CBER Pediatric Study Deferrals and Deferral Extensions[1]

This report provides the number of pediatric study deferrals requested[2], the number of deferrals granted[3], the number of deferral extensions requested, the number of deferral extensions granted, and a table detailing the granted deferrals and deferral extensions, through 12/31/2024. The information in the table is presented in the order the deferrals were granted, with the most recently granted deferral listed first.

Total deferrals[4] requested: 64
Total deferrals granted: 77
Total deferral extensions[5] requested: 47
Total deferral extensions granted: 41

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125812/0	Humacyte Global Inc.	Human Acellular Vessel - SYMVESS	12/19/2024	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	6/30/2029	
125796/0	ModernaTX, Inc.	Respiratory Syncytial Virus Vaccine, mRNA (mRNA-1345) - MRESVIA	5/31/2024	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	12/31/2025	
					n/a	n/a	2/28/2028	
					n/a	n/a	12/31/2026	
					n/a	n/a	3/31/2029	
					n/a	n/a	12/31/2031	
					n/a	n/a	12/31/2027	

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125743/0	**Green Cross Corporation**	**Original BLA for licensure for GCC 10% IGIV - Alyglo**	12/15/2023	Ready for approval for use in adults before pediatric studies are complete Note: Deferral is for patients 2 to < 17 years of age	n/a	n/a	11/30/2026	
125251/382	**Octapharma Pharmazeutika Produktionsges.m.b.H.**	**von Willebrand Factor/Coagulation Factor VIII Complex (Human) - Wilate**	12/1/2023	Ready for approval for use in adults before pediatric studies are complete Note: Deferral is for patients 2 to < 6 years of age	yes	Because of delays involving study participants, study sites, and/or study management.	~~5/312024~~ 9/30/2025	Deferral extension granted on 6/26/2024
125770/0	**Pfizer Ireland Pharmaceuticals**	**Meningococcal Groups A, B, C, W and Y Vaccine - PENBRAYA**	10/20/2023	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	5/31/2027	
					n/a	n/a	11/30/2030	
125742/276	**BioNTech Manufacturing GmbH**	**COVID-19 Vaccine, mRNA - COMIRNATY**	9/11/2023	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	4/30/2025	released & replaced [sBLA.686]
					n/a	n/a	9/30/2026	

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125769/0	**Pfizer Inc.**	**Respiratory Syncytial Virus Vaccine - ABRYSVO**	5/31/2023	**0 to <2yo: additional safety or effectiveness data have not been collected;** **2 to <18 yrs of age: ready for approval in adults and pediatric studies have not been completed.**	3/26/2025	delays due to safety and/or pharmacokinetic issues	~~9/30/2024~~ 6/30/2025	5/6/2025 (submitted)
					n/a	n/a	6/30/2025	6/5/2025 (submitted)
					n/a	n/a	6/30/2026	
					n/a	n/a	6/30/2028	
125775/0	**GlaxoSmithKline Biologicals**	**Respiratory Syncytial Virus Vaccine Recombinant, Adjuvanted - AREXVY**	5/3/2023	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	5/30/2026	
					n/a	n/a	5/30/2028	
125777/0	**Valneva Austria GmbH**	**Chikungunya Vaccine, Live - IXCHIQ**	11/9/2023	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	11/30/2024	3/14/2025 (submitted)
					n/a	n/a	1/31/2026	
					n/a	n/a	6/30/2027	
					n/a	n/a	2/28/2029	
					n/a	n/a	10/31/2030	

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125752/0	**ModernaTX, Inc.**	**COVID-19 Vaccine, mRNA**	1/31/2022	Ready for approval for use in adults before pediatric studies are complete	9/13/2024	Delays involving study participants, sites, and/or management	~~12/31/2024~~ 6/30/2030	
					n/a	n/a	7/31/2024	3/28/2023 (fulfilled)
125752/68			9/11/2023	Ready for approval for use in >12yo before pediatric studies in 2y to <12yo are complete	1st DE: 9/13/2024 2nd DE: 12/17/2024	Delays involving study participants, sites, and/or management	~~3/31/2024~~ ~~6/30/2030~~ 1/25/2025	1/5/2025
125742/0	BioNTech Manufacturing GmbH	**COMIRNATY** COVID-19 mRNA Vaccine	8/23/2021	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	10/31/2023	7/8/2022 (fulfilled)
					n/a	n/a	10/31/2024	(closed/released)
					5/20/2022	Delays involving study participants, sites, and/or management	~~10/31/2024~~ 12/31/2024	Released and replaced with 2 new PMRs [sBLA.656]

