

Johnson & Johnson
PHARMACEUTICAL RESEARCH
& DEVELOPMENT, L.L.C.

1125 Trenton-Harbourton Road
PO Box 200, Titusville, NJ 08560

0688 '03 FEB 27 10:59
February 26, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Dr. Charles Hoiberg

Re: Comments on *Draft Guidance M4 Common Technical Document – Quality: Questions and Answers/Location Issues*

Dear Dr. Hoiberg:

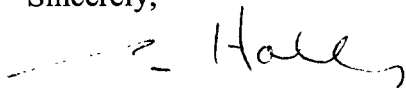
The above referenced FDA draft guidance *M4 Common Technical Document – Quality: Questions and Answers/Location Issues*, dated September 12, 2002 and published in the *Federal Register* on December 30, 2002 has been reviewed by scientists at Johnson & Johnson Pharmaceutical Research and Development, LLC. The following comment has been identified and is summarized as follows:

Under Section 2. General Issues, 2.3 Table of Contents Formatting (page 5) under Module 3, last sentence in the first paragraph, the draft guidance states “*The lower Table of Contents described under 2.3 Document Pagination and Segregation...*”.

The Document Pagination and Segregation is incorrectly cross referenced as section 2.3. The cross reference should be revised to read *2.2 Document Pagination and Segregation*.

We greatly appreciate the opportunity to comment on this draft guidance and look forward to working closely with the FDA on future documents. If you have questions or need assistance, please contact me directly at 609/730-3425.

Sincerely,



Sue Halley
Manager
Regulatory Sciences
Global Chem-Pharm Regulatory Affairs
Johnson & Johnson Pharmaceutical Research and Development, LLC

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