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SENT VIA UNITED PARCEL SERVICE

JUN 1 2000

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

Dear Madam/Sir:

Re: Docket Number 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Reference is made to the Draft Guidance, "International Conference on Harmonisation; Draft Revised Guidance on Q1A (R) Stability Testing of New Drug Substances and Products" published in the Federal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 has reviewed this draft revised rule; our comments are as follows:

Drug Product, Test Attributes, Test Procedures, and Acceptance Criteria

- With reference to the text, "it should include specific upper limits for degradation products, the justification for which should be influenced by the levels observed in material used in preclinical studies and clinical trials," we suggest instead, "... the justification for which should be in accordance with the ICH guideline 'Impurities in New Drug Products.'"

Annex 1

- With reference to the definition of "pilot scale," which states, "... generally taken to be at a minimum scale of one-tenth that of full production ...," we suggest that a definition of scale-up would also be helpful. If pilot scale batches being a fraction of production scale are acceptable, why not provide for batches made in multiples greater than 1X of production scale as long as the process is well characterized and the scale-up is justifiable.

93D-0139

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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,

A handwritten signature in black ink that reads "Carol Stinson-Fisher". The signature is written in a cursive style with a large, stylized 'C' and 'F'.

Carol Stinson-Fisher
Technical Regulatory Associate
Regulatory Affairs Department
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CSF/mrsc

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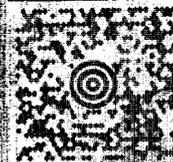
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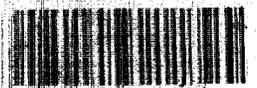
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