Grasses, Timothy Phleum pratense		3/22/1974				
103058	Pollens - Grasses, Timothy Phleum pratense		9/29/1950				
103879	Pollens - Grasses, Timothy Phleum pratense		3/13/1924				
101387	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		6/14/1930				
101844	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		6/14/1930				
102232	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		6/14/1930				
103113	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		3/12/1974				
103880	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		3/13/1924				
101845	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia elatior		9/15/1958				
103059	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia elatior		9/29/1950				
125416	Pooled Plasma (Human), Solvent/Detergent Treated	OCTAPLAS	1/17/2013				
103317	Positive Skin Test Control-Histamine		3/12/1974				
103754	Positive Skin Test Control-Histamine	Histatrol	9/29/1950				
103891	Positive Skin Test Control-Histamine		3/13/1924				
125234	Protein C Concentrate (Human)	Ceprotin	3/30/2007				
125421	Prothrombin Complex Concentrate (Human)	Kcentra	4/29/2013				
101144	Rabies Immune Globulin (Human)	BayRab; HyperRab	6/12/1974				
103932	Rabies Immune Globulin (Human)	Imogam	4/27/1984				
103334	Rabies Vaccine	RabAvert	10/20/1997				
103931	Rabies Vaccine	Imovax Rabies	6/9/1980				
103820	Rabies Vaccine Adsorbed	BioRab	3/18/1988				
101141	Rho(D) Immune Globulin (Human)	BayRho-D; HypRho-D; HyperRHO S/D Full Dose; HyperRHO S/D Mini-Dose	6/11/1971				
103777	Rho(D) Immune Globulin (Human)	RhoGAM; MICRhoGAM	4/10/1968				
103649	Rho(D) Immune Globulin Intravenous (Human)	WinRho SDF Lyophilized; WinRho SD; WinRho SDF Liquid	3/24/1995				
125070	Rho(D) Immune Globulin Intravenous (Human)	Rhophylac	2/12/2004				
125265	Rotavirus Vaccine, Live, Oral	Rotarix	4/3/2008				
125122	Rotavirus Vaccine, Live, Oral, Pentavalent	RotaTeq	2/3/2006				

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BLA STN	PRODUCT (PROPER) NAME	PROPRIETARY NAME	DATE OF LICENSURE (mo/day/yr)	DATE OF FIRST LICENSURE (mo/day/yr)	REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr)	INTERCHANGEABLE(I)/ BIOSMILAR (B)	WITHDRAWN
125478	Short Ragweed Pollen Allergen Extract	RAGWITEK	4/17/2014				
125197	sipuleucel-T	Provenge	4/29/2010				
125158	Smallpox (Vaccinia) Vaccine, Live	ACAM2000	8/31/2007				
125471	Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract	ORALAIR	4/1/2014				
101322	Tetanus and Diphtheria Toxoids Adsorbed		7/27/1970				
103171	Tetanus and Diphtheria Toxoids Adsorbed	TENIVAC	11/3/2003				
103921	Tetanus and Diphtheria Toxoids Adsorbed	DECAVAC	3/7/1955				
101142	Tetanus Immune Globulin (Human)	BayTet; HyperTet	10/17/1957				
103913	Tetanus Toxoid Adsorbed		5/25/1934				
125106	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed	Boostrix	5/3/2005				
125111	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed	ADACEL	6/10/2005				
103738	Thin-Layer Rapid Use Epicutaneous Patch Test	T.R.U.E. TEST	8/15/1997				
125248	Thrombin topical (Recombinant)	RECOTHROM	1/17/2008				
102865	Thrombin, Topical (Bovine)	Thrombin-JMI; ThromboColl	2/3/1986				
125247	Thrombin, Topical (Human)	Evithrom	8/27/2007				
125473	Timothy Grass Pollen Allergen Extract	GRASTEK	4/11/2014				
103782	Tuberculin, Purified Protein Derivative	Aplisol	4/15/1980				
103941	Tuberculin, Purified Protein Derivative	Tubersol	9/26/1969				
103123	Typhoid Vaccine Live Oral Ty21a	Vivotif	12/15/1989				
103936	Typhoid Vi Polysaccharide Vaccine	Typhim Vi	11/28/1994				
125109	Vaccinia Immune Globulin Intravenous (Human)	CNJ-016	5/2/2005				
103552	Varicella Virus Vaccine Live	Varivax	3/17/1995				
125430	Varicella Zoster Immune Globulin (Human)	VariZIG	12/20/2012				
103882	Venoms, Honey Bee Venom		3/13/1924				
103969	Venoms, Honey Bee Venom	Pharmalgen	10/8/1991				
103883	Venoms, Mixed Vespid Venom Protein		3/13/1924				
103970	Venoms, Mixed Vespid Venom Protein	Pharmalgen	10/8/1991				
103884	Venoms, Wasp Venom Protein		3/13/1924				
103971	Venoms, Wasp Venom Protein	Pharmalgen	10/8/1991				
103885	Venoms, White Faced Hornet Venom Protein		3/13/1924				
103972	Venoms, White Faced Hornet Venom Protein	Pharmalgen	10/8/1991				
103886	Venoms, Yellow Hornet Venom Protein		3/13/1924				
103973	Venoms, Yellow Hornet Venom Protein	Pharmalgen	10/8/1991				
103887	Venoms, Yellow Jacket Venom Protein		3/13/1924				

