

PURDUE

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April 25, 2003

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

Re: Docket Nos. 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539 (Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures--Scope and Application;" Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide

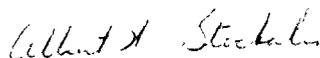
Dear Sir or Madam:

Attached please find the comments of Purdue Pharma L.P. to the referenced draft guidance documents issued by the FDA on February 21, 2003. Attachment 1 provides our comments to the Scope and Applications document.

We would like to commend the FDA team on the development of this guidance. We appreciate the hard work and effort required in preparing such guidance. We trust that our comments reflect the detailed review we have performed and can be incorporated to make the document even more useful to the industry.

Please be assured that Purdue Pharma L.P. welcomes the opportunity to work with the FDA in preparing and reviewing such guidance on complex issues like 21 CFR Part 11. If I can be of assistance with regard to these comments, please do not hesitate to contact me.

Sincerely,



Albert W. Stockalis
Senior Director, Information Systems Quality Assurance
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Attachment

00D-1543

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cc: Dr. Theresa Muchnick, Vice President, Corporate QA,
Purdue Pharma L.P.
Dr. Frank J. Sena, Executive Director, Corporate Compliance
Purdue Pharma, L.P.
Dr. Anthony C. Santopolo, Vice President, Regulatory Affairs
Purdue Pharma L.P.