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125741/0	Merck Sharp & Dohme Corp.	**VAXNEUVANCE** Pneumococcal 15-valent Conjugate Vaccine [CRM197 Protein], adsorbed -	7/16/2021	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	4/30/2022	6/17/2022 (fulfilled)
					n/a	n/a	12/31/2021	6/17/2022 (fulfilled)
					n/a	n/a	7/31/2021	6/17/2022 (fulfilled)
					n/a	n/a	12/31/2022	6/17/2022 (fulfilled)
125731/0	Wyeth Pharmaceuticals LLC	**PREVNAR 20** 20-valent Pneumococcal Conjugate Vaccine	6/8/2021	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	12/31/2022	10/26/2022 (fulfilled)
					n/a	n/a	12/31/2022	10/26/2022 (fulfilled)
					n/a	n/a	12/31/2022	10/26/2022 (fulfilled)
125587/70	Octapharma Pharmazeutika Produktionsges. m.b.H.	**PANZYGA** Immune Globulin Intravenous (Human)-ifas	2/11/2021	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	6/30/2025	

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125701/0	Sanofi Pasteur Inc.	**MenQuadfi** Meningococcal (Groups A, C, Y, W) Polysaccharide Tetanus Toxoid Conjugate Vaccine	4/23/2020	Ready for approval for use in adults before pediatric studies are complete	9/19/2022	delays involving study participants, sites, and/or management due to the COVID-19 pandemic.	~~8/31/2023~~ 10/31/2024	5/23/2025 (fulfilled)
					9/19/2022	delays involving study participants, sites, and/or management due to the COVID-19 pandemic.	~~8/31/2024~~ 10/31/2024	5/23/2025 (fulfilled)
					9/19/2022	delays involving study participants, sites, and/or management due to the COVID-19 pandemic.	~~2/28/2023~~ 10/31/2024	5/23/2025 (fulfilled)
125696/0	Aimmune Therapeutics, Inc.	**Palforzia** Peanut (Arachis hypogaea) Allergen Powder	1/31/2020	Ready for approval for use in adults before pediatric studies are complete	6/22/2021 (125696/110)	because of delays involving study participants, sites, and/or management due to the COVID-19 pandemic.	6/30/2022	7/26/2024 (fulfilled)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125692/0	Seqirus Inc.	**AUDENZ** Influenza A (H5N1) Monovalent Vaccine, Adjuvanted	1/31/2020	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	The product is in the Strategic National Stockpile (SNS) and pediatric studies are contingent on on H5N1 pandemic	
125510/143	Seqirus Inc.	**FLUAD** Influenza Vaccine, Adjuvanted	2/21/2020	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	4/30/2019	4/28/2020 (fulfilled/released)
125641/0	Laboratoire Francais du Fractionnement et des Biotechnologies S.A.	**SEVENFACT** Coagulation Factor VIIa (Recombinant)	4/1/2020	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	7/10/2020	5/25/2022 (fulfilled)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125682/0	**Sanofi Pasteur Inc.**	**DENGVAXIA** **Dengue Tetravalent Vaccine (Live, Attenuated)**	5/1/2019	Ready for approval for use in individuals 9 through 16 years of age before studies in pediatric subjects 2 years to <9 years are complete	8/29/2019	(125682/5)	10/1/2020	7/27/2023 (fulfilled)
					8/29/2019	(125682/5)	10/1/2020	7/27/2023 (fulfilled)
					8/29/2019	(125682/5)	10/1/2020	7/27/2023 (fulfilled)
