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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:

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.

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.

The following comments and recommendations respond to questions and issues raised in the Federal Register notice soliciting public comments:

- Retiring or relaxing any authorities currently in the Pediatric Rule is inappropriate and would be to the detriment of children.
- The Pediatric Rule should mirror the scope of the BPCA and apply to all labeled and potential indications as well as new indications. If a company submits a supplemental indication to the FDA, it invokes the Pediatric Rule. It is important that appropriate pediatric studies be conducted for that new use; and if the current label lacks appropriate pediatric use information (e.g., for neonates) the FDA should also include in their requirement for pediatric studies of the new indication, any pediatric studies that may be needed for the currently labeled or potential indications.
- In determining the process of when pediatric studies are conducted, the FDA should rely on the detailed process for requesting pediatric studies of already marketed drugs and securing labeling that is outlined in the BPCA.

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- It is essential that the Pediatric Rule remain in place because it is the only mechanism that ensures that biological products will be studied and available for children.
- Appropriate formulations are an essential component of providing medications for the pediatric population. It is a requisite for studies in infants and younger children to develop age appropriate formulations, if necessary. Failure to require needed formulations for specific age populations negates the intent of the BPCA and the Pediatric Rule.
- BPCA limits its reference to "recommendation" for formulation changes only to studies completed under public contract. This provision was included to acknowledge that once a formulation is developed in the study phase, while it may be necessary to manufacture that formulation, it may not always be possible to scale up the formulation for distribution to the general public.

Thank you for your consideration of these comments.

Sincerely,

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