

Center for Biologic Evaluation and Research  
List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date

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OF FIRST LICENSURE (mo/day/yr)	REFERENCE PRODUCT EXCLUSIVITY EXPIRY DATE (mo/day/yr)	INTERCHANGEABLE(I)/BIOSMILAR (B)	WITHDRAWN
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	NA	NA		
101452	Albumin (Human)	Buminate; Buminate 25%; Buminate 5%; Buminate 20%; Flexbumin	3/3/1954	NA	NA		
101993	Albumin (Human)		9/7/1979	NA	NA		
102366	Albumin (Human)	AlbuRx	7/23/1976	NA	NA		
102478	Albumin (Human)	Albutein	8/15/1978	NA	NA		
103352	Albumin (Human)		2/17/1995	NA	NA		
103955	Albumin (Human)	Albuminar; Albuminar-5; Albuminar-20; Albuminar-25	5/17/1949	NA	NA		
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	NA	NA		
125039	Alpha-1-Proteinase Inhibitor (Human)	Aralast; Aralast NP	12/23/2002	NA	NA		
125078	Alpha-1-Proteinase Inhibitor (Human)	Zemaira	7/8/2003	NA	NA		
125325	Alpha-1-Proteinase Inhibitor (Human)	Glassia	7/1/2010				
103324	Animal Allergens, Standardized Cat Hair		7/11/1930	NA	NA		
103368	Animal Allergens, Standardized Cat Hair		3/22/1974	NA	NA		
103397	Animal Allergens, Standardized Cat Hair		9/15/1958	NA	NA		
103473	Animal Allergens, Standardized Cat Hair		3/12/1974	NA	NA		
103810	Animal Allergens, Standardized Cat Hair		12/16/1971	NA	NA		
103889	Animal Allergens, Standardized Cat Hair		3/13/1924	NA	NA		
103061	Animal Allergens, Standardized Cat Pelt		9/29/1950	NA	NA		
103890	Animal Allergens, Standardized Cat Pelt		3/13/1924	NA	NA		
125562	Intravenous (Human)	Anthrasil	3/24/2015				
103821	Anthrax Vaccine Adsorbed	BioThrax	11/4/1970	NA	NA		
101130	Antihemophilic Factor (Human)	Koate Koate-DVI	1/24/1974	NA	NA		
101448	Antihemophilic Factor (Human)	Hemofil M	3/11/1966	NA	NA		
103953	Antihemophilic Factor (Human)	Monoclote-P; Monoclote	9/18/1972	NA	NA		
103332	Antihemophilic Factor (Recombinant)	Kogenate; Helixate FS; Kogenate FS	2/25/1993	NA	NA		
103375	Antihemophilic Factor (Recombinant)	Recombinate; Bioclote (Armour)	12/10/1992	NA	NA		
103779	Antihemophilic Factor (Recombinant)	ReFacto	3/6/2000	NA	NA		
125466	Antihemophilic Factor (Recombinant)	Novoeight	10/15/2013				
125487	Antihemophilic Factor (Recombinant), Fc Fusion protein	ELOCTATE	6/6/2014				
125574	Antihemophilic Factor (Recombinant), Full Length	KOVALTRY	3/16/2016				
125566	Antihemophilic Factor (Recombinant), PEGylated	ADYNOVATE	11/13/2015				
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	NA	NA		
125512	Antihemophilic Factor (Recombinant), Porcine Sequence	OBIZUR	10/23/2014				
125555	Antihemophilic Factor (Recombinant), rAHF	Nuwiq	9/4/2015				
125591	Antihemophilic Factor (Recombinant), Single Chain	Solchayn; AFSSTYLA	5/25/2016				

