Aventis Pharmaceuticals

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February 1, 2000

Via fax and UPS

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

Re: Docket No. 00N-1545
Applications for FDA Approval to Market a New Drug; Proposed Revision of Postmarketing Reporting Requirements; 65 Fed Reg 66665 (Nov. 7, 2000)

Dear Sir/Madam:

Aventis Pharmaceuticals is pleased to provide the following comment on the above-referenced proposed rule entitled, "Applications for FDA Approval to Market a New Drug; Proposed Revision of Postmarketing Reporting Requirements". The proposal would implement a provision of FDAMA regarding sole manufacturers of certain drugs that are life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition.

In view of the type of drugs aimed at in this proposed rule, we have no objections to the FDA proposal.

Thank you for your consideration.

Sincerely,

James Boyd

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

00N-1545 C2

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