



DEC 20 2001

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

Subject: Docket OOD-1543
McNeil Comments to FDA Draft Guidance for Industry on 21CFR Part 11;
Electronic Records; Electronic Signatures – Glossary of Terms

Dear Sir or Madam:

McNeil Consumer & Specialty Pharmaceuticals (McNeil) submits the following comments on the proposed "Draft Guidance for Industry on 21CFR Part 11; Electronic Records; Electronic Signatures – Glossary of Terms".

This document is somewhat of a duplication of FDA's Glossary of Computerized Systems and Software Development Terminology. McNeil recommends that the existing publication be updated to incorporate new terms rather than creation of a new guidance for those terms.

If you have any questions regarding McNeil's comments, please contact me at 215-273-8733.

Sincerely,

McNeil Consumer & Specialty Pharmaceuticals

Jacqueline U. Linse
Director, Global Submissions and
CMC Regulatory

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