

**CBER Drug and Biologic Accelerated Approvals Based on a Surrogate Endpoint
As of December 31, 2022
Total Approvals 24**

NDA and BLA Accelerated Approvals

Application Number	Proprietary Name	Established Name	Applicant	CBER Received Date	Accelerated Approval Date	Total Time to Accelerated Approval (Months)	Accelerated Approval Indication	Conversion-Withdrawal Status	Full Approval Conversion-Withdrawal Date
BLA 103661 Supplement 1010	Carticel SM Service	Autologous Cultured Chondrocytes	Vericel Corporation	10/28/1999	4/28/2000	6.0	Articular Cartilage Defects in the knee	Converted	6/21/2007
BLA 125127	Fluarix	Influenza Virus Vaccine	GlaxoSmithKline Biologicals	5/25/2005	8/31/2005	3.2	for the prevention of influenza in adults 18 years and older	Converted	10/2/2009
BLA 125254	Afluria	Influenza Vaccine	Seqirus Pty Ltd	3/30/2007	9/28/2007	6.0	For active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine	Converted	12/2/2011
BLA 125317	RiaSTAP	Fibrinogen Concentrate (Human)	CSL Behring GmbH	7/18/2008	1/16/2009	6.0	Treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia	Converted	6/4/2021
BLA 125317 Supplement 125	RiaSTAP	Fibrinogen Concentrate (Human)	CSL Behring GmbH	10/4/2013	9/9/2016	35.2	indicated for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency (afibrinogenemia and hypofibrinogenemia)	Converted	6/4/2021
BLA 125347	Hiberix	Haemophilus B Conjugate Vaccine (Tetanus Toxoid Conjugate)	GlaxoSmithKline Biologicals	3/17/2009	8/19/2009	5.1	active immunization for the prevention of invasive disease caused by Haemophilus influenzae type b	Converted	4/30/2018
BLA 125297	Agriflu	Influenza Virus Vaccine	Seqirus Inc.	7/11/2008	11/27/2009	16.6	active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine	Converted	10/29/2010
BLA 125385	Corifact	Human Factor XIII Concentrate (Human)	CSL Behring GmbH	8/18/2010	2/17/2011	6.0	Routine prophylactic treatment of congenital factor XIII deficiency.	Converted	1/24/2013
BLA 125163 Supplement 176	FluLaval; FluLaval Quadrivalent	Influenza Vaccine	ID Biomedical Corporation of Quebec	8/10/2010	6/9/2011	10.0	indicated for prevention of influenza in persons 3 to 8 years	Converted	8/15/2013
BLA 125324 Supplement 262	Pevnar 13	Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)	Wyeth Pharmaceuticals LLC	12/2/2010	12/30/2011	12.9	to include the prevention of pneumonia and invasive disease caused by <i>S. pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in persons 50 years of age or older	Converted	5/22/2015
BLA 103914 Supplement 5541	Fluzone High Dose	Influenza Virus Vaccine	Sanofi Pasteur Inc.	12/1/2011	6/27/2012	6.9	indicated for prevention of influenza in adults 65 years of age and older	Converted	10/31/2014
BLA 125285 Supplement 78	FluBlok	Influenza vaccine	Protein Sciences Corporation	10/23/2013	10/29/2014	12.2	is indicated for active immunization against disease caused by influenza virus subtypes A and type B contained in the vaccine. Influenza vaccine is approved for use in persons 50 years of age and older	Converted	10/7/2016
BLA 125549	Trumenba	Meningococcal Group B Vaccine	Wyeth Pharmaceuticals LLC	6/16/2014	10/29/2014	4.4	Active immunization to prevent invasive meningococcal disease caused by <i>N. meningitidis</i> serogroup B in individuals 10 through 25 years of age.	Converted	3/13/2017
BLA 125549 Supplement 17	Trumenba	Meningococcal Group B Vaccine	Wyeth Pharmaceuticals LLC	3/27/2015	4/14/2016	12.6	two-dose schedule (a dose administered at 0 and 6 months) of Trumenba for active immunization to prevent invasive disease caused by <i>Neisseria meningitidis</i> serogroup B	Converted	11/19/2021
BLA 125408 Supplement 127	FLUCELVAX QUADRIVALENT	Influenza Vaccine	Seqirus Inc.	4/24/2015	5/23/2016	13.0	indicated for prevention of influenza in persons 4 years to <18 years of age	Converted	3/3/2021
BLA 125692	AUDENZ	Influenza A (H5N1) Monovalent Vaccine, Adjuvanted	Seqirus Inc.	2/1/2019	1/31/2020	12.0	For active immunization of influenza in persons 6 months through 17 years of age	Converted	11/17/2021
BLA 125109	CNJ-016	Vaccinia Immune Globulin Intravenous (Human)	Emergent BioSolutions Canada Inc.	11/1/2004	5/2/2005	6.0	conditions, which are complications resulting from smallpox vaccination: Eczema vaccinatum Progressive vaccinia Severe generalized vaccinia	Not Yet Converted	
BLA 125546	Bexsero	Meningococcal Group B Vaccine	GlaxoSmithKline Biologicals	7/24/2014	1/23/2015	6.0	active immunization to prevent invasive disease caused by <i>Neisseria meningitidis</i> serogroup B. Meningococcal Group B Vaccine is approved for use in individuals 10 through 25 years of age	Not Yet Converted	
BLA 125510	FLUAD	Influenza Virus Vaccine, Adjuvanted	Seqirus Inc.	11/25/2014	11/24/2015	12.0	For active immunization of persons 65 years of age and older against influenza disease caused by influenza virus subtypes A and B contained in the vaccine.	Not Yet Converted	
BLA 125586	Andexxa	coagulation factor Xa (recombinant), inactivated-zhzo	AstraZeneca AB	12/18/2015	5/3/2018	28.5	For patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding	Not Yet Converted	
BLA 125510 Supplement 143	Fluad Quadrivalent	Influenza vaccine, adjuvanted	Seqirus Inc.	1/22/2019	2/21/2020	13.0	for active immunization of persons 65 years of age and older against influenza disease caused by seasonal influenza virus subtypes A and types B	Not Yet Converted	

BLA 125508 Supplement 868	GARDASIL 9	Human Papillomavirus 9-valent Vaccine, Recombinant	Merck Sharp & Dohme Corp	12/13/2019	6/12/2020	6.0	to add prevention of oropharyngeal and other head and neck cancers caused by Human Papillomavirus (HPV)	Not Yet Converted	
BLA 125731	Prevnar 20	Pneumococcal 20-valent Conjugate Vaccine	Wyeth Pharmaceuticals LLC	10/8/2020	6/10/2021	8.0	prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of	Not Yet Converted	
BLA 125755	Skysona	elivaldogene autotemcel	bluebird bio Inc.	10/18/2021	9/16/2022	10.9	indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD)	Not Yet Converted	