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Date: JUN 04 2002

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

Re: Docket Number 00D-1033 CDER 2001167
Response to FDA Call for Comments
Guidance for Industry on Information Program on Clinical Trials for Serious or
Life-Threatening Diseases and Conditions

Dear Sir or Madam:

Reference is made to the FDA "Guidance for Industry on Information Program on Clinical
Trials for Serious or Life-Threatening Diseases and Conditions" dated March 2002.

AstraZeneca has reviewed this guidance and our comments are attached.

Sincerely,

Mark Scott, PhD
Executive Director
Oncology Therapy Area-Regulatory Affairs Leader
US Drug Development

MS/JT/kc

Enclosure

00D-1033

US Regulatory Affairs
AstraZeneca Pharmaceuticals LP
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Section	Page or Line Number	Comment or proposed replacement text
III.A.2	Page 3	Patient eligibility criteria could be considered sensitive information that could provide other sponsors a competitive advantage. We recommend removing this requirement.
III.A.3	Page 3	The specific location of a trial site could also be considered sensitive information that could be used unfairly by other sponsors. We recommend that this requirement be removed.
III.D	Pages 4 and 5	The definition for a serious or life-threatening disease or condition appears to be very broad and encompasses most of the diseases or conditions that are currently under investigation in the medical community. It is stated that determining the seriousness of a disease is a matter of judgment, but it isn't clear whose judgment this should be, ie the FDA's or the sponsor's. How would the sponsor have to justify their decision? In addition, using such a broad definition would result in a very large register with substantial workload implications for both the FDA and industry. We recommend that the definition be revised to be more focussed, provide more specific examples, and that the overall scope be more limited.
IV.K	Page 8	What is the process for submitting certification to the FDA for an exemption to the process? What is the timeframe for submission of this certification?

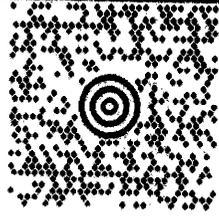
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TO:

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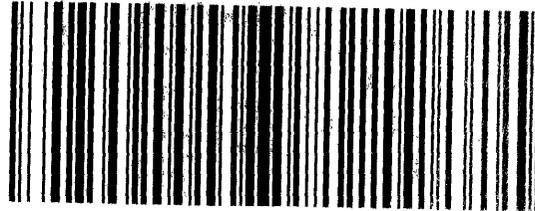
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