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January 18, 2001

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

Subject: Docket No. 00D-1562, CDER 112, FDA Draft Guidance for Industry on Cancer Drug and Biological Products – Clinical Data in Marketing Applications (65 *Federal Register* 218, November 9, 2000)

Dear Madam/Sir:

Genentech is pleased to have the opportunity to offer comments on the Draft Guidance for Industry on Cancer Drug and Biological Products – Clinical Data in Marksting Applications. We applaud the Food and Drug Administration in its efforts to provide general principles for data collection and submission to the industry on cancer clinical data in marketing applications. We have included the following comments on the draft document in an effort to support FDA in this endeavor.

G. Efficacy Data and Tumor Measurements

1. ***. . . when survival data is the main efficacy endpoint, evaluation of tumor response may not be critical for a determination of efficacy, and recording tumor measurements for the database may not always be important.***

   With regard to the above statement, please clarify if it is necessary to have an independent review of the source data that investigators use to determine tumor measurements. In particular, for data collected during a labeling-enabling clinical trial, when survival is the main efficacy sndpoint.

2. ***The schedule for collection of baseline and follow-up data for* full *evaluation of efficacy should be specified in the protocol. In addition to the investigator's***

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evaluation of* efficacy, *all raw data collected for evaluating efficacy should be recorded on the GRF and submitted to FDA.

With regard to the above statements, in the case where approval is to be based on response rate or time to progression, please clarify if it is sufficient to record all tumor measurements on the CRF **or if submission of the actual** images is **required as part of the marketing application.**

Thank you very much for the opportunity to comment on this proposed rule. We look forward to the publication of the final rule.

Sincerely,

Robert Garnick, Ph.D.
Vice President
Regulatory Affairs

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FAX COVER SHEET

Date: January 19, 2001

To: Dockets Management Branch, Food and Drug Administration

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From: Michele Donovan

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Message:

Attached please find Genentech's comments to Docket No. 00D-1562, CDER 112, FDA Draft Guidance for Industry on Cancer Drug and Biological Products – Clinical Data in Marketing Applications (65 Federal Register 218, November 9, 2000). I contacted a Dockets Management Branch representative on January 12, 2001 to inform her our comments would be late, and she said they would still be accepted. A hard copy of this facsimile is being mailed today. If you have any questions, please do not hesitate to contact me.

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