

## Annual Pediatric Labeling Changes Summary Through 2021

BPCA

Type of Labeling Change	Boxed Warning with Pediatric Information	Expanded Age to Include Pediatric Age Groups Not Previously Included	Specific Pediatric Dosing Change/Adjustment	New or Enhanced Pediatric Safety Information	Safety & Effectiveness Not Established in Pediatrics	TOTAL Number of Labeling Changes
2021	0	1	0	0	2	3
2020	0	2	0	0	2	4
2019	0	2	0	3	2	4
2018	0	1	0	1	2	4
2017	1	7	0	2	4	10
2016	0	1	0	1	1	2
2015	0	4	0	0	3	7
2014	0	1	1	2	1	3
2013	0	1	0	0	3	4
2012	0	1	0	0	2	3
2011	0	1	0	1	4	5
2010	1	1	0	2	3	6
2009	1	4	0	6	4	10
2008	0	1	0	2	5	7
2007	1	4	0	0	1	5

**PREA**

<b>Type of Labeling Change</b>	<b>Boxed Warning with Pediatric Information</b>	<b>Expanded Age to Include Pediatric Age Groups Not Previously Included</b>	<b>Specific Pediatric Dosing Change/Adjustment</b>	<b>New or Enhanced Pediatric Safety Information</b>	<b>Safety &amp; Effectiveness Not Established in Pediatrics</b>	<b>TOTAL Number of Labeling Changes</b>
<b>2021</b>	1	40	1	2	4	46
<b>2020</b>	0	36	1	7	4	40
<b>2019</b>	0	41	2	3	2	48
<b>2018</b>	0	28	0	3	2	32
<b>2017</b>	0	31	0	2	3	34
<b>2016</b>	0	45	1	1	4	50
<b>2015</b>	0	26	3	2	4	35
<b>2014</b>	0	24	1	3	4	31
<b>2013</b>	0	22	1	5	2	31
<b>2012</b>	0	20	0	7	4	24
<b>2011</b>	0	17	2	2	2	22
<b>2010</b>	0	23	0	5	1	26
<b>2009</b>	0	18	1	2	1	22
<b>2008</b>	0	30	2	7	2	32
<b>2007</b>	0	5	0	1	0	6

**BPCA+PREA**

<b>Type of Labeling Change</b>	<b>Boxed Warning with Pediatric Information</b>	<b>Expanded Age to Include Pediatric Age Groups Not Previously Included</b>	<b>Specific Pediatric Dosing Change/Adjustment</b>	<b>New or Enhanced Pediatric Safety Information</b>	<b>Safety &amp; Effectiveness Not Established in Pediatrics</b>	<b>TOTAL Number of Labeling Changes</b>
<b>2021</b>	1	16	0	4	6	22
<b>2020</b>	0	5	1	0	1	6
<b>2019</b>	0	12	0	3	2	14
<b>2018</b>	0	11	1	1	1	13
<b>2017</b>	0	11	0	1	1	11
<b>2016</b>	0	1	0	0	1	3
<b>2015</b>	0	12	0	2	1	12
<b>2014</b>	0	4	1	0	1	5
<b>2013</b>	0	5	1	1	0	6
<b>2012</b>	0	3	0	2	4	7
<b>2011</b>	0	5	1	2	1	7
<b>2010</b>	0	2	0	0	1	3
<b>2009</b>	0	7	0	1	3	9
<b>2008</b>	0	11	2	2	8	19
<b>2007</b>	0	1	0	0	1	1

## **Information**

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.

Data for the current year represents labeling changes up to the date the report was generated.

The total number of pediatric labeling changes reflects the number of pediatric labeling changes in a given calendar year pursuant to BPCA and/or PREA. The total number of pediatric labeling changes will not necessarily equal the number of labeling change types highlighted in this report.

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