QUINTILES

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November 5, 2001

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

Subject: **Docket No. 01D-0368**
Comments on Draft Guidance for Industry: Submitting Marketing Applications According to the ICH/CTD Format - General Considerations

Dear Madam/Sir:

Quintiles, Inc. has established a Global CTD Team with members of Quintiles Regulatory and Technical Services from Europe, Japan, Canada and the United States. The team has reviewed the Draft Guidance for Industry entitled, "Submitting Marketing Applications According to the ICH-CTD Format - General Considerations" [Docket No. 01D-0368] and wishes to comment. Within Section IV, General Issues for Submissions, cross-referencing documents is addressed in subsection L. This subsection states, "You should reference documents by volume, CTD module, tab identifier, and page number." Since each CTD module will start with a volume 1, the Quintiles CTD Team suggests that the application would be more navigable if the cross referencing were in the following order: CTD module, volume, tab identifier, and page number. In addition, this method of cross-referencing would be more consistent with the rules governing medicinal products in the European Union, Volume 2 Notice to Applicants, Volume 2B, Presentation and content of the dossier Common Technical Document (CTD), July 2001, 2001 Edition, which provides the following example of cross referencing on page 10 of 18: (e.g., see Module 3, Vol. 5, P.4.3 Method Validation, p 23). Consistency between the regions in this regard will prevent the need for re-work when a marketing application in the CTD format is submitted in more than one region.

We appreciate your consideration of our comments. If you should have any questions or comments, do not hesitate to contact me.

Sincerely,

Marguerite Enlow

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