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102475	Antihemophilic Factor/von Willebrand Factor Complex (Human)	Alphanate	8/15/1978	NA	NA		
103960	Antihemophilic Factor/von Willebrand Factor Complex (Human)	Humate-P	4/1/1999	NA	NA		
101447	Anti-Inhibitor Coagulant Complex	Autoplex; Feiba VH; FEIBA NF	12/21/1979	NA	NA		
125284	Antithrombin (Recombinant)	ATryn	2/6/2009				
103196	Antithrombin III (Human)	Thrombate III	12/30/1991	NA	NA		
103869	Anti-thymocyte Globulin (Rabbit)	Thymoglobulin	12/30/1998	NA	NA		
101098	Antivenin (Crotalidae) Polyvalent		2/8/1954	NA	NA		
101062	Antivenin (Latroedectus mactans)	Lactroedectus Mactans	2/13/1936	NA	NA		
101099	Antivenin (Micrurus fulvius)	Micrurus Fulvius	8/28/1967	NA	NA		
103661	Autologous Cultured Chondrocytes autologous cultured chondrocytes on porcine collagen membrane	Carticel SM Service	8/22/1997	NA	NA		
125603		MACI	12/13/2016				
125348	Azficel-T	LaViv	6/21/2011				
102821	BCG Live	Tice BCG	6/21/1989	NA	NA		
103943	BCG Live	TheraCys	5/21/1990	NA	NA		
103050	BCG Vaccine		6/21/1989	NA	NA		
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	NA	NA		
125267	C1 Esterase Inhibitor (Human)	Cinryze	10/10/2008				
125287	C1 Esterase Inhibitor (Human)	Berinerst	10/9/2009				
125495	C1 Esterase Inhibitor (Recombinant)	RUCONEST	7/16/2014	7/16/2014	7/16/2026		
103257	Candida albicans Skin Test Antigen for Cellular Hypersensitivity	Candin	11/27/1995	NA	NA		
125335	Centruroides (Scorpion) Immune F(ab') <sub>2</sub> (Equine) Injection	Anascorp	8/3/2011				
125597	Cholera Vaccine Live Oral	Vaxchora	6/10/2016				
103249	Coagulation Factor IX (Human)	AlphaNine HP; AlphaNine; AlphaNine SD	12/31/1990	NA	NA		
103957	Coagulation Factor IX (Human)	Mononine	8/20/1992	NA	NA		
103677	Coagulation Factor IX (Recombinant)	BeneFIX BeneFIX RTS	2/11/1997	NA	NA		
125426	Coagulation Factor IX (Recombinant)	IXINITY	4/29/2015				
125446	Coagulation Factor IX (Recombinant)	RIXUBIS	6/26/2013				
125582	Coagulation Factor IX (Recombinant), Albumin Fusion Protein	IDELVION	3/4/2016				
125444	Coagulation Factor IX (Recombinant), Fc Fusion Protein	ALPROLIX	3/28/2014				
103665	Coagulation Factor VIIa (Recombinant)	NovoSeven; NovoSeven RT	3/25/1999	NA	NA		
125506	Coagulation Factor X (Human)	COAGADEX	10/20/2015				
125398	Coagulation Factor XIII A Subunit (Recombinant)	TRETTEN	12/23/2013				
125354	Coccidioides immitis Spherule-Derived Skin Test Antigen	Spherusol	7/29/2011				
125488	Crotalidae Immune F(ab') <sub>2</sub> (Equine)	Anavip	5/6/2015				
103788	Crotalidae Polyvalent Immune Fab (Ovine)	CroFab	10/2/2000	NA	NA		
103189	Cytomegalovirus Immune Globulin Intravenous (Human)	CytoGam	4/17/1990	NA	NA		
103141	Digoxin Immune Fab (Ovine)	Digibind	4/22/1986	NA	NA		
103910	Digoxin Immune Fab (Ovine)	DigiFab	8/31/2001	NA	NA		
103647	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	Infanrix	1/29/1997	NA	NA		

