

Annual Pediatric Labeling Changes Summary

BPCA

This table presents an annual summary of the labeling changes made as a result of pediatric studies conducted under section 505A of the Federal Food, Drug, & Cosmetic Act.

Type of Labeling Change	2007*	2008
	Total = 5	Total = 25
Boxed Warning with Pediatric Information	1	0
Expanded Age to Include Pediatric Age Groups Not Previously Included. Includes New Indication in Pediatric Population	4	12
Specific Pediatric Dosing Change/adjustment	0	1
New or Enhanced Pediatric Safety Information	0	4
Safety & Effectiveness Not Established in Pediatrics	2	12

PREA

This table presents an annual summary of the labeling changes made as a result of pediatric studies conducted under section 505B of the Federal Food, Drug, & Cosmetic Act.

Type of Labeling Change	2007*	2008
	Total = 6	Total = 31
Boxed Warning with Pediatric Information	0	0
Expanded Age to Include Pediatric Age Groups Not Previously Included. Includes New Indication in Pediatric Population	5	31
Specific Pediatric Dosing Change/adjustment	0	2
New or Enhanced Pediatric Safety Information	1	7
Safety & Effectiveness Not Established in Pediatrics	0	0

Data is updated and reported on an annual basis.

*FDAAA was signed September 27, 2007. Data for 2007 represents labeling changes made between September 27, 2007 and December 31, 2007.

For more information, please visit

<http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/UCM163159.pdf>