Aventis Pharmaceuticals

Aventis

January 5, 2000

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. 00D-1562
Draft Guidance for Industry on Cancer Drug and Biological Products—Clinical Data in Marketing Applications

Dear Sir/Madam:

Aventis Pharmaceuticals is pleased to have the opportunity to comment officially on the "Draft Guidance for Industry on Cancer Drug and Biological Products—Clinical Data in Marketing Applications" in response to the Federal Register notice of November 9, 2000. While we agree with many of the recommendations given in the Draft Guidance on the clinical data sponsors must submit to support new drug applications for cancer drugs, we offer the following comments for your consideration.

E. Laboratory Tests
Lines 160-162 "All original applications should contain a database of all laboratory tests from a specified number of patients."

We ask that the Agency clarify this point since the approach is new for the reporting of laboratory tests in a "specified number of patients". Does the Agency consider that there is usually a large amount of laboratory data being submitted which are not relevant for the assessment of the safety profile? What types of patients' data should be collected, e.g., males and females, which phase of investigation, etc.? Also, is there a statistical approach that is recommended by the Agency to quantify this "specified number" of patients?

E-1. Baseline Tests
Line 175-177 "Such baseline studies should include electrolytes, ... urinalysis."

Aventis believes that baseline electrolytes and urinalysis data collection should depend on the development phase since they are not always collected, especially when the drug is well characterized.

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G. Efficacy Data and Tumor Measurements

Lines 222-224 "The CRF should document the target lesions identified during the baseline visit, or at least prior to treatment. Retrospective identification of such lesions would rarely be considered reliable."

Response Review Meetings are performed after chemotherapy treatment and before the statistical analysis. This review is independent from the treatment and is always performed after reviewing all tumor assessments of a patient during the same meeting. Therefore, are the tumor evaluation performed during the Response Review Meetings still considered as reliable by the Agency?

On behalf of Aventis Pharmaceuticals, we appreciate the opportunity to comment on "Draft Guidance for Industry on Cancer Drug and Biological Products—Clinical Data in Marketing Applications" and thank you for your consideration.

Sincerely,

James Boyd

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