

Genentech

IN BUSINESS FOR LIFE

DEPARTMENT OF REGULATORY AFFAIRS

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June 2, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject: **Docket No. 2005D-0112**
Comments on Clinical Trial Endpoints for the Approval of Cancer Drugs and
Biologics (DRAFT GUIDANCE)

Dear Dockets Management Branch:

Enclosed are comments, provided by Genentech, for the Draft Guidance Clinical Trial
Endpoints for the Approval of Cancer Drugs and Biologics.

Thank you for providing us the opportunity to comment on this Draft Guidance.
We hope that you will find our comments useful and constructive

If you have any questions regarding this submission, please contact Michelle Tallin,
Associate Director, Regulatory Affairs at (650) 225-6098.

Sincerely,

for 
Robert L. Garnick, Ph.D.
Senior Vice President
Regulatory Affairs, Quality,
and Compliance

2005D_0112

Docket-021 ss

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This submission contains information that constitutes trade secrets and/or is confidential within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §331 [j]), the Freedom of Information Act (5 U.S.C. §552[b][4] and 18 U.S.C. Section 1905) and 21 CFR Sections 312.130, 314.430, 601.50, and 601.51 and may not be revealed or disclosed without the prior written authorization of Genentech, Inc.

Draft Guidance for Review and Comment

**Draft Guidance for Industry
Clinical Trial Endpoints
For the Approval of Cancer Drugs and Biologics**

Docket No. 2005D-0112

**Issued for Comment April 1st, 2005
Comments due June 3rd, 2005**

**Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080-4990**

GENERAL COMMENTS

The following comments are provided by Genentech, Inc. We welcome FDA's efforts to publish recommendations on the use of endpoints in cancer clinical trials. In general, this draft guidance provides clarity on the development and use of cancer clinical trial endpoints for the approval of cancer drugs and biologics. There are however some areas where we feel further clarification would be useful.

Specific comments on the Guidance are included in the following table.

Table1-1

**Specific Comments for Draft Guidance
"Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics"**

Section	Line Reference	FDA Guidance	Genentech Comment
III.	143-144	Table 1.	The tabular presentation is very much appreciated and makes reading of the data very clear. We would however like to know if the endpoints are listed in any particular order such as preference.
III.	143-144	Table 1. Row 2 Disease-Free Survival "Not a validated survival surrogate in most settings"	Please provide clarification as to what settings are considered part of 'most' settings
III.	148-149	Table 1. Row 6 Symptom Endpoints	Please provide further guidance as to when symptom endpoints may be adequate either alone or in preference to survival and response endpoints
III. B. 3. a.	302-314	TTP vs. PFS	Please provide guidance as to if and how data obtained from TTP based trial results may be interpreted and used to determine PFS. It is our experience that some non-US trials still use TTP as a preferred endpoint

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