



Date: JUN 2 2005

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

Re: Docket Number 2005D-0112
Response to FDA Call for Comments
Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Cancer
Drugs and Biologics

Dear Sir or Madam:

Reference is made to the April 04, 2005 Federal Register notice announcing the request for comments on the draft guidance for industry entitled "Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics".

AstraZeneca has reviewed this guidance and our comments and recommendations are attached (see Tab 1). Also included is a copy of the draft guidance, in which the AstraZeneca comments and recommendations have been highlighted for ease of review (see Tab 2).

Please direct any questions or requests for additional information to me, or in my absence, to Phil Damstetter, Regulatory Affairs Manager, at (302) 885-3585.

Sincerely,

Ronald C. Falcone
Regulatory Affairs Director
US Regulatory Affairs
Telephone: (302) 886-2715
Fax: (302) 886-2822

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Enclosures

2005D-0112

US Regulatory Affairs
AstraZeneca Pharmaceuticals LP
1800 Concord Pike PO Box 8355 Wilmington DE 19803-8355