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January 8, 2001

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

SUBJECT: RESPONSE TO DOCKET NO. 00D-1562

Dear Sir/Madam:

Enclosed herein are our comments to the "Draft Guidance for Industry on Cancer Drug and Biological Products - Clinical Data in Marketing Applications."

We believe that this draft guidance has the very laudable goal of focusing the research efforts on the important parameters that will allow Investigators, Sponsors, and the Agency to make meaningful conclusions without overburdening patients, Sites and Sponsors. The proposed reduction in the amount of safety data collected is marked and we wanted to commend the Agency for this initiative.

The major concern that has arisen in the review of the draft document (e.g., lines 340-342, 361-363 or 372-374) is related to the risk that a Sponsor may be taking in not collecting data, or not collecting enough data, as the programs are being conducted, with the real possibility of being requested to provide additional information retrospectively. Although the examples provided in the guidance are sound, there is always a balance between the actual activity demonstrated and the safety profile that may influence the Agency's or ODAC's thinking, once the application is submitted or ready to be submitted. Because of the potential duplication of Research activities, having to change the development plans at a late stage carries a very significant burden to, not only the Sponsor, but also probably the Investigators, and the patients. The worse example would be to have to repeat a trial in a patient population already studied to capture additional information that could have been collected in the first trial at a minimal additional burden.

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We wanted to express the concern that a mechanism whereby the outcome of discussions with the Agency on the type and amount of data to be collected would lead to a durable, or "binding" agreement is not clearly addressed in the current version of the document. We believe that in the absence of such a clear mechanism or procedure, the option of facilitating the development of Products in Cancer indications, as provided by this guidance, may not be able to be leveraged in actuality.

We appreciate the opportunity to provide comments on this draft guidance.

Respectfully submitted,

Richard W. Tkach

Richard W. Tkach, JD
Associate Director,
Worldwide Regulatory Affairs
Licensing, FDA Liaison and Compliance

RT/jv

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