

CBER Pediatric Study Deferrals and Deferral Extensions¹

This report provides the number of pediatric study deferrals requested², the number of deferrals granted³, the number of deferral extensions requested, the number of deferral extensions granted, and a table detailing the granted deferrals and deferral extensions, through 12/31/2022. The information in the table is presented in the order the deferrals were granted, with the most recently granted deferral listed first.

Total deferrals⁴ requested: 53

Total deferrals granted: 67

Total deferral extensions⁵ requested: 36

Total deferral extensions granted: 30

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	n/a n/a n/a	n/a n/a n/a	12/31/2024 7/31/2024 3/31/2024	
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 5/20/2022	n/a n/a Delays involving study participants, sites, and/or management	10/31/2023 10/31/2024 4/31/2024 12/31/2024	7/8/2022 (fulfilled)
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 n/a n/a	n/a n/a n/a n/a	4/30/2022 12/31/2021 7/31/2021 12/31/2022	9/31/2021 (submitted) 9/30/2021 (submitted) 9/30/2021 (submitted) 9/30/2021 (submitted)

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
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 (submitted)
					n/a	n/a	12/31/2022	10/26/2022 (submitted)
					n/a	n/a	12/31/2022	10/26/2022 (submitted)
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	
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	
					9/19/2022	delays involving study participants, sites, and/or management due to the COVID-19 pandemic.	8/31/2024 10/31/2024	
					9/19/2022	delays involving study participants, sites, and/or management due to the COVID-19 pandemic.	2/28/2023 10/31/2024	

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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	
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	Study is complete but delay in submitting results

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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	Study is complete but delay in submitting results
				Pediatric studies in ages 6 months-<2 years should be delayed until additional safety or effective data have been collected.	8/29/2019	(125682/5)	10/1/2020	Study is complete but delay in submitting results
					8/29/2019	(125682/5)	10/1/2020	Study is complete but delay in submitting results
					n/a	n/a	3/31/2028	Study is complete but delay in submitting results
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	

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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	12/18/2019 (study complete but delay in analyzing results)
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	n/a	n/a	6/30/2023	
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)

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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.	40/31/2022 10/31/2026	
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	6/30/2024	
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	n/a	n/a	7/31/2023	
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 Allergenic Extract	3/1/2017	Ready for approval for use in adults before pediatric studies are complete	n/a n/a	n/a n/a	7/1/22 7/1/22	12/22/2021 (released) 12/22/2021 (released)

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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	n/a	n/a	12/31/25	
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	Delays involving study participants, sites, and/or management due to difficulty recruiting eligible pediatric subjects The 2 nd DE (125392/449) received on 12/10/2020, and granted On Jan 29, 2021	3/31/2021 3/31/2024	
125285/433	Protein Sciences Corporation	FluBlok Influenza Vaccine	7/15/2020	replace PREA PMR #1 (125285/194) pediatric study PSC17 with VAP0004	n/a	n/a	12/31/2023	
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	5/7/2020 (released/replaced)
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	n/a n/a	12/31/16 12/31/17	12/31/2016 12/31/2017

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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	n/a n/a	2/28/21 2/28/2021	10/14/2021 (fulfilled)
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	delayed

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125510/0	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	12/22/16
					n/a	n/a	12/31/17	12/22/16
					n/a	n/a	9/30/19	10/4/2019
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	

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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)
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 6/7/2018	n/a Due to continuing interaction between applicant and FDA	12/31/15 3/31/18 6/30/2024	12/31/2015
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	n/a n/a	9/30/19 9/30/19	6/17/2020 (fulfilled) 6/17/2020 (released)10/
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	
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	1/30/2017 1/30/2017 n/a	Because of delays involving study participants, sites, and/or management Because of delays involving study participants, sites, and/or management n/a	2/28/17 12/31/17 8/30/17 5/31/21 5/31/21	12/18/2020 (submitted) 7/8/2021 (delayed) 12/18/2020 (submitted)

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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 n/a n/a	n/a n/a n/a n/a	4/30/15 06/30/19 10/31/20 12/31/22	9/9/16 9/9/16 (released) 9/9/16 (released)
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	1/27/16
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	1/27/16
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	11/13/13

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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 9/1/2017	Because of delays involving study participants, sites, and/or management Because of delays involving study participants, sites, and/or management	9/30/16 7/31/18 10/31/17 10/31/20	7/31/2018 (fulfilled) 10/30/2020 (fulfilled)
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	n/a n/a	11/30/15 06/30/17	2/2/16 (released and replaced with supplement # 194) 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	

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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) 11/16/15 2 nd extension	Delays involving study participants, sites, and/or management Additional time required to prepare the study report and/or submission	3/31/14 4/23/15 6/14/2019 12/31/15 1/31/17	5/22/2020 (fulfilled) 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)
125408/0	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 n/a n/a	n/a n/a n/a n/a	5/31/14 11/30/14 11/30/16 11/30/18	5/28/14 11/20/14 11/30/16 5/23/16 (released & replaced with supplement # 101)

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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	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	8/25/17
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	(released on 7/15/15)
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	6/30/15
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	2/4/15

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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	4/31/12 2/28/14	6/19/14
125350/0	CSL Behring AG	Hizentra (Immune Globulin Subcutaneous (Human), 20% Liquid) <i>Injectable</i>	3/4/10	Ready for approval for use in adults before pediatric studies are complete.	6/28/13	n/a	8/31/10	8/20/10
125324/0	Wyeth Pharmaceuticals Inc.	Pprevnar 13 (Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)) <i>Injectable</i>	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	3/28/12
125300/0	Novartis Vaccines and Diagnostics, Inc.	Menveo (Meningococcal [Groups A, C, Y, and W 135] Oligosaccharide Diphtheria CRM197 Conjugate Vaccine) <i>Injectable</i>	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 n/a 6/28/13 6/28/13	n/a n/a n/a Delays involving study participants, sites, and/or management Delays involving study participants, sites, and/or management	3/31/10 3/31/11 3/31/11 4/31/11 1/30/13 7/31/12 1/30/13	4/1/10 4/13/11 4/13/11 1/30/13 1/30/13

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125297/0	Novartis Vaccines and Diagnostics, Inc.	Agriflu (Influenza Vaccine) <i>Injectable</i>	11/27/09	Ready for approval for use in adults before pediatric studies are complete.	7/9/13 7/9/13	Delays involving study participants, sites, and/or management Delays involving study participants, sites, and/or management	4/31/12 2/28/13 4/31/13 7/31/13	2/28/13 8/1/13
125259/0	GlaxoSmithKline Biologicals	Cervarix (Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant) <i>Injectable</i>	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
125329/0	Bio Products Laboratory	Gammplex (Immune Globulin Intravenous (Human), 5% Liquid) <i>Injectable</i>	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)) <i>Injectable</i>	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) <i>Injectable</i>	3/30/09	Ready for approval for use in adults before pediatric studies are complete.	n/a n/a	n/a n/a	9/30/12 9/30/12	7/18/12 7/18/12

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125248/0	ZymoGenetics, Inc.	Recothrom (Thrombin topical (Recombinant)) <i>Solution</i>	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
070012	Fresenius Kabi Deutschland GmbH	Voluven (6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection) <i>Injectable</i>	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) <i>Injectable</i>	9/28/07	Ready for approval for use in adults before pediatric studies are complete.	n/a n/a n/a	n/a n/a n/a	6/30/10 6/30/10 6/30/10	6/30/10 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	<ul style="list-style-type: none">• Delays developing an age-appropriate formulation• Product quality and stability issues• Comparator drug shortage
Delays involving study participants, sites, and/or management	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.