



**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**Re: Docket No. 00D-1539 - Draft Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Maintenance of Electronic Records**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Attached please find the comments of Purdue Pharma L.P. to the referenced draft guidance document issued by the FDA on September 4, 2002.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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*Purdue Pharma L.P.*

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,



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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.

**Attachment 1** – Comments on “Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures Maintenance of Electronic Records” Draft Guidance.  
Docket No. 00D-1539

**1. Purpose**

No comment.

**2. Scope**

No comment.

**1.1 Applicability**

No comment.

**2.2 Audience**

No comment.

**3. Definitions and Terminology**

No comment.

**4. Regulatory Requirements**

**4.1 What Does Part 11 Require?**

Section 11.50, Page 5 describes the requirement for information in the “signature manifestation” that must be included as part of any human readable form of the electronic record. Specific content of electronic records may appear in reports with specific content of other electronic records. The manifestation information from all records could not reasonably be incorporated into such reports.

The manifestation information cited is often included as part of the signature block in cases where encryption is used (digital signature), meaning it would not necessarily be part of the record being signed, but part of the signature applied to the record. In the case of digital signatures, does the agency wish this information to appear in both places?

**4.2 What Do Predicate Rules Require?**

No comment.

**5. General Considerations For Electronic Records Maintenance**

No comment.

**5.1 Procedures For Electronic Records Maintenance Should Be Established and Followed**

No comment.

**5.2 *Factors That Might Affect The Reliability of Electronic Records During the Required Retention Period Should Be Identified and Controlled***

Could be difficult to demonstrate retention of the metadata.

**5.3 *Continued Availability And Readability Of Electronic Record Information Should Be Ensured***

Does the term "representative number" mean "statistically significant"? The tape reading example does not describe if the number of records read from the tape were randomly selected or if any documentation needs to be provided describing the representativeness of the records read.

For step 5.2 and 5.5 as well, how long is indefinitely? Predicate rules govern the minimum length of time that documents need to be maintained (this can be expanded to hardware/software/applications used to generate or store these documents) - some are 2 years, some are 5 years, etc.

**5.4 *Electronic Records Should Be Stored Under Appropriate Environmental Conditions***

Sentence 2, can complete records of the monitoring results be maintained or is it sufficient to have recent values displayed in such a way that a trend could be discerned? If complete records are expected, what are the requirements for *their* maintenance?

**5.5 *The Ability To Process An Electronic Record's Information Throughout Its Records Retention Period Should Be Preserved***

No comment.

**5.6 *Copying Processes Should Produce Accurate And Complete Copies***

When it mentions using computer technologies to perform the same kinds of processing on information in the maintained electronic record does that mean that the same function needs to be used or can something comparable be used, for example, using 'browse' versus 'search' to locate a record?

## **6 Approaches To Maintenance Of Electronic Records**

No comment.

### **6.1 The Time Capsule Approach**

This approach seems pretty impractical and is unlikely to happen with systems being installed today. However, it may be of benefit for any legacy systems still out there, but the organization should be planning on ways to avoid it in preference to an approach of upgrade / migration.

Sentence 3: This is a very broad statement. Would changes to the networking environment to which the system is attached be included in “any” changes?

### **6.2 The Electronic Records Migration Approach**

Metadata migration could be difficult to demonstrate.

Section 6.2.1 defines migration as “generally” involves a transformation. To avoid confusion the word “generally” should be removed so that the difference between a “copy” which would not require an audit trail, and “migration” which would require an audit trail, is strictly defined.

Section 6.2.1.2, Page 17 prescribes migrated data contain the same information as the original data. The example the agency provided regarding laboratory animal data is clear. Other cases exist, however, where a summary of the original data may fulfill “same information” requirement. For example, the original record(s) contain an equipment reading every five seconds during a process. Maintaining that degree of detail long after the process is complete is unnecessary. The migrated data might only contain data that was out of range. Migrated data may also contain statistical summaries of time samples, for example, the min, max, and average of readings for every five-minute interval. In cases where such summaries can be reasonably documented, would they be allowed?

Section 6.2.1.5, Sentence 2: The word “caveat” is inappropriate in this context.

It is not clear whether it is acceptable to move from one electronic file format to another, for example, original data in a SAS dataset - can it be transformed to SAS transport files or not? Similar situations exist with ASCII files.

For migrations, does the agency expect to see the addition of the old audit trail to a new system as a creation step in the audit trail of the new system?

On page 22, it states that an electronic record that supplements the migrated electronic record should explain the correlation between the old

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and new color representations, does this need to be electronic, couldn't this be included in the migration plan and report?