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103666	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	Daptacel	5/14/2002	NA	NA		
103922	Diphtheria & Tetanus Toxoids & Acellular Pertussis Vaccine Adsorbed	Tripedia	5/16/1949	NA	NA		
103919	Diphtheria & Tetanus Toxoids Adsorbed		1/29/2003	NA	NA		
103944	Diphtheria & Tetanus Toxoids Adsorbed		4/11/1997	NA	NA		
125525	Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine	Quadracel	3/24/2015				
125260	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed and Inactivated Poliovirus Vaccine DTaP & Hepatitis B (Recombinant) & Inactivated Polio Virus Vaccine	Kinrix	6/24/2008				
103907	Factor IX Complex	PEDIARIX	12/13/2002	NA	NA		
102476	Factor IX Complex	Profilinone HP; Profilinone HT; Profilinone SD; Profilinone	7/20/1981	NA	NA		
103112	Factor IX Complex	Bebulin VH Bebulin	8/21/1970	NA	NA		
125385	Factor XIII Concentrate (Human)	Corifact	2/17/2011				
125010	Fibrin Sealant (Human)	Crosseal EVICEL	3/21/2003	NA	NA		
125266	Fibrin Sealant (Human)	ARTISS	3/19/2008				
125523	Fibrin Sealant (Human)	RAPLIXA	4/30/2015				
103980	Fibrin Sealant (Tisseel)	TISSEEL	5/1/1998	NA	NA		
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	NA	NA		
103237	Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)	PedvaxHIB	12/20/1989	NA	NA		
103935	Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)	ActHIB; OmniHIB	3/30/1993	NA	NA		
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	NA	NA		
103850	Hepatitis A Inactivated & Hepatitis B (Recombinant) Vaccine	Twinrix	5/11/2001	NA	NA		
103475	Hepatitis A Vaccine Inactivated	Havrix	2/22/1995	NA	NA		
103606	Hepatitis A Vaccine Inactivated	VAQTA	3/29/1996	NA	NA		
101146	Hepatitis B Immune Globulin (Human)	BayHep B; HyperHep B S/D	9/23/1977	NA	NA		
103945	Hepatitis B Immune Globulin (Human)	Nabi-HB	10/23/2001	NA	NA		
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	NA	NA		
103239	Hepatitis B Vaccine (Recombinant)	Engerix-B	8/28/1989	NA	NA		
125391	HPC, Cord Blood		5/24/2012				
125407	HPC, Cord Blood	DuCord	10/4/2012				
125413	HPC, Cord Blood	ALLOCORD	5/30/2013				
125432	HPC, Cord Blood		6/13/2013				
125585	HPC, Cord Blood		1/28/2016				
125594	HPC, Cord Blood	CLEVECORD	9/1/2016				
125592	House Dust Mites Allergens Extract	Odactra	3/1/2017				

