AstraZeneca

Date: 01/20/03

Ms. Kimberly Topper
Center for Drug Evaluation and Research
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20857

RE: Federal Register, Docket No. 02N-0518

Dear Ms. Topper:

Reference is made to the FDA call for public comment on, " Preparation for International Conference on Harmonization [ICH] Meetings in Tokyo, Japan, Including Progress on Implementation of the Common Technical Document [CTD] and Update on New Topics".

AstraZeneca Pharmaceuticals has the following comments for the FDA in preparation for the ICH meeting regarding CTD:

We are advocating that the FDA and the ICH take a flexible approach regarding data already submitted as part of approved applications; by default, there should be no requirement for companies to rework documentation already approved where cross-references can suffice. For example, drug substance documentation that exists in an approved, pre-CTD, New Drug Application (NDA) could easily be cross-referenced in a NDA or supplement in CTD format.

If a sponsor believes that reformatting previously filed and approved material is advantageous, according to the product life cycle, the assumption is that these efforts would be acceptable.

AstraZeneca believes this proposal is in the best interest of both the FDA and Industry in that reformatting and reassessment of approved data introduces a time and effort burden for both parties; we believe that an expectation for sponsors to "re-format" data would substantially decrease Industry productivity and the rate at which the FDA can approve new medicines for the common good.

Looking to the future, AstraZeneca also advocates that the ICH set a date, perhaps in a year or two, for formal consultation regarding the CTD guidances. This would be a prime opportunity for industry to comment on lessons learned from building CTD submissions and for regulatory authorities to share review experiences.

AstraZeneca continues to support the ongoing efforts of the FDA and the ICH worldwide in this endeavor.

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This submission is being provided in duplicate.

Please direct any questions or requests for additional information to me, or in my absence, to Cindy Faulkner, Associate Director Regulatory Skills Center at (302) 886-8185.

Sincerely,

Carol Stinson-Fisher for

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