



American Red Cross

May 13, 2004

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Anne M. Henig
Center for Drug Evaluation and Research (HFD-6)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852
heniga@cder.fda.gov

RE: Docket No. 2004N-0133 “Electronic Record; Electronic Signatures; Public Meeting”, *Federal Register* Notice, April 08, 2004

The American Red Cross (ARC or Red Cross) appreciates this opportunity to provide comments concerning the Food and Drug Administration’s (FDA or the agency) intention to modify existing regulations contained at 21 CFR Part 11. We believe that the regulation, as written, is too broad and difficult to interpret. We applaud the agency’s willingness to reconsider the scope of the regulation and some of the details contained therein and in the related Guidance for Industry: Part 11, Electronic Records, Electronic Signatures – Scope and Application, issued in August 2003.

The Red Cross has numerous computer systems that contain electronic records. We rely heavily on these computer systems to qualify over 4 million donors and process over 7 million blood donations each year. Our reliance on electronic records is a necessity and will steadily increase. We are committed to ensuring the integrity and quality of the data maintained in our electronic systems and encourage the agency to take this opportunity to provide clarity and appropriate scope for Part 11 requirements. We applaud the agency’s efforts to date to limit the scope of Part 11 appropriately and the current effort by the agency to seek information about this very important regulation from the Public On June 11, 2004.

Red Cross strongly supports limiting the applicability of Part 11 to fewer records, notably those that are critical to the safety of blood donors, recipients, and products. Red Cross believes that a risk-based approach to determining the applicability of Part 11 to electronic records is an enlightened approach that will enable blood providers to concentrate efforts on the right critical systems and relieve the burden of trying to achieve Part 11 compliance for systems that play a relatively insignificant role in preparing and maintaining records of core manufacturing activities.

Red Cross has concerns with the current Part 11 requirements in particular with respect to validation, audit trails and transferability of electronic records for long term or indefinite retention. Red Cross is pleased that the agency has decided not to

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take enforcement action in these areas at this time; however Red Cross believes that it will be important for the Agency to be more specific about when and how the revised Part 11 requirements will apply to these specific activities.

Red Cross encourages the agency to eliminate the validation requirements contained in Part 11, since these requirements are well documented in predicate rules, such as the current good Manufacturing Practices (cGMPs) contained in 21 CFR Parts 211 and 820. Detailed requirements for validation of computer systems are also contained in a number of FDA Guidance documents, and therefore the validation requirements contained in Part 11 are duplicative and unnecessary. While it is true that the user must validate systems prior to implementation, this is well established in the blood industry and does not need further emphasis in Part 11.

Establishing an audit trail for electronic records is the most costly aspect of