Aventis Pharmaceuticals

June 27, 2001

Via fax and UPS

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

Re: Docket No. 99N-1852
Draft Guidance for Industry: Reports on the Status of Postmarketing Studies – Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997; 66 Fed Reg, p. 17912-17914 (April 4, 2001)

Dear Sir/Madam:

Aventis Pharmaceuticals and Aventis Behring together are pleased to provide the following comments on the above-referenced draft guidance for industry entitled "Reports on the Status of Postmarketing Studies – Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." The guidance would provide recommendations on procedures, content, and format for submitting a postmarketing study status report for an approved human drug or licensed biological product; timeframes for FDA's review of postmarketing studies; and information about postmarketing studies that will be available to the public.

Aventis Pharmaceuticals and Aventis Behring (henceforth: Aventis) strongly support FDA's efforts in providing the industry with guidance in fulfilling FDA's reporting requirements. We are directly affected by this guidance and offer the following comments for your consideration:

99N-1852 C 10

General Comment

Aventis feels there is a lack of clarity in the guidance as to what must be reported, specifically, that there is confusion between postmarketing commitments and other postmarketing studies.

Specific Comments on the Guidance Proposal

Aventis comments appear as boxed text below the draft guidance reference.

II.A, Lines 1-2 (p. 2)
"Postmarketing studies are those performed by you, a drug or biologics applicant, after FDA has granted approval to market its product."

As the text addresses the reader in the second person, using the pronoun *"its"* in the second part of the sentence is confusing. The word *"its"* should be changed to *"your,"* such that the sentence reads *"...performed by you, a drug or biologics applicant, after FDA has granted approval to market your product."*

III.C, Lines 3-5 (p. 9)
"The annual status reports required by 21 CFR 314.81(b)(2) and 601.70 are due within 60 days of the anniversary of the NDA, ANDA, or BLA approval in the United States."

This statement could be misunderstood as referring to the period beginning 60 days prior to the anniversary date, and ending 60 days following it. Aventis suggests clarifying the guidance text by changing the phrase *"within 60 days of the anniversary"* to *"within 60 days after the anniversary date."* The same wording should be used also on page 10, last paragraph, lines 3-4, and again on page 12, line 4.

III.E, Lines 1-8 (p. 12)
"When a postmarketing study has been completed, you should submit a final report as a separate submission to the NDA, ANDA, or BLA.... The cover letter, regardless of the type of submission (e.g., supplement, annual report, other), should always prominently identify the submission as ***POSTMARKETING COMMITMENT – STUDY FINAL REPORT****...."*

- Aventis suggests deleting the phrase *"regardless of the type of submission (e.g., supplement, annual report, other),"* because it contradicts the preceding sentence, which states that final report should be a separate submission. As a separate submission, it would not be part of a supplement, annual report, or any other type of submission.
- When should the final report be submitted, in relation to the completion of the study?

Appendix B, Title (p. 21)
"POSTMARKETING STATUS SUMMARY"

Aventis suggests that the title of the web-site posting be clarified to read: "POSTMARKETING COMMITMENT STATUS SUMMARY."

Appendix B, Lines 4-6 (p. 21)
"U.S. Approval Date: 12/31/97
Annual Report Due Date: 12/31/99
Annual Report Received: 02/01/00."

Section III.C, paragraph 1 states that the annual report is due within 60 days of the anniversary. Therefore, the Annual Report Due Date shown in this example is incorrect. It should read *"Annual Report Due Date: 02/29/00."*

Thank you for your consideration.

Sincerely,

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

On behalf of: James Boyd

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

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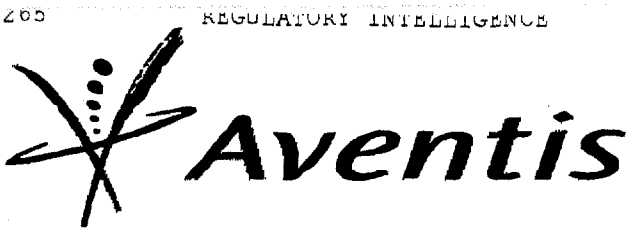

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FAX

Date: June 27, 2001

Number of pages including cover sheet: 5

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REMARKS: ☐ Urgent ☐ For your review ☐ Reply ASAP ☐ Please comment

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To Whom It May Concern:

Aventis Pharmaceuticals and Aventis Behring together are pleased to provide comments on the above mentioned Draft Guidance.

We will also be sending a copy by UPS.

Regards,

Patti Stasiulaitis

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