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December 28, 2004

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

Re: Docket No. 2004D-0440: Draft Guidance for Computerized Systems Used in Clinical Trials

Dear Sir or Madam:

Attached please find the comments of Purdue Pharma L.P. to the referenced draft guidance document issued by the FDA in September 2004.

We would like to commend the FDA team on the revision 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 Clinical Systems compliance. 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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cc: Dr. Kathy Shady, Vice President, Corporate Quality,
Purdue Pharma L.P.
Dr. Frank J. Sena, Executive Director, Quality Systems Compliance
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Dr. Anthony C. Santopolo, Vice President, Regulatory Affairs
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Albert Stockalis, Senior Director, Information Systems Quality Assurance
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Attachment 1 – Comments on "Guidance for Industry, Computerized Systems Used in Clinical Trials" Draft Guidance. Docket No. 2004D-0440

I. Introduction

None

II. Background

This draft guidance states that "Computerized medical devices, diagnostic laboratory instruments, and instruments in analytical laboratories that are used in clinical trials are not the subject of this guidance." Would electronic patient diaries, ambulatory diagnostic instruments such as Holter monitors and cognitive testing devices fall into this category? If not, please explain the differentiation.

III. General Principles

Could a paper record serve as a certified copy of an electronic record?

IV. Overall Approach to Meeting Part 11 Requirements

None

V. Standard Operating Procedures

None

VI. Data Entry

None

A. Computer Access Controls

None

B. Audit Trails or Other Security Measures

This section references the FDA's right to review an investigative site's electronic records activities and associated audit trails. Can such an FDA audit/review result in invalidated study data? Does this imply that Sponsor must audit a site's electronic systems before a trial to ensure compliance? If so, this could place an enormous (and costly) burden on the sponsor. In addition, does this also apply to international sites?

Examples of computerized systems that may not need electronic audit trails would be helpful. For example, could a risk assessment process be used to determine if a diagnostic device that records data to a flashcard which can only be accessed by a single reader device (which has an audit trail) need to have an audit trail?

C. Date/Time Stamps

None

VII. System Features

None

A. Systems Used for Direct Entry of Data

None

B. Retrieval of Data and Record Retention
None

VIII. System Security

In line 298 it states "The establishment of and adherence to written policies that hold individuals accountable for actions initiated under their electronic signatures." What type of evidence would you (FDA) be expecting to review to verify compliance to these written policies?

Please explain the sentence in line 303 that states "We recommend that procedures and controls be implemented to prevent the data from being altered, browsed, queried, or reported via external software applications that do not enter through the protective system software."

IX. System Dependability

Comment is same as VI.B. Although investigators are not generally responsible for validation unless they originated or modified software, many sites could still be impacted (e.g. Phase 1, SMOs, and potentially University hospitals).

A. Legacy Systems
None

B. Off-the-Shelf Software
None

C. Change Control
None

X. System Controls
None

XI. Training of Personnel
None

XII. Copies of Records and Record Inspection
None

XIII. Certification of Electronic Signatures
None

Definitions
None

References
None