

Pediatric Formulations

In accordance with sections 505A(f)(6)(D) and 505B(f)(6)(F) of the Federal Food, Drug, and Cosmetic Act, as amended by the FDA Amendments Act (FDAAA), the following tables provide the number of pediatric formulations developed and not developed.

FDAAA was signed September 27, 2007. These tables reflect applications submitted under FDAAA between September 27, 2007 and December 31, 2018.

BPCA - 505A(f)(6)(D)

Total Number of Pediatric Formulations Developed	= 3
Total Number of Pediatric Formulations Not Developed	= 0

PREA - 505B(f)(6)(F)

Total Number of Pediatric Formulations Developed	= 16
Total Number of Pediatric Formulations Not Developed	= 0

Both BPCA and PREA

Total Number of Pediatric Formulations Developed	= 14
Total Number of Pediatric Formulations Not Developed	= 0