



Purdue Pharma L.P.

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December 3, 2002

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Re: Docket No. 00D-1539 - Draft Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Maintenance of Electronic Records

Dear Sir or Madam:

Attached please find the comments of Purdue Pharma L.P. to the referenced draft guidance document issued by the FDA on September 4, 2002. Attachment 1 provides our comments to the draft Maintenance 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.

00D-1539

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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,



Anne D. Vento
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Attachment

cc: Albert W. Stockalis, Director, Information Systems Quality Assurance
Purdue Pharma, L.P.
Dr. Frank J. Sena, Ex. Director, Corporate Compliance
Purdue Pharma, L.P.
Dr. Theresa Muchnick, Vice President, Corporate QA,
Purdue Pharma L.P.
Dr. Anthony C. Santopolo, Vice President, Regulatory Affairs
Purdue Pharma L.P.