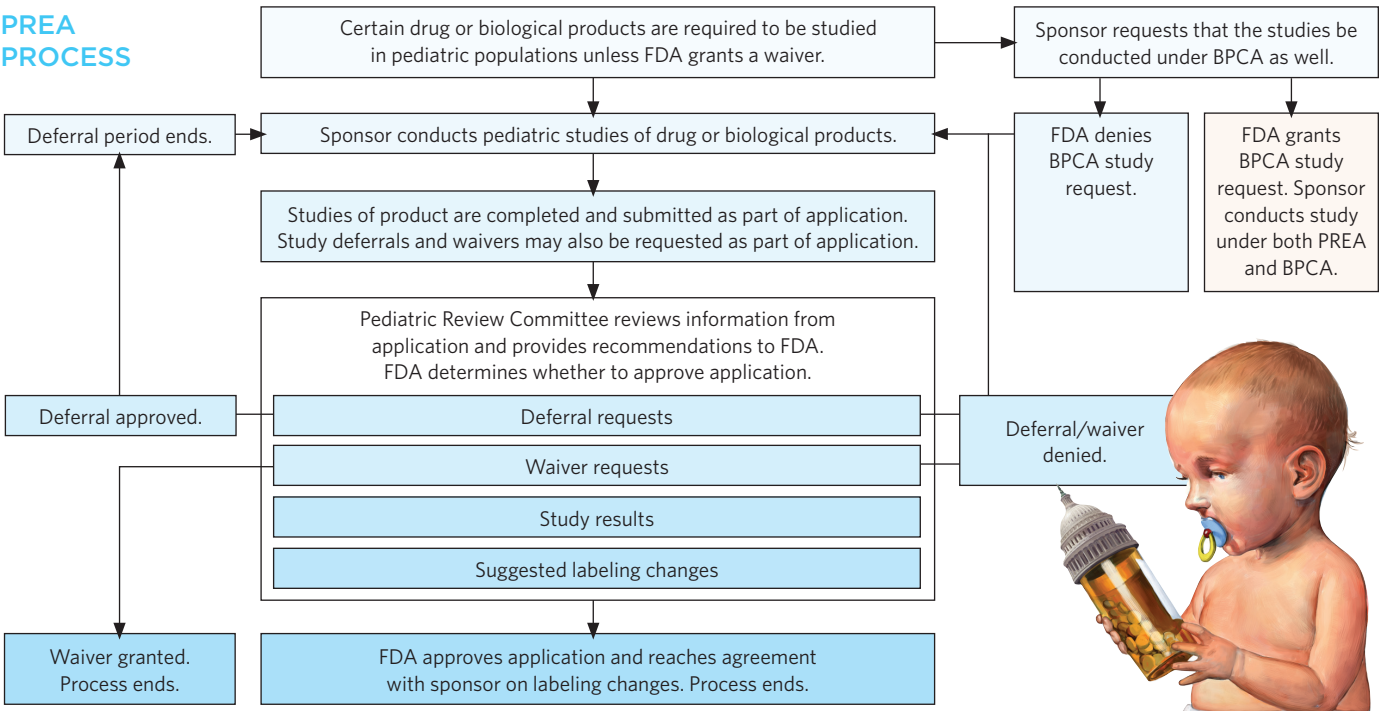
HOW THE LAWS WORK

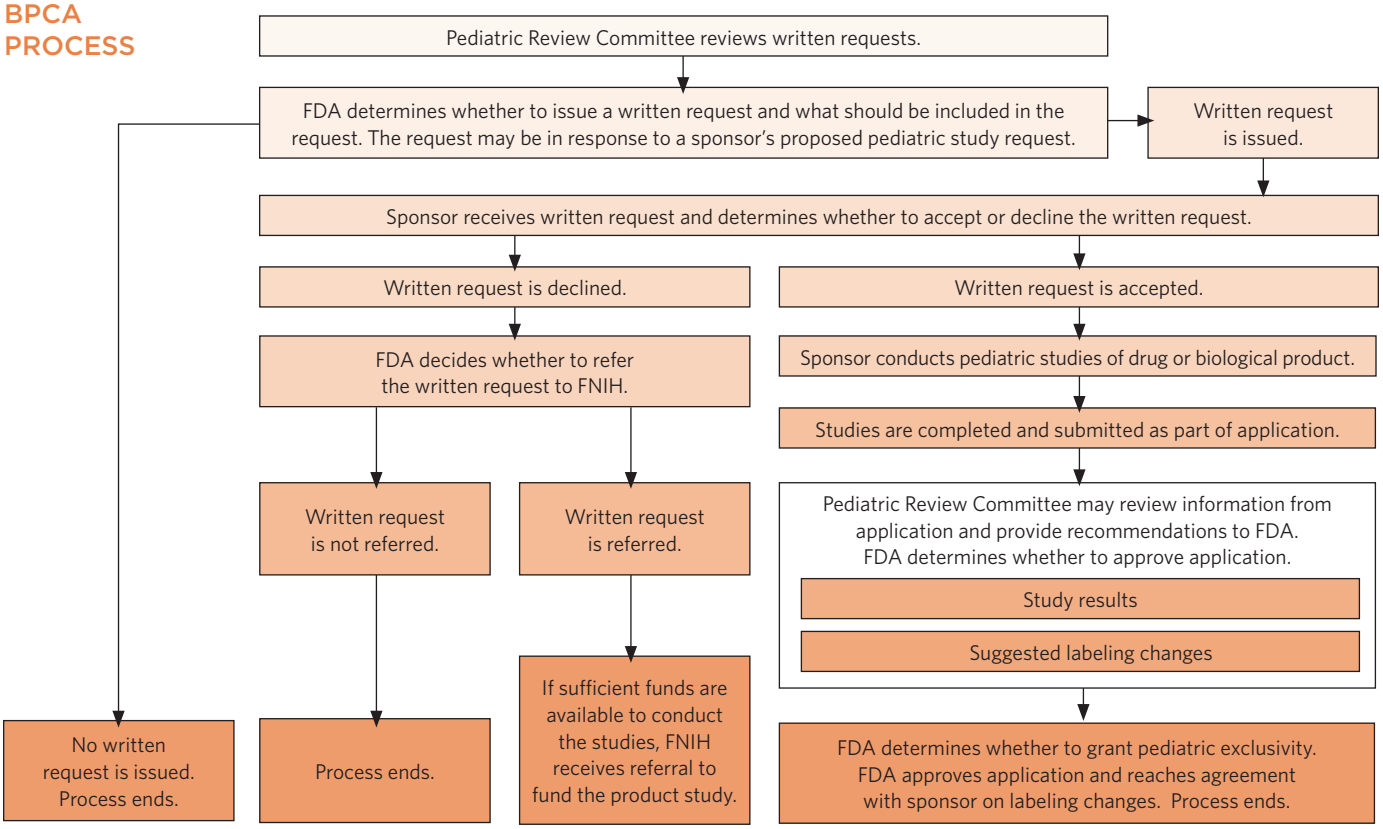
The Pediatric Research Equity Act (PREA) of 2003 requires that companies developing new drugs that could be used to treat a condition in children perform clinical trials in kids before winning FDA approval. The Best Pharmaceuticals for Children Act (BPCA) of 2002 offers

PREA PROCESS



PEDIATRIC RESEARCH EQUITY ACT (PREA): Any new drug that could be used to treat a condition that exists in pediatric populations must be tested under PREA before gaining FDA approval. Companies seeking approval can defer conducting the trials or apply for a waiver, but if pediatric testing is completed and submitted to FDA, it may change the labeling on packages containing the new product.

BPCA PROCESS



BEST PHARMACEUTICALS FOR CHILDREN ACT (BPCA): Often already-approved drugs are tested under BPCA. If the FDA determines the need for pediatric testing of a drug, for example if it's being prescribed to a large number of children off-label, they may request that its maker perform the trials in exchange for a marketing exclusivity extension, which can be very lucrative.

MATT COLLINS (BABY); SOURCE: US GOVERNMENT ACCOUNTABILITY OFFICE REPORT - GAO-11-457, "PEDIATRIC RESEARCH," MAY, 2011. THE SCIENTIST, MARCH 2012