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JUN 05 2000

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

Dear Madam/Sir:

Re: Docket No. 93D-0139

Reference is made to the Draft Guidance, "International Conference on Harmonisation; Draft Revised Guidance on Q1A(R) Stability Testing of New Drug Substances and Products" published in the Federal Register on April 21, 2000.

AstraZeneca Pharmaceuticals LP reviewed this draft revised rule and submitted comments on June 2, 2000. We are submitting an additional comment as follows:

Drug Product, *Selection of Batches*

- With reference to the scale of batches used for formal stability studies, the first paragraph of this section states that studies are to be provided on "... at least three batches of the drug product. Two of the three batches should be at least pilot scale. The third batch may be smaller" This second paragraph of this section also states, "laboratory scale batches are not acceptable for formal stability studies." These two ideas are unclear when examined with respect to each other. Please define what the acceptable scale of the third batch would be, given the first two batches studied are pilot scale or smaller, if the third batch may not be laboratory scale.

AstraZeneca thanks you for the opportunity to comment on this important guidance. Please do not hesitate to contact me should you require clarification on any of the above comments.

Sincerely,



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Regulatory Affairs Department
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93D-0139

CSF/mrsc

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