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103974	Venoms, Yellow Jacket Venom Protein	Pharmalgen	10/8/1991				
125251	von Willebrand Factor/Coagulation Factor VIII Complex (Human)	Wilate	12/4/2009				
103915	Yellow Fever Vaccine	YF-Vax	5/22/1953				
125123	Zoster Vaccine Live	Zostavax	5/25/2006				

Key -

BLA STN: Biologic License Application Submission Tracking Number

Product (Proper) Name: The nonproprietary name designated by FDA for a biological product at the time of licensure under the PHS Act (section 351(a)(1)(B)(i) of the PHS Act and 21 CFR 600.3(k) of the FD&C Act).

Proprietary Name: Brand/Trade Name

Date of Licensure: The date the application was approved/licensed for marketing. Date of licensure for each application was identified through FDA records.

Date of First Licensure: The date from which reference product exclusivity began to run. Under 351(k)(7)(C), the date of first licensure does not include date of licensure if the application is a subsequent application filed by the same or related sponsor of the biological product for a change (not including a modification to the structure of its previously approved biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, or if the change is a modification to the structure of the previously approved biological product that does not result in a change in safety, purity, or potency. If the FDA determines that these conditions apply to the application, FDA will denote this as "not applicable" (NA) to mean that there is no date of first licensure for the purpose of reference product exclusivity.

Reference Product Exclusivity Expiry Date: The reference product exclusivity expiry date indicates (1) the date that is 12 years from the date of first licensure as described in 351(k)(7); plus (2) any pediatric exclusivity granted pursuant to section 505(A) of the FD&C Act, if applicable. The reference product exclusivity expiry date is the date on which a 351(k) application referencing the reference product may be licensed assuming it is not blocked by orphan exclusivity and otherwise meets the requirements for licensure under 351(k). To determine whether there is unexpired orphan exclusivity for an indication for which the reference product is licensed, please refer to the searchable database for Orphan Designated and/or Approved Products (http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/HowtoapplyforOrphanProductDesignation/default.htm).

Interchangeable (I)/Biosimilar (B): Identification of those BLAs approved/licensed under 351(k) that were licensed as either interchangeable or biosimilar to the reference product. Such products will be listed under the reference product identified in the 351(k) application.

Withdrawn: The BLA has been withdrawn or is no longer being marketed. This does not specify whether withdrawn for reasons of of safety and/or effectiveness.

BLA STN Products with the Product (Proper) Name "Multiple Products: Non-standardized Allergenics products" include several specific non-standardized allergenics products that have been licensed under a single BLA STN over a period of time. For ease of reference, the original date of licensure of the first product licensed was used