Notice of Pediatric Formulations Not Marketed[1] or Not Introduced into the Market within 1 Year of the Publication of Notice that Pediatric Exclusivity was Granted

The table below identifies those drugs for which pediatric formulations were developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) but that were not introduced onto the market within one year of the date of publication of the notice required under 21 U.S.C. 355a(e)(1) that pediatric exclusivity had been granted.

NDA #	Product	Sponsor	PE Pub Date[2]	Approval Date	Marketing Start Date
210709	Tekturna (aliskiren) Oral Pellets	Noden Pharma DAC	October 19, 2017	November 14, 2017	Not Currently Marketed
21518/017	VESIcare (solifenacin succinate) tablets	Astellas	August 10, 2017		
207027	Promacta (eltrombopag) for oral suspension	Novartis Pharmaceuticals Corporation	August 19, 2015	August 24, 2015	September 27, 2018
204736	Aciphex Sprinkle (rabeprazole sodium delayed-release capsules)	Cerecor, Inc.	December 20, 2012	March 26, 2013	March 1, 2018
22157	Xyzal (levocetirizine dihydrochloride) Oral Solution	Sanofi-Aventis U.S. LLC	September 15, 2009	January 28, 2008	July 24, 2017
22020/002	Protonix (pantoprazole sodium) For Delayed-Release Oral Suspension	Wyeth Pharmaceuticals	February 26, 2009	November 12, 2009	
22257	Valcyte (valganciclovir) Oral Solution	Hoffman-LaRoche	August 1, 2008[3]	August 28, 2009	August 28, 2009

1. Complies with 21 U.S.C. 355a(e)(2) of the Federal Food, Drug, and Cosmetic Act.
2. Date of Public Notice Indicating that Pediatric Exclusivity has been Granted.
3. Valcyte was not permitted to market before it was approved on August 28, 2009. Because of this fact, it was not possible to market the pediatric formulation within the one year after the date of publication of the notice required under 21 U.S.C. 355a(e)(1) stating that pediatric exclusivity had been granted.