

PEDIATRIC CARDIOVASCULAR PROGRAM

Duke University Medical Center
Durham, NC 27710

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July 5, 2002

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Dockets Management Branch
(HFA-305)

Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, MD 20852

<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). Significant progress toward pediatric drug studies and labeling has been made over the last five years.

The March 2002 proposal by the FDA to suspend the Pediatric Rule will put children at risk. We will lose the ground we have fought so hard to secure for the children.

The Pediatric Rule is an essential tool in ensuring that children have the quality and quantity of drugs they need. The Pediatric Rule makes medications for children a certainty, not an option.

- All components of the current 1998 Pediatric Rule must remain in place. Securing properly studied medicines for children must not be left to chance.
- Every pediatric study requested through BPCA or required by the Pediatric Rule must incorporate and reflect the spirit and intent of the ethical standards articulated in Subpart D.
- In assessing whether an adult indication occurs in children, FDA should consider the pathophysiology of disease in children vs adults, metabolic pathway, and mechanism of action of the drug to decide appropriateness and necessity of pediatric studies. Retiring or relaxing any authorities currently in the Pediatric Rule is inappropriate and would be to the detriment of children.
- The Pediatric Rule should apply to all labeled and potential indications as well as new indications.
- The rule should apply to child specific indications that may not exist, or exist to a minimum degree in the adult population. It is essential that studies in infants and younger children are carried out to develop age appropriate formulations.

Sincerely,


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02N-0152

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DUKE
CHILDREN'S
Hospital & Health Center

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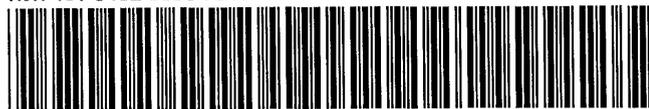
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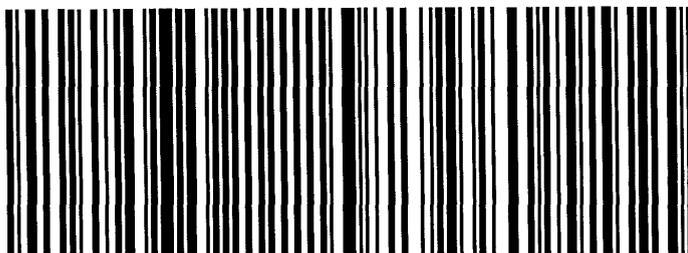
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