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125508	Human Papillomavirus 9-valent Vaccine, Recombinant	Gardasil 9	12/10/2014				
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	NA	NA		
125105	Immune Globulin Infusion (Human)	Polygam LQ; KIOVIG; GAMMAGARD LIQUID	4/27/2005				
125402	Immune Globulin Infusion (Human), 10% with Recombinant Human Hyaluronidase	HYQVIA	9/12/2014				
125046	Immune Globulin Injection (Human) 10% Caprylate/Chromatography Purified	Gamunex-C; GAMMAKED (Kendrion)	8/27/2003	NA	NA		
102367	Immune Globulin Intravenous (Human)	Sandoglobulin; Panglobulin; Carimune; Carimune NF	6/7/1984	NA	NA		
103133	Immune Globulin Intravenous (Human)	Gammagard Gammagard S/D Iivegam	2/18/1986	NA	NA		
125062	Immune Globulin Intravenous (Human)	OCTAGAM	5/21/2004	NA	NA		
125077	Immune Globulin Intravenous (Human)	Flebogamma 5%; Flebogamma; Flebogamma 5% DIF	12/15/2003	NA	NA		
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				
125596	Immune Globulin Subcutaneous (Human), 20% Solution	CUVITRU	9/13/2016				
125419	Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted		11/22/2013				
125285	Influenza Vaccine	FluBlok	1/16/2013	1/16/2013	1/16/2025		
125297	Influenza Vaccine	Agriflu	11/27/2009				
125020	Influenza Vaccine Live, Intranasal	FluMist; FluMist Quad	6/17/2003	NA	NA		
125510	Influenza Vaccine, Adjuvanted	FLUAD	11/24/2015				
103837	Influenza Virus Vaccine	FluVirin	8/12/1988	NA	NA		
103914	Influenza Virus Vaccine	Fluzone; Fluzone High Dose; Fluzone Intradermal; Fluzone Quadrivalent	12/9/1999	NA	NA		
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	NA	NA		
101834	Insects (Whole Body), Mite Dermatophagoides farinae		9/15/1958	NA	NA		
102212	Insects (Whole Body), Mite Dermatophagoides farinae		3/12/1974	NA	NA		
102224	Insects (Whole Body), Mite Dermatophagoides farinae		3/12/1974	NA	NA		
103060	Insects (Whole Body), Mite Dermatophagoides farinae		9/29/1950	NA	NA		
103870	Insects (Whole Body), Mite Dermatophagoides farinae		3/13/1924	NA	NA		
101378	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		7/11/1930	NA	NA		
101835	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		9/15/1958	NA	NA		
102213	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		3/12/1974	NA	NA		
102225	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		3/12/1974	NA	NA		
103752	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		9/29/1950	NA	NA		
103871	Insects (Whole Body), Mite Dermatophagoides pteronyssinus		3/13/1924	NA	NA		

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125280	Japanese Encephalitis Vaccine, Inactivated, Adsorbed	Ixiaro	3/30/2009				
103676	Lymphocyte Immune Globulin, Anti-thymocyte Globulin (Equine)	Atgam	11/17/1981	NA	NA		
101069	Measles, Mumps and Rubella Virus Vaccine Live	M-M-R II	4/22/1971	NA	NA		
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				
125546	Meningococcal Group B Vaccine	BEXSERO	1/23/2015				
125549	Meningococcal Group B Vaccine	TRUMENBA	10/29/2014				
125089	Meningococcal Groups (A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine	Menactra	1/14/2005	NA	NA		
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	NA	NA		
103923	Meningococcal Polysaccharide Vaccine, Group C	Menomune-C	7/11/1975	NA	NA		
103925	Meningococcal Polysaccharide Vaccine, Groups A and C Combined	Menomune-A/C	12/13/1976	NA	NA		
103926	Meningococcal Polysaccharide Vaccine, Groups A, C, Y, W135 Combined	Menomune	11/23/1981	NA	NA		
102932	Multiple Products Allergen Patch Test Kit		4/20/1988	NA	NA		
101376	Multiple Products Non-standardized Allergens		7/11/1930	NA	NA		
102223	Multiple Products Non-standardized Allergens		7/11/1930	NA	NA		
103753	Multiple Products Non-standardized Allergens		9/29/1950	NA	NA		
103888	Multiple Products Non-standardized Allergens		3/13/1924	NA	NA		
101833	Multiple Products Non-standardized Allergens		7/11/1930	NA	NA		
102211	Multiple Products Non-standardized Allergens		3/12/1974	NA	NA		
101084	Normal Horse Serum		1/2/1959	NA	NA		
103569	Plague Vaccine		10/5/1994	NA	NA		
101140	Plasma Protein Fraction (Human)	Plasmanate	10/2/1958	NA	NA		
101454	Plasma Protein Fraction (Human)	Protenate; Protenate 5%	6/16/1960	NA	NA		
125324	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Pevnar 13	2/24/2010				
103905	Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Pevnar	2/17/2000	NA	NA		
101094	Pneumococcal Vaccine, Polyvalent	Pneumovax 23	11/21/1977	NA	NA		
103930	Poliovirus Vaccine Inactivated	IPOL	12/21/1990	NA	NA		
103940	Poliovirus Vaccine Inactivated (Human Diploid Cell)	Poliovax	11/20/1987	NA	NA		
101379	Pollens - Grasses, Bermuda Grass Cynodon dactylon		6/14/1930	NA	NA		
101836	Pollens - Grasses, Bermuda Grass Cynodon dactylon		6/14/1930	NA	NA		
102214	Pollens - Grasses, Bermuda Grass Cynodon dactylon		6/14/1930	NA	NA		
102226	Pollens - Grasses, Bermuda Grass Cynodon dactylon		3/22/1974	NA	NA		
103051	Pollens - Grasses, Bermuda Grass Cynodon dactylon		9/29/1950	NA	NA		
103872	Pollens - Grasses, Bermuda Grass Cynodon dactylon		3/13/1924	NA	NA		
101380	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		6/14/1930	NA	NA		
101837	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		6/14/1930	NA	NA		
102215	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		6/14/1930	NA	NA		
103052	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		9/29/1950	NA	NA		
103421	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		3/22/1974	NA	NA		

