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

Subject: **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"

21 June, 2001

Dear Sir/Madam:

Thank you for the opportunity to comment on the 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"published in the Federal Register on April 4, 2001. Outlined below are Genzyme's comments for your consideration.

1. On Page 15 of the draft guidance, FDA states that "(i)f more than one study is being conducted under a commitment, the status of the overall commitment will be based on the progress of studies. . . . If one study is progressing according to the projected schedule but the other is behind schedule, the commitment should be categorized as delayed." As FDA well knows, clinical trials can be delayed for a variety of reasons, some beyond the Sponsor's control. Consider the hypothetical scenario where a Sponsor has committed to conducting five postmarketing studies, and has completed four. If the fifth study was delayed due to a problem at an institution, the Sponsor would be required to categorize the commitment as delayed under the draft guidance. We believe that such a categorization would not accurately reflect the activity surrounding the postmarketing study commitment, and request that FDA accept a status report on each clinical trial comprising the commitment, rather than a single status report reflecting the lowest common denominator.

2. Some commitments have multiple components with different timelines. In such a case, we respectfully request that FDA review components as they are completed and submitted, rather than delaying review until all required components have been completed. We value FDA's opinions, and are concerned that a delay in review will delay necessary feedback.

3. On Page 15, FDA also states that "(t)he original schedule serves as the basis for defining a study as delayed, even if a revised schedule has been provided." If a particular phase of a schedule has been delayed, does this mean that every component of the schedule is considered to be delayed or ongoing? For example, a delay in patient enrollment would necessarily push out the timelines for the subsequent study components such as interim and final data analyses and follow-up which are, by definition, dependent on patient enrollment. These phases are

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not themselves delayed, they are delayed as the inevitable result of a delay in a previous phase. Further, if Sponsors are bound to report against an original timeline, what is the purpose of creating and submitting a revised timeline?

4. In Appendix B, FDA lists the Annual Report Due Date as 12/31/99, and the Annual Report Received Date as 02/01/00. These dates imply that FDA received the Annual Report after it was due. We respectfully suggest that the Annual Report Date should reflect the 60 day window.

Genzyme appreciates the opportunity to comment on the 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." Please contact me at (617) 374-7275 or Juliette Shih at (617) 761-8929 should you have any questions regarding this letter.

Cordially,

Robert E. Yocher
Vice President
Regulatory Affairs

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