BPCA Process for Joint FDA-Industry Planning of Pediatric Research

A. Sponsor submits a PPSR to FDA outlining what pediatric research it would like to do in exchange for 6 months additional exclusivity. The process may begin at either A. or B. Sponsor agrees to WR C. If the research is completed B. FDA issues WR to the sponsor according to WR, sponsor gets 6 outlining the research that it must months additional exclusivity regardless conduct, including timeline for of whether the drug proves effective completion and number of patients. in a pediatric population or not. Sponsor declines WR E. If the NIH research shows pediatric D. FDA may issue WR to NIH if the efficacy, new indications can be added sponsor declines or the drug is already to the drug's FDA label, but it requires off patent. Sponsor does not obtain any agreement of the drug's sponsor. exclusivity benefits from research conducted by NIH.