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103873	Pollens - Grasses, Bluegrass, Kentucky (June) Poa pratensis		3/13/1924	NA	NA		
101381	Pollens - Grasses, Fescue, Meadow Festuca elatior		6/14/1930	NA	NA		
101838	Pollens - Grasses, Fescue, Meadow Festuca elatior		6/14/1930	NA	NA		
102216	Pollens - Grasses, Fescue, Meadow Festuca elatior		3/12/1974	NA	NA		
102227	Pollens - Grasses, Fescue, Meadow Festuca elatior		3/22/1974	NA	NA		
103053	Pollens - Grasses, Fescue, Meadow Festuca elatior		9/29/1950	NA	NA		
103874	Pollens - Grasses, Fescue, Meadow Festuca elatior		3/13/1924	NA	NA		
101382	Pollens - Grasses, Orchard Grass Dactylis glomerata		6/14/1930	NA	NA		
101839	Pollens - Grasses, Orchard Grass Dactylis glomerata		6/14/1930	NA	NA		
102217	Pollens - Grasses, Orchard Grass Dactylis glomerata		3/12/1974	NA	NA		
102228	Pollens - Grasses, Orchard Grass Dactylis glomerata		3/22/1974	NA	NA		
103054	Pollens - Grasses, Orchard Grass Dactylis glomerata		9/29/1950	NA	NA		
103875	Pollens - Grasses, Orchard Grass Dactylis glomerata		3/13/1924	NA	NA		
101383	Pollens - Grasses, Redtop Agrostis alba		6/14/1930	NA	NA		
101840	Pollens - Grasses, Redtop Agrostis alba		6/14/1930	NA	NA		
102218	Pollens - Grasses, Redtop Agrostis alba		3/12/1974	NA	NA		
102229	Pollens - Grasses, Redtop Agrostis alba		3/22/1974	NA	NA		
103055	Pollens - Grasses, Redtop Agrostis alba		9/29/1950	NA	NA		
103876	Pollens - Grasses, Redtop Agrostis alba		3/13/1924	NA	NA		
101384	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		6/14/1930	NA	NA		
101841	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		6/14/1930	NA	NA		
102219	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		6/14/1930	NA	NA		
102230	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		3/22/1974	NA	NA		
103056	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		9/29/1950	NA	NA		
103877	Pollens - Grasses, Ryegrass, Perennial Lolium perenne		3/13/1924	NA	NA		
101385	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		6/14/1930	NA	NA		
101842	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		6/14/1930	NA	NA		
102220	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		3/12/1974	NA	NA		
103057	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		9/29/1950	NA	NA		
103624	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		3/22/1974	NA	NA		
103878	Pollens - Grasses, Sweet Vernal Grass Anthoxanthum odoratum		3/13/1924	NA	NA		
101386	Pollens - Grasses, Timothy Phleum pratense		6/14/1930	NA	NA		
101843	Pollens - Grasses, Timothy Phleum pratense		6/14/1930	NA	NA		
102221	Pollens - Grasses, Timothy Phleum pratense		6/14/1930	NA	NA		
102231	Pollens - Grasses, Timothy Phleum pratense		3/22/1974	NA	NA		
103058	Pollens - Grasses, Timothy Phleum pratense		9/29/1950	NA	NA		
103879	Pollens - Grasses, Timothy Phleum pratense		3/13/1924	NA	NA		
101387	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		6/14/1930	NA	NA		
101844	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		6/14/1930	NA	NA		
102232	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		6/14/1930	NA	NA		