				Pediatric studies in ages 6 months-<2 years should be delayed until additional safety or effective data have been collected.	n/a	n/a	3/31/2028	6/30/2023 (released)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125690/0	**Merck Sharp & Dohme Corp**	**ERVEBO** **Ebola Zaire Vaccine**	12/19/2019	Ready for approval for use in adults and the pediatric study has not been completed	4/16/2021	delays involving study participants, sites, and/or management; additional time required to prepare the study report and/or submission.	6/30/2022	7/27/2023 (fulfilled)
103914/6290	Sanofi Pasteur Inc.	**Fluzone; Fluzone High Dose; Fluzone Intradermal; Fluzone Quadrivalent** Influenza Virus Vaccine	11/4/2019	Ready for approval for use in adults and the pediatric study has not been completed	n/a	n/a	4/30/2021	6/9/2022 (submitted)
					n/a	n/a	6/30/2025	
					n/a	n/a	1/31/2024	7/1/2020 (released)
					n/a	n/a	1/31/2025	7/1/2020 (released)
					n/a	n/a	1/31/2025	7/1/2020 (released)
125251/244	Octapharma Pharmazeutika Produktionsges.m.b.H.	**Wilate** von Willebrand Factor/Coagulation Factor VIII Complex (Human)	9/25/2019	Ready for approval for use in adults and the pediatric study has not been completed	n/a	n/a	12/31/2019	3/22/2024 (fulfilled)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125590/0	ADMA Biologics, Inc.	**ASCENIV** Immune Globulin Intravenous (Human), 10% Liquid	4/1/2019	Ready for approval for use in adults and the pediatric study has not been completed	5/11/2023	1). Delays involving study participants, sites, and/or management 2). Recruitment challenges. COVID-19 pandemic impacted the start-up activities at every clinical site	~~6/30/2023~~ 6/30/2026	
125668/0	Octapharma Pharmazeutika Produktionsges. m.b.H.	**CUTAQUIG** Immune Globulin Subcutaneous (Human) - hipp	12/12/2018	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	12/31/2020	11/19/2021 (fulfilled)
125587/0	Octapharma USA, Inc.	**Panzyga** Immune Globulin Intravenous (Human) – ifas	8/2/2018	Ready for approval for use in adults before pediatric studies are complete	9/9/2022	Delays involving study participants, sites, and/or management.	~~10/31/2022~~ 12/31/2028	
125640/0	Instituto Grifols, S.A.	**VISTASEAL** Fibrin Sealant (Human)	11/1/2017	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	9/27/2024	
125201/728	CSL Behring AG	**Privigen** Immune Globulin Intravenous (Human), 10% Liquid	9/14/2017	Ready for approval for use in adults before pediatric studies are complete	2/3/2023	Delays involving study participants, sites, and/or management and acknowledge the particular enrollment and recruitment challenges	7/31/2030	

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125613/0	Kamada Ltd.	**KEDRAB** Rabies Immune Globulin (Human)	8/23/2017	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	1/15/21	5/17/2021 (fulfilled)
125612/0	Octapharma Pharmazeutika Produktionsges. m.b.H.	**FIBRYGA** Fibrinogen (Human)	6/7/2017	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	6/30/21	12/23/2020 (fulfilled)
125592/0	ALK – Abello A/S	**Odactra** House Dust Mites Allergenics Extract	3/1/2017	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	7/1/22	12/22/2021 (released)
					n/a	n/a	7/1/22	12/22/2021 (released)
125603/0	Vericel Corporation	**MACI** Autologous Cultured Chondrocytes Seeded on a Porcine Collagen Membrane	12/13/16	Ready for approval for use in adults before pediatric studies are complete	4/8/2023	Delays involving study participants, sites, and/or management	12/31/2025	

