Aventis Pharmaceuticals

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July 13, 2001

Sent via fax and UPS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. OON-0074
Interim Rule - Additional Safeguards for Children in Clinical Investigations of FDA-Related Products [FR April 24, 2001]

Dear Sir/Madam:

Aventis Pharmaceuticals is pleased to have the opportunity to comment on the "Interim Rule on Additional Safeguards for Children in Clinical Investigations of FDA-Related Products". This interim rule would bring FDA regulations into compliance with provisions of the Children's Health Act of 2000, which requires that within 6 months of its enactment all research involving children that is conducted, supported, or regulated by the Department of Health and Human services (HHS) be in compliance with HHS regulations providing additional protections for children involved as subjects in research.

After reviewing this interim rule, Aventis has no objections to the FDA proposal.

Sincerely,

James Boyd

James Boyd, Ph.D., MBA
N.A. Regulatory Center Head
Global Drug Regulatory Affairs

OON-0074

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