Center for Biologic Evaluation and Research  
List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date

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)/BIOSIMILAR (B)	WITHDRAWN
103113	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		3/12/1974	NA	NA		
103880	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia artemisiifolia		3/13/1924	NA	NA		
101845	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia elatior		9/15/1958	NA	NA		
103059	Pollens - Weeds and Garden Plants, Ragweed, Short Ambrosia elatior		9/29/1950	NA	NA		
125416	Pooled Plasma (Human), Solvent/Detergent Treated	OCTAPLAS	1/17/2013				
103317	Positive Skin Test Control-Histamine		3/12/1974	NA	NA		
103754	Positive Skin Test Control-Histamine	Histatrol	9/29/1950	NA	NA		
103891	Positive Skin Test Control-Histamine		3/13/1924	NA	NA		
125234	Protein C Concentrate (Human)	Ceprotrin	3/30/2007				
125421	Prothrombin Complex Concentrate (Human)	Kcentra	4/29/2013				
101144	Rabies Immune Globulin (Human)	BayRab HyperRab	6/12/1974	NA	NA		
103932	Rabies Immune Globulin (Human)	Imogam	4/27/1984	NA	NA		
103334	Rabies Vaccine	RabAvert	10/20/1997	NA	NA		
103931	Rabies Vaccine	Imovax Rabies	6/9/1980	NA	NA		
103820	Rabies Vaccine Adsorbed	BioRab	3/18/1988	NA	NA		
101141	Rho(D) Immune Globulin (Human)	BayRho-D; HypRho-D; HyperRHO S/D Full Dose HyperRHO S/D Mini-Dose	6/11/1971	NA	NA		
103777	Rho(D) Immune Globulin (Human)	RhoGAM MICRhoGAM	4/10/1968	NA	NA		
103649	Rho(D) Immune Globulin Intravenous (Human)	WinRho SDF Lyophilized; WinRho SD; WinRho SDF Liquid	3/24/1995	NA	NA		
125070	Rho(D) Immune Globulin Intravenous (Human)	Rhophylac	2/12/2004	NA	NA		
125265	Rotavirus Vaccine, Live, Oral	Rotarix	4/3/2008				
125122	Rotavirus Vaccine, Live, Oral, Pentavalent	RotaTeq	2/3/2006				
125579	Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test	Rubber Panel T.R.U.E. TEST	3/3/2017				
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				
125518	Talimogene laherparepvec	IMLYGIC	10/27/2015				
101322	Tetanus and Diphtheria Toxoids Adsorbed		7/27/1970	NA	NA		
103171	Tetanus and Diphtheria Toxoids Adsorbed	TENIVAC	11/3/2003	NA	NA		
103921	Tetanus and Diphtheria Toxoids Adsorbed	DECAVAC	3/7/1955	NA	NA		
101142	Tetanus Immune Globulin (Human)	BayTet; HyperTet	10/17/1957	NA	NA		
103913	Tetanus Toxoid Adsorbed		5/25/1934	NA	NA		
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	NA	NA		
125248	Thrombin topical (Recombinant)	RECOTHROM	1/17/2008				
102865	Thrombin, Topical (Bovine)	Thrombin-JMI; ThromboColl	2/3/1986	NA	NA		
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	NA	NA		

**Center for Biologic Evaluation and Research**  
**List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations to Date**

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
103941	Tuberculin, Purified Protein Derivative	Tubersol	9/26/1969	NA	NA		
103123	Typhoid Vaccine Live Oral Ty21a	Vivotif	12/15/1989	NA	NA		
103936	Typhoid Vi Polysaccharide Vaccine	Typhim Vi	11/28/1994	NA	NA		
125109	Vaccinia Immune Globulin Intravenous (Human)	CNI-016	5/2/2005				
103552	Varicella Virus Vaccine Live	Varivax	3/17/1995	NA	NA		
125430	Varicella Zoster Immune Globulin (Human)	VariZIG	12/20/2012				
103882	Venoms, Honey Bee Venom		3/13/1924	NA	NA		
103969	Venoms, Honey Bee Venom	Pharmalgen	10/8/1991	NA	NA		
103883	Venoms, Mixed Vespidae Venom Protein		3/13/1924	NA	NA		
103970	Venoms, Mixed Vespidae Venom Protein	Pharmalgen	10/8/1991	NA	NA		
103884	Venoms, Wasp Venom Protein		3/13/1924	NA	NA		
103971	Venoms, Wasp Venom Protein	Pharmalgen	10/8/1991	NA	NA		
103885	Venoms, White Faced Hornet Venom Protein		3/13/1924	NA	NA		
103972	Venoms, White Faced Hornet Venom Protein	Pharmalgen	10/8/1991	NA	NA		
103886	Venoms, Yellow Hornet Venom Protein		3/13/1924	NA	NA		
103973	Venoms, Yellow Hornet Venom Protein	Pharmalgen	10/8/1991	NA	NA		
103887	Venoms, Yellow Jacket Venom Protein		3/13/1924	NA	NA		
103974	Venoms, Yellow Jacket Venom Protein	Pharmalgen	10/8/1991	NA	NA		
125577	von Willebrand Factor (Recombinant)	VONVENDI	12/8/2015				
125251	von Willebrand Factor/Coagulation Factor VIII Complex (Human)	Wilate	12/4/2009				
103915	Yellow Fever Vaccine	YF-Vax	5/22/1953	NA	NA		
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 will not be the date a particular application was licensed if that 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.

FDA will generally make a determination of date of first licensure for reasons of regulatory necessity and /or at the request of the 351(a) application license holder.

The Agency will denote the date of first licensure as "not applicable" (NA) if:

- The product was licensed under 351(a) and the date it was licensed falls under any exclusion identified in 351(k)(7) (C) or

- More than 12 years (or 12 years and 6 months in the case of a product that has earned pediatric exclusivity) have passed since the date of licensure of the product and thus

any reference product exclusivity that the product may have had would have expired thus obviating the need for a determination of whether any exclusion under 351(k)(7) (C) applies.

In such cases a corresponding NA notation will also be placed in the next column "Reference Product Exclusivity Expiry Date".

**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/DevelopingProductsforRareDiseases/Conditions/HowtoapplyforOrphanProductDesignation/default.html>).

For the explanation of the notation "NA" please see the definition of "Date of First Licensure" above.

**Interchangeable (I)/Biosimilar (B):** Identification of those biological products approved/licensed under 351(k) that were licensed as either interchangeable with or biosimilar to the reference product. Such products will be listed under the 351(a) BLA referenced in the 351(k) application. Biosimilarity has been demonstrated for the condition(s) of use (e.g. indication(s) dosing regimen(s) strength(s) dosage form(s) and route(s) of administration described in the biosimilar product's Full Prescribing Information).

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

BLA STN Products with the Product (Proper) Name "Multiple Products: Non-standardized Allergenic products" include several specific non-standardized allergenic 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.

**Note:** The List of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations reflects all BLAs that were active at the time the "Purple Book" was originally published on September 9 2014. FDA will continue to update the list when FDA licenses a biological product under section 351(a) or section 351(k) of the PHS Act and/or makes a determination regarding date of first licensure for a biological product licensed under section 351(a) of the PHS Act, and to reflect other changes in the status of these biological products, as appropriate.