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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1601
Rockville, MD 20852

RE: DOCKET 01D-0368
Comments to Draft Guidance

Dear Sir/Madam:

Reference is made to the draft guidance entitled "Submitting Marketing Applications According to the ICH-CTD Format-General Considerations" Docket 01D-0368. At this time, Johnson & Johnson Pharmaceutical Research and Development, L.L.C. welcomes the opportunity to comment on this guidance document. The draft guidance has been reviewed and comments provided herein. General comments have been provided, followed by specific comments to particular sections.

GENERAL COMMENTS

1. We would like to propose that this guidance encompass investigational new drug applications (INDs) in addition to the new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biological license applications (BLAs) referred to in this document. As submissions begin to be prepared using the format of the electronic CTD, this would allow a submission history to be built beginning with the initial IND.

2. For the tab identifiers required for each appendix, we recommend that FDA propose a desired (or required) level of hierarchy for each appendix to be tabbed.

3. We would appreciate a position statement from FDA regarding the use of color in paper CTD submissions.

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SPECIFIC COMMENTS

III. A. Module 1-Administrative and Prescribing Information Section

1. Proposed revision is directed toward the section "Module 1-Administrative and Prescribing Information Section" (page 3). We recommend that a numbering scheme be proposed for Module 1 to maintain consistency.

We appreciate the opportunity to comment on this draft guidance, and thank FDA in advance for its thoughtful consideration of our comments.

Sincerely,

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Marlene Lepkoski
Director
Global Regulatory Affairs, Regulatory Operations