Aventis Pharmaceuticals

August 18, 2003

Via Fax and UPS

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

Re: Docket No. 2003D-0231
Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format-Postmarketing Periodic Adverse Drug Experience Reports; 68 FR 37504 (June 24, 2003)

Dear Sir/Madam:

Aventis Pharmaceuticals is pleased to provide the following comments on the above-referenced draft guidance for industry entitled, *"Providing Regulatory Submissions in Electronic Format-Postmarketing Periodic Adverse Drug Experience Reports"*. This guidance discusses issues related to the electronic submission of postmarketing periodic adverse drug experience reports for drug products marketed for human use with new drug applications (NDAs) and abbreviated new drug applications (ANDAs), and therapeutic and blood products marketed for human use with biologics license applications (BLAs). This guidance does not apply to vaccines, whole blood or components of whole blood.

Page 2 Line 57
II. General Issues

Will there be a test period for submission of descriptive information by physical media?

2003D-0231

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Aventis Pharmaceuticals Inc. · www.aventis.com
200 Crossing Boulevard · PO Box 6890 · Bridgewater, NJ 08807-0890 · Telephone (908) 304-7000

Page 3, Line 100
II. D. Sending in the submission

Does FDA have a recommendation for frequency of sending periodic ICSRs? Although lines 172-178 outline the time frames for submissions for quarterly and annual reports, these are currently done in batch by paper. With the use of the gateway, does FDA recommend routine submission of periodic (e.g. weekly or monthly) ICSRs, so as not to 'clog' the gateway with very large files?

Page 4, lines 114-115
The *Expedited Safety Reports* guidance also indicates that you should send ICSR attachments to the FDA on physical media

Since Aventis already submits secure email to FDA, can ICSR attachments be submitted to FDA via secure email, rather than via physical media?

Page 4, Lines 128-133;
2. Descriptive information
Page 9, Lines 354-360;
B. Descriptive information
Page 10, Lines 388-406
2. Descriptive information for human drugs and biological products

What are the limitations to the size of the descriptive information file?

On behalf of Aventis Pharmaceuticals, we appreciate the opportunity to comment on the draft guidance for industry entitled, *"Providing Regulatory Submissions in Electronic Format-Postmarketing Periodic Adverse Drug Experience Reports"* and thank you for your consideration.

Sincerely,

Erin A. Floyd for S.C.

Steve Caffe, MD
Vice President, Head US Regulatory Affairs