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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20652
<http://www.fda.gov/dockets/ecomments>

Docket Number: 02N-0152

Dear Sir or Madam:

As a pediatrician who cares for infants and children every day, I welcome the opportunity to comment on the relationship between the 1998 Pediatric Rule and the Best Pharmaceuticals for Children Act (P.L. 107-109). As a member of the American Academy of Pediatrics (AAP), I know that the AAP has advocated for appropriately tested and labeled medications for infants, children and adolescents for over 40 years.

A dual approach to obtaining essential pediatric data was instituted in the late 1990's. This approach combines: 1) incentives for voluntary studies of drug safety and dosing by industry (extended in January 2002 in the Best Pharmaceuticals for Children Act [BPCA]); and 2) a regulation requiring pediatric studies of new drugs and some already marketed drugs, known as the Pediatric Rule.

In March 2002 the FDA proposed to suspend the Pediatric Rule. While this proposal was reversed, this action indicates that children are at risk of losing the ground we have fought so hard to secure for them.

I believe that all components of the 1998 Pediatric Rule must be preserved. It is a comprehensive approach to securing pediatric studies. FDA has not yet invoked all the provisions of the Pediatric Rule; however, together they weave a safety net for children to ensure that children have appropriate drugs available for their use.

Thank you for your consideration of these comments.

Sincerely,

02N-0152

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