

November 18, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1060
Rockville, MD 20852.

Dear Dockets Manager,

Listed below are comments and suggestions from the Pharmacia Corporation on “Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records”, docket number 00D-1539.

Guidance for Industry

21 CFR Part 11; Electronic Records; Electronic Signatures

Maintenance of Electronic Records (Docket 00D-1539)

In section 5.2, the guidance includes flash memory devices in a list of media that record data and metadata. Up until this time, the inclusion of information that resides in flash memory under 21 CFR Part 11 electronic records requirements has been unclear. If it is the intent of FDA to consider information in flash memory as electronic records that potentially fall under Part 11, the agency should directly make such an assertion and include content in guidance that describes how records in flash memory should be managed.

In section 5.3, the guidance states, “Throughout the records retention period, the ability to process information in an electronic record should not diminish”. This is a change in scope from the original requirements of Part 11. Specifically, section 11.10(b) requires “The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency.” The ability to process information in an undiminished form is not included. Furthermore, preamble comment 69 emphasized the need to provide “accurate and complete” copies of records to the agency, which was expected to “reduce the costs of providing copies by making clear that firms need not maintain obsolete equipment in order to make copies that are “true” with respect to format and computer system.” Introducing processability as a requirement will dramatically raise the cost for maintaining electronic records and would represent an incremental cost for implementing Part 11 that has not been truly accounted for in the past.

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In section 6.2, the guidance states, “However, you should carefully consider when it would be prudent to discard the old electronic records and/or system.” It is suggested that the wording be changed to, “However, you should consider when you need to maintain the old electronic records.” The change in wording is intended to shift the emphasis from making this a “prudent” requirement in most cases to a consideration that would only be exercised in exceptional cases. Also, it clearly distinguishes the keeping of old records from the need to maintain the old system and the ability to process the records.

In section 6.2.1.3, the guidance states, “Where a migration, in effect, creates a new electronic record (by transforming the old electronic record) then, per section 11.10(e), the audit trail for the migrated electronic record would have to cover this creation.” Beyond the issues of cost and system performance, this represents a significant broadening of the requirement for audit trails to record operator entries and actions that create, modify or delete electronic records. In preamble comment 72, “At this time, the agency’s primary concern relates to the integrity of human actions. Should the agency’s experience with part 11 demonstrate a need to require audit trails of device operations and entries, the agency will propose appropriate revisions to these regulations.” The migration of electronic records will generally occur utilizing migration software that is planned, specified, designed, built, tested and implemented to execute the planned migration. This will typically not be a human activity that operates on individual records, but is a machine activity that is validated and has a deterministic result. The controls required are similar to those that are used to assure proper device operations and entries. It is more appropriate to document the overall process as a collective whole rather than track the migration through the audit trails of each individual record. If FDA feels there is a demonstrated need to require audit trails for device operations and entries, they should propose revisions to the original rule and remove this requirement from the guidance.

In section 6.2.1.5, the guidance includes a description of a sequence of procedures for digital signature verification that could be employed to migrate digitally signed records. The example cited includes the use of a trusted third party from outside of the organization that has responsibility for the records. The implication of the example is that the responsible organization would not be able to demonstrate the continuity of record integrity without employing a trusted third party. It is suggested that the sequence of procedures be removed from the guidance. By requiring a trusted third party, the procedures call for controls of the migration process that exceed controls expressed for

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the establishment of the original records. In other words, use of a trusted third party to execute digital signatures and create digitally signed records has not been noted as a requirement in the final rule or other draft guidance. Calling for a higher level of control for the migration of such records is excessive.

The comments and suggestions included here are a result of the collection and summarization of responses throughout Pharmacia. We welcome and appreciate the chance to provide feedback. All of the feedback is offered in the spirit of making the final rule and draft guidance clear and functional. If any of the comments and suggestions are not clear, please feel free to contact me at the email address shown below.

Sincerely,



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