

Annual Pediatric Labeling Changes Summary

Utilizing BPCA Legislation

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	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
	Total = 4 labeling changes	Total = 7 labeling changes	Total = 10 labeling changes	Total = 4 labeling changes	Total = 5 labeling changes	Total = 4 labeling changes	Total = 5 labeling changes	Total = 4 labeling changes	Total = 7 labeling changes	Total = 3 labeling changes	Total = 9 labeling changes	Total = 5 labeling changes
Boxed Warning with Pediatric Information	1	0	0	0	0	0	0	0	0	0	0	0
Expanded Age to Include Pediatric Age Groups Not Previously Included. Includes New Indication in Pediatric Population	3	1	4	0	1	1	2	2	4	1	6	2
Specific Pediatric Dosing Change/adjustment	0	0	0	0	0	0	0	1	0	0	0	0
New or Enhanced Pediatric Safety Information	0	2	6	1	0	1	0	2	0	2	2	1
Safety & Effectiveness Not Established in Pediatrics	1	5	4	3	4	3	3	1	3	2	3	2

Utilizing PREA Legislation

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.

with Pediatric Information												
Expanded Age to Include Pediatric Age Groups Not Previously Included. Includes New Indication in Pediatric Population	1	12	7	2	5	6	5	4	11	1	12	11
Specific Pediatric Dosing Change/adjustment	0	2	0	0	1	1	1	1	0	0	0	1
New or Enhanced Pediatric Safety Information	0	2	1	0	1	1	1	0	2	0	1	1
Safety & Effectiveness Not Established in Pediatrics	1	8	3	0	0	0	0	1	3	1	2	2

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.

Please note that a single labeling change can have several types of labeling changes.

For more information, please visit <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/UCM163159.pdf>