AstraZeneca

2796 '01 JAN -8 A9:44

January 5, 2001

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

Re: Docket No. 00D-1562

Dear Sir or Madam:

Reference is made to the November 9, 2000, ***Federal Register***, Volume 65, No. 218, announcing the availability of "Draft Guidance for Industry on Cancer Drug and Biological Products – Clinical Data in Marketing Application Availability."

AstraZeneca Pharmaceuticals LP has reviewed this Guidance, and our comments are attached.

Thank you for your consideration.

Sincerely,

Mr G Melville

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MGM/mrsc

00D-1562

US Regulatory Affairs
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AZ0009 (8/00)

Docket Number: 00D - 1562

Federal Register: November 9, 2000, Volume 65, Number 218, Notices, Page 67389 - 67390

General Comments:

• Comment 1
Section II, A, lines 47-61: There is no mention of the Guidance Document entitled: *Fast Track Drug Development Programs – Designation, Development and Application Review*, which would appear to be relevant to background discussion regarding considerations for evaluation of cancer treatments.

• Comment 2
Section III, G, bullet point 2, page 6: Unmeasurable disease is not discussed. Could FDA clarify its expectations regarding data collection for unmeasurable disease?

• Comment 3
Guidance is silent on collection of pharmacokinetic information. Should there be a section on Pharmacokinetics?

• Comment 4
In FDA's hypothetical example, it was extremely interesting reading the scenario of Cancer F. This example describes Drug A, having suggested activity in cancer F, where Drug A was compared to Drug C, an "unapproved therapy". However, it is not specified whether Drug C is an "unapproved therapy" or is an approved therapy at an "unapproved dose". Therefore this example validates evaluating Drug A against an "unapproved dose of an unapproved therapy". Could FDA clarify its intent?

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Section	Page No.	Line No. or Paragraph No. (if applicable)	Comment
Section II, E	5	Line 200	These data should also document whether the abnormality resolved implies collection of a "Yes/No" response. Is that sufficient, or is time to resolution needed in some instances?
Section III, B Section III, E	4 5	Line 126 Line 165	In these sections, FDA states that information should be collected "in a specified number" of patients for each new population. For other sections, there is more clarity on "specified number." As worded, this implies that this data may not need to be collected for all patients. Could FDA
Section IV	9	Line 332	((2) demonstration that tumors were refractory to available therapy) Suggest also add somewhere in example (as in text) that adequate definition of refractory provided.

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