AstraZeneca

4250 '03 JUL -3 A9:17

Date: ~~JUL 02 2003~~

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

RE: Docket Number [01D-0435]
Response to eCTD Guidance [Federal Register 2 April 2003]

Dear Sir or Madam:

Reference is made to the eCTD Guidance published in the Federal Register 2 April 2003. We understand that this Federal Register Publication is the same eCTD specification (version 3.0) that ICH published "ICH M2 EWG Electronic Common Technical Document Specification."

AstraZeneca continues to support the following principles, each one of which the company relates to meeting the CTD original objectives via the eCTD delivery mechanism:

- The eCTD must be accessible to all territories. The eCTD may not eliminate the need for paper review.
- The eCTD must not present a technical burden to any territory.
- The eCTD must be consistent with and facilitate CTD review. The eCTD must not lead to or drive toward any negative change in review process.
- The eCTD must not lead to a longer review time in any territory.
- Change control procedures, post approval, should be significantly and noticeably improved.
- The eCTD should result in one set of summary technical documentation (relating, where applicable to the Common Technical Document), not bigger than the current requirements.
- The eCTD should not require any legacy documents, previously filed in paper, or electronic format to be reworked.

01D-0435 C10

US Regulatory Affairs
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AstraZeneca eagerly awaits the Step 5 document, and the readiness of agencies to work with the company on eCTD. AstraZeneca has extensively reviewed the eCTD Guidance published in the Federal Register 2 April 2003 and our comments are attached.

Please direct any questions or requests for additional information to me, or in my absence, to Donna Whiting at (302) 886-2133.

Sincerely,

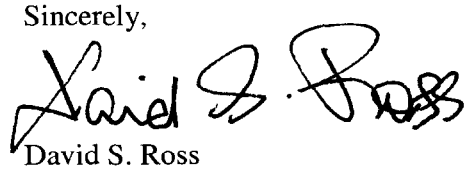

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Table 1 General Comments

Reference in eCTD Guidance [Federal Register 2 April 2003]	Comment
Appendix 1, Page 1-2, Lifecycle Management, First Paragraph Regarding, "the initial submission being self-contained ... [with] no references to other submissions".	Please advise as to how this guidance applies to combination products containing two (2) or more monocomponents that were the subject of previous submissions. In these cases, the sponsor has to make a specific submission for the combination product, but often data on the monocomponents are relevant too. If our eCTD had to contain the original submission data for the two (2) monocomponents as well as the data on the combination, it would exceed the current 50 MB limit for electronic clinical documents. We recognize that if monocomponent submissions were eCTDs in the same format, they would be electronically compatible with the combination submissions, and we would not need to either resubmit or include the monocomponent data.
Appendix 4: File Organization for the eCTD, Page 4-19, row 90 Regarding, "For a drug product containing more than one excipient, the information requested for sections 3.2.P.4.1 – 3.2.P.4.4 should be provided in its entirety for each excipient."	Please clarify whether this means that for compendial excipients, all relevant information must be placed in 3.2.P.4. Please can you clarify whether for non-compendial excipients, a separate 3.2.P.4.1 to 3.2.P.4.4 is required for each excipient.
Appendix 4: File Organization for the eCTD, Page 4-23, row 116 and 117 (Container Closure System).	Please advise as to whether we are limited to only two documents (rows 116 and 117) for container/closure system? Please clarify how to submit multiple container/closure documents, e.g. blisters and/or bottles or multi-unit dispensers? Please state where more than two documents would be filed.