PEDIATRIC EXCLUSIVITY LABELING CHANGES AS OF SEPTEMBER 1, 2001

(Source: www.fda.gov/cder/pediatric/labelchange.htm)

Delay	Exclusivity Granted (Labeled)	Product	Indications	Label Changes
9 Months	12/6/99 (8/11/00)	Etodolac-Lodine (Wyeth Ayerst)	Relief of signs & symptoms of Juvenile Rheumatoid Arthritis	New indication in 6 years -16 years Higher dose (per kg basis) in younger children which is approximately 2 times the lower dose recommended for adults
2 Months	5/22/01 (7/19/01)	Buspirone - Buspar (Bristol-Myers Squibb)		• Safety and effectiveness **were not established** in patients 6 to 17 years of age for treatment of General Anxiety Disorder at doses recommended for use in adults • PK parameters (AUC and Cmax) of buspirone and its active metabolite were found to be equal to or higher in children and adolescents than that of adults
8 Months	1/3/00 (9/28/00)	Fluvoxamine-Luvox (Solvay)	Treatment of obsessions and compulsions in patients with OCD	Determined that a dose adjustment (increased dose) may be necessary in adolescents and girls 8 - 11 year of age may require lower doses
18 Months	8/11/99 (2/23/01)	Propofol - Diprivan (AstraZeneca)	Induction and/or maintenance of anesthesia	• Maintenance of anesthesia- age decreased down to 2 months from 3 years • Induction of anesthesia remains the same- 3 years of age and above • Concomitant administration with fentanyl may result in serious bradycardia • Abrupt discontinuation following prolonged infusion may result in flushing of hands and feet, agitation, tremulousness and hyperirritability • Propofol is not indicated for pediatric ICU sedation as safety has not been established. In a single multicenter trial of ICU sedation in critically ill pediatric patients (patients with upper respiratory tract infections excluded), the incidence of mortality (causality not established) was 9% in the propofol arm versus 4% in the standard sedative agents arm