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125392/163	Ethicon, Inc.	**EVARREST** Fibrin Sealant Patch	10/7/16	Ready for approval for use in adults before pediatric studies are complete	1/29/2019 1/30/2024	Delays involving study participants, sites, and /or management due to difficulty recruiting eligible pediatric subjects The 2nd DE (125392/449) received on 12/10/2020, and granted 0n Jan 29, 2021 delays involving study participants, sites, and/or management.	~~3/31/2021~~ ~~3/31/2024~~ 12/31/2025	Deferral extension granted 1/30/2024
125285/433	Protein Sciences Corporation	**FluBlok** Influenza Vaccine	7/15/2020	replace PREA PMR #1 (125285/194) pediatric study PSC17 with VAP0004; Due to the ongoing COVID-19 pandemic and low rates of influenza virus circulation during the last two seasons, conduct of an efficacy study of Flublok Quadrivalent is infeasible.	n/a	n/a	12/31/2023	4/18/2022 (released/replaced with 2 new PMRs)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125285/194	Protein Sciences Corporation	**FluBlok** Influenza Vaccine	10/7/16	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	6/30/20	7/15/2020 (released/replaced)
125285/471	Protein Sciences Corporation	**FluBlok** Influenza Vaccine	4/18/2022 reissued new PMR #1	Replaced 125285/433	n/a	Delays involving study participants, sites, and/or management due to COVID-19 pandemic	12/31/2023	3/31/2025 (fulfilled)
125285/471	Protein Sciences Corporation	**FluBlok** Influenza Vaccine	4/18/2022reissued new PMR #2	Replaced 125285/433	11/13/2023	Delays involving study participants, sites, and/or management; due to COVID-19 pandemic	12/31/2023	3/31/2025 (fulfilled)
125254/565	bioCSL Pty Ltd	**AFLURIA** Influenza Vaccine	8/26/16	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	12/31/16	8/31/2027 (fulfilled)
					n/a	n/a	12/31/17	10/4/2028 (fulfilled)
125597/0	PaxVax Bermuda Ltd	**Vaxchora** Cholera Vaccine Live Oral	6/10/16	Ready for approval for use in adults before pediatric studies are complete	5/2/2019	Due to continuing interaction between applicant and FDA	~~6/30/19~~ 9/30/2020	12/23/2020 (fulfilled)
125408/127	Novartis Vaccines and Diagnostics, Inc.	**Flucelvax Quadrivalent** Influenza Vaccine	5/23/16	Ready for approval in persons 4 yrs to <18 yrs of age and the pediatric study in children 6 mons to <4 yrs of age has not been initiated.	n/a	n/a	2/28/21	10/14/2021 (fulfilled)

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125408/101	Novartis Vaccines and Diagnostics, Inc.	**Flucelvax** Influenza Vaccine	5/23/16	Ready for approval in persons 4 yrs to <18 yrs of age and the pediatric study in children 6 mons to <4 yrs of age has not been initiated.	n/a	n/a	2/28/21	3/3/2021 (released)
125549/17	Wyeth Pharmaceuticals Inc.	**TRUMENBA** Meningococcal Group B Vaccine	4/14/16	Two-dose regimen is ready for approval for use in persons 10 through 25 years of age and the study in children 1 year to less than 10 years of age has not been completed.	n/a	n/a	5/31/21	5/24/2022 (released)
125549/773	Wyeth Pharmaceuticals Inc.	**TRUMENBA** Meningococcal Group B Vaccine	5/24/2022	Request for Release of PREA PMR #5 (125549/0) and PREA PMR #2 (125549/17) (both Study B1971051); and to Replace with new PREA PMR Study C3511005.	n/a	n/a	4/26/2026	2-dose regimen: partial waiver granted 6/18/2024 3-dose: released/replaced 6/30/2025
125549/827	Wyeth Pharmaceuticals Inc.	**TRUMENBA** Meningococcal Group B Vaccine	5/24/2022 Reissued new PMR	3-dose regimen is ready for approval for use in individuals 10yo - 25yo before pediatric studies in 1 to <10yo are complete	n/a	n/a	5/31/2027	

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125510/0	Seqirus (previously Novartis Vaccines and Diagnostics, Inc.)	**FLUAD** Influenza Vaccine, Adjuvanted	11/24/15	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	4/30/19	3/29/2019 (fulfilled)
					n/a	n/a	4/30/19	3/29/2019 (fulfilled)
					n/a	n/a	2/28/23	1/22/2019 (released)
					n/a	n/a	2/28/23	1/22/2019 (released)
125566/0	Baxter Healthcare Corporation	**ADYNOVATE** Antihemophilic Factor (Recombinant), PEGylated	11/13/15	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	6/30/16	2/25/2016 (fulfilled)
					n/a	n/a	12/31/17	2/25/2016 (fulfilled)
					n/a	n/a	9/30/19	6/14/2021 (fulfilled)

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125523/0	ProFibrix, BV.	**Raplixa** Fibrin Sealant (Human)	4/30/15	ineffective or impractical in pediatric patients ages 0 to 18 years	9/8/16	Because of delays involving study participants, sites, and/or management.	~~3/31/16~~ 12/31/18	10/11/2018 (released)
125426/31	Aptevo Bio Therapeutics LLC	**IXinity** Coagulation Factor IX (Recombinant)	10/17/2018	Ready for approval for use in adults before pediatric studies are complete	10/17/2018	Delays due to issues with the study drug and delays involving study participants, sites, and management	12/14/2021	(delayed)
					7/26/2022	Delays involving study participants, sites, and/or management	1/30/2023	(delayed)
					7/23/2023	Additional time required to prepare the study report and/or submission.	6/30/2023	3/22/2024 (fulfilled)
125426/0	Cangene Corporation	**IXinity** Coagulation Factor IX (Recombinant)	4/29/15	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	12/31/17	1/20/2016 (released & replaced with supplement # 31)
125392/33	Ethicon, Inc.	**EVARREST** Fibrin Sealant Patch	3/26/15	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	3/31/17	3/31/2017 (released)

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125546/0	Novartis Vaccines and Diagnostics, Inc.	**BEXSERO** Meningococcal Group B Vaccine	1/23/15	The product is ready for approval for use in persons 10 through 25 years of age and the studies in children 6 weeks to less than 10 years of age have not been completed.	n/a	n/a	12/31/15	3/15/2023 (submitted)
					6/7/2018 2nd granted 8/19/2024	Due to continuing interaction between applicant and FDA delays due to continuing interaction between the applicant and the FDA; additional time required to prepare the study report and/or submission	~~3/31/18~~ ~~6/30/2024~~ 6/30/2026	
125471/0	Stallergenes, Inc.	**Oralair** Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract	4/1/14	Ready for approval for use in adults before pediatric studies are complete	7/15/16	Because of delays involving study participants, sites, and/or management	~~12/31/16~~ 12/31/17	11/9/2018 (fulfilled)

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125478/0	Merck Sharp & Dohme Corp.	**Ragwitek** Short Ragweed Pollen Allergen Extract	4/17/14	Ready for approval for use in adults before pediatric studies are complete	n/a	n/a	9/30/19	6/17/2020 (fulfilled)
					n/a	n/a	9/30/19	6/17/2020 (released)
125402/0	Baxter Healthcare Corporation	**HYQVIA** Immune Globulin Infusion (Human), 10% with Recombinant Human Hyaluronidase	9/12/2014	The pediatric study should be delayed until additional safety data pertaining to Recombinant Human Hyaluronidase immunogenicity are available.	n/a	n/a	7/31/27	4/7/2023 (fulfilled)

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125549/0	Wyeth Pharmaceuticals Inc.	**TRUMENBA** Meningococcal Group B Vaccine	10/29/14	Ready for approval for use in adults before pediatric studies are complete	1/30/2107	Because of delays involving study participants, sites, and/or management	~~2/28/17~~ 12/31/17	10/12/2017 (submitted)
					1/30/2017	Because of delays involving study participants, sites, and/or management	~~8/30/17~~ 5/31/18	3/15/2018 (submitted)
					n/a	n/a	5/31/21	5/24/2022 (released)
125419/0	ID Biomedical Corporation of Quebec	Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted-	11/22/13	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	4/30/15	9/9/2016 (fulfilled)
					n/a	n/a	06/30/19	9/9/16 (released)
					n/a	n/a	10/31/20	9/9/16 (released)

					n/a	n/a	12/31/22	Schedule revised under 125419/39 Final Protocol Submission: 2 weeks after notification by the FDA to finalize the protocol in the event of an imminent H5N1 influenza virus pandemic (human to human H5N1 transmission) Study Completion Date: 16 months after initiation of the study Final Report Submission: 4 months after completion of data collection

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125163/254	ID Biomedical Corporation of Quebec	**FluLaval Quadrivalent** Influenza Virus Vaccine	08/16/13	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	03/31/16	1/27/2016 (fulfilled)
125163/253	ID Biomedical Corporation of Quebec	**FluLaval Quadrivalent** Influenza Virus Vaccine	08/15/13	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	03/31/16	1/27/2016 (fulfilled)
125446/0	Baxter Healthcare Corporation	**Rixubis** Coagulation Factor IX (Recombinant)	06/26/13	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	01/31/14	11/13/2013 (fulfilled)
125416/0	Octapharma Pharmazeutika Produktionsges. m.b.H.	**Octaplas** Pooled Plasma (Human), Solvent/ Detergent Treated	1/17/2013	Ready for approval for use in adults before pediatric studies are complete.	8/10/16	Because of delays involving study participants, sites, and/or management	~~9/30/16~~ 7/31/18	7/31/2018 (fulfilled)
					9/1/2017	Because of delays involving study participants, sites, and/or management	~~10/31/17~~ 10/31/20	10/30/2020 (fulfilled)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125285/0	Protein Sciences Corporation	**FluBlok** Influenza Vaccine	1/16/13	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	11/30/15	2/2/16 (released and replaced with supplement # 194)
					n/a	n/a	06/30/17	10/7/16 (released & replaced with supplement# 194)
125389/0	Biotest Pharmaceuticals Corporation	**Bivigam** (Immune Globulin Intravenous (Human)	12/19/12	Ready for approval for use in adults before pediatric studies are complete.	~~11/18/16~~ 4/15/2021	Because of delays due to issues with the study drug and/or comparator drug	~~10/31/17~~ ~~6/30/21~~ 12/31/2022	12/8/2023 (fulfilled)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125127/513	GlaxoSmithKline Biologicals	**Fluarix Quadrivalent** (Influenza Virus Vaccine)	12/14/12	Ready for approval for use in adults before pediatric studies are complete.	8/23/13 (first extension)	Delays involving study participants, sites, and/or management	~~3/31/14~~ ~~12/31/15~~ 6/14/2019	5/22/2020 (fulfilled)
					11/16/15 2nd extension	Additional time required to prepare the study report and/or submission	~~12/31/15~~ 1/31/17	1/19/17 (fulfilled)
125392/0	Ethicon, Inc.	**EVARREST** (Fibrin Sealant Patch)	12/5/12	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	3/31/17	10/7/16 (released & replaced under supplement #163)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125408/0	Seqirus (previously Novartis Vaccines and Diagnostics GmbH)	**Flucelvax** (Influenza Vaccine)	11/20/12	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	11/30/2024	3/3/2021 (released)
					n/a	n/a	11/30/14	5/23/2016 (fulfilled)
					n/a	n/a	11/30/16	3/3/2021 (released)
					n/a	n/a	11/30/18	5/23/16 (released & replaced with supplement# 101)
125408/101	Seqirus	**Flucelvax** (Influenza Vaccine)	5/23/2016	approval in persons 4 years to <18 years of age and the pediatric study in children 6 months to <4 years of age has not been initiated.	n/a	n/a	2/28/2021	3/3/2021 (released)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125408/127	Seqirus	**Flucelvax Quadrivalent** (Influenza Vaccine)	5/23/2016	ready for approval for use in persons 4 years of age and older and the pediatric study in children 6 months to <4 years of age has not been completed.	n/a	n/a	2/28/2021	10/14/2021 (fulfilled)
125400/0	Organogenesis, Inc.	**GINTUIT** (Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen)	3/9/12	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	3/31/17	(delayed) PREA non compliance letter issued on 6/29/17
103738/5074	SmartPractice Denmark ApS	**T.R.U.E. Test** (Multiple Products: Allergen Patch Test Kit - Thin Layer Rapid Use Epicutaneous Test)	2/29/12	Ready for approval for use in adults before pediatric studies are complete.	12/30/13	Delays involving study participants, sites, and/or management	~~12/31/13~~ ~~12/31/15~~ 3/16/16	10/26/2016 (fulfilled on 8/25/2017)
125384/0	Kedrion, S.p.A.	**Kedbumin** (Albumin (Human)	6/3/11	Ready for approval for use in adults before pediatric studies are complete.	2/3/14	Delays involving study participants, sites, and/or management	~~12/31/13~~ 5/31/15	7/15/2015 (released)
125280/19	Intercell AG	**Ixiaro** (Japanese Encephalitis Virus Vaccine Inactivated)	10/14/10	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	6/30/15	6/16/2017 (fulfilled in 4/13/2018)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125046/619	Grifols Therapeutics Inc.	**Gamunex** (Immune Globulin Intravenous (Human), 10%, Caprylate/ Chromatography Purified (IGIV-C))	10/13/10	Ready for approval for use in adults before pediatric studies are complete.	12/27/13	Delays involving study participants, sites, and/or management	~~2/13/14~~ 6/30/14	2/4/2015 (fulfilled on 12/4/2015)
125351/0	Takeda Pharma A/S	**TachoSil** (Fibrin Sealant Patch)	4/5/10	Ready for approval for use in adults before pediatric studies are complete.	7/3/13	Delays involving study participants, sites, and/or management	~~12/31/12~~ 2/28/14	6/20/2014 (fulfilled on 8/5/2015)
125350/0	CSL Behring AG	**Hizentra** (Immune Globulin Subcutaneous (Human), 20% Liquid) *Injectable*	3/4/10	Ready for approval for use in adults before pediatric studies are complete.	6/28/13	n/a	8/31/10	8/20/2021 (fulfilled in 2/17/2011)
125324/0	Wyeth Pharmaceuticals Inc.	**Prevnar 13** (Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)) *Injectable*	2/24/10	Other - Ready for approval for routine immunization in infants and children 6 weeks through 5 years of age, and the pediatric study in children 6 through 16 years of age is not complete.	n/a	n/a	12/31/11	3/28/2012 (fulfilled on 1/25/2013)

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125300/0	Novartis Vaccines and Diagnostics, Inc.	**Menveo** (Meningococcal [Groups A, C, Y, and W 135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine) *Injectable*	2/19/10	Other - Ready for approval for use in adults and adolescents, and pediatric studies for younger age groups of 2 months through 10 years are not complete.	n/a	n/a	3/31/10	4/1/10
					n/a	n/a	3/31/11	4/13/11
					n/a	n/a	3/31/11	4/13/11
					6/28/13	Delays involving study participants, sites, and/or management	~~12/31/11~~ 1/30/13	1/30/13
					6/28/13	Delays involving study participants, sites, and/or management	~~7/31/12~~ 1/30/13	1/30/13
125297/0	Novartis Vaccines and Diagnostics, Inc.	**Agriflu** (Influenza Vaccine) *Injectable*	11/27/09	Ready for approval for use in adults before pediatric studies are complete.	7/9/13	Delays involving study participants, sites, and/or management	~~1/31/12~~ 2/28/13	2/28/13
					7/9/13	Delays involving study participants, sites, and/or management	~~1/31/13~~ 7/31/13	8/1/13
125259/0	GlaxoSmithKline Biologicals	**Cervarix** (Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant) *Injectable*	10/16/09	Other - Ready for approval in females 10 through 25 years of age.	n/a	n/a	6/30/10	6/17/2010

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
125329/0	Bio Products Laboratory	**Gammaplex** (Immune Globulin Intravenous (Human), 5% Liquid) *Injectable*	9/17/09	Ready for approval for use in adults before pediatric studies are complete.	9-25-13	Delays involving study participants, sites, and/or management	~~12/31/12~~ 12/31/14	9/29/2014
125347/0	GlaxoSmithKline Biologicals	**Hiberix** (Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)) *Injectable*	8/19/09	Other - Ready for approval in children 15 months – 4 years of age and the study in patients 6 weeks – 14 months has not been completed.	n/a	n/a	12/31/13	1/7/2014
125280/0	Intercell AG	**Ixiaro** (Japanese Encephalitis Virus Vaccine Inactivated) *Injectable*	3/30/09	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	9/30/12	7/18/12
					n/a	n/a	9/30/12	7/18/12
125248/0	ZymoGenetics, Inc.	**Recothrom** (Thrombin topical (Recombinant)) *Solution*	1/17/08	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	12/31/10	7/13/10

BLA/NDA Number	Sponsor	Product	Deferral Granted[6]	Reason for Deferral[7]	Deferral Extension Granted	Reason for Deferral Extension[8]	Study Due[9]	Study Complete[10]
070012	Fresenius Kabi Deutschland GmbH	**Voluven** (6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection) *Injectable*	12/27/07	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	12/27/10	5/10/11
125254/0	CSL Limited	**Afluria** (Influenza Virus Vaccine) *Injectable*	9/28/07	Ready for approval for use in adults before pediatric studies are complete.	n/a	n/a	6/30/10	6/30/10
					n/a	n/a	6/30/10	6/30/10
					n/a	n/a	6/30/10	6/30/10

[1] This report is prepared annually in response to Sections 505B(f)(6)(D)(i), 505B(f)(6)(D)(ii), and 505B(f)(6)(I) of the Food, Drug and Cosmetic Act ("FD&C Act"), as amended by the Food and Drug Administration Safety and Innovation Act ("FDASIA").

[2] Requests for deferrals were identified in NDAs and BLAs submitted to CBER. This number includes deferral requests contained in applications, some of which the Agency has not yet approved, or for which the Agency has determined that a deferral is not appropriate. This number does not include deferral requests for products exempt from PREA (e.g., orphan drugs).

[3] Granted deferrals were identified in approval letters.

[4] FDA began reporting deferral information in response to the Food and Drug Administration Amendments Act of 2007 (FDAAA), which was enacted 09/27/07.

[5] Section 505B(a)(3)(B) of the FD&C Act outlines the process for deferral extensions. FDA began reporting deferral extension information in response to FDASIA, which was enacted 07/09/12.

[6] The "Deferral Granted" date is the date the application is approved, since deferrals are granted within approval letters.

[7] Section 505B(a)(3)(A) of the FD&C Act lists the appropriate reasons for granting deferrals.

[8] Section 505B(a)(3)(B) of the FD&C Act discusses deferral extensions. Additional information about the reasons deferral extension were granted is included in this table:

Reasons for deferral extensions	**Examples of the types of scenarios associated with each reason**
Delays due to issues with the study drug and/or comparator drug	• Delays developing an age-appropriate formulation • Product quality and stability issues • Comparator drug shortage
Delays involving study participants, sites, and/or management	• Difficulty recruiting study participants • High rate of site personnel turnover • Additional time needed to address expected issues in study conduct
Delays due to safety and/or pharmacokinetic issues	• Additional safety data are required • Must review new pharmacokinetic data before proceeding with the study • Study proceeding with a more cautious approach due to new potential safety signals
Delays due to continuing interaction between the applicant and the FDA	• The FDA placed the study on clinical hold • The FDA requested a change in the protocol • The applicant and the FDA are negotiating a different study to fulfill the PREA requirement

Additional time required to prepare the study report and/or submission	• Delays collecting and compiling the study data • Additional time required to analyze the study data • Additional time required to prepare a supplemental NDA with appropriate pediatric labeling

[9] Each study due date represents one pediatric postmarketing study requirement (PMR). Where deferral extensions have been granted, the original study due date is struck through, and the new study due date is listed below the original date.

[10] "Study Complete" dates indicate when the FDA received studies. If upon review of a study, the FDA determines that a PREA PMR requirement was not met, this date will be removed. If the FDA releases a PMR, it is deleted from this table unless the PMR is superseded by another PMR (the Study Complete date may be revised in this circumstance). Therefore, the total number of deferrals granted may be more than the number of rows in the table. Some deferred pediatric studies have been released/replaced with new studies and revised timelines. These are reflected in this table along with the supplement # that corresponds to the new study. These new studies may have design changes or, in the case of seasonal influenza, may replace the trivalent formulation with quadrivalent.