***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 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.**

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| NDA # | Product | Sponsor | PE Pub Date[2] | Approval Date |
|---|---|---|---|---|
| 22020/002 | PROTONIX (pantoprazole sodium) For Delayed-Release Oral Suspension | Wyeth Pharmaceuticals | February 26, 2009 | November 12, 2009 |
| 22-257 | Valcyte (valganciclovir) | Hoffman-LaRoche | August 1, 2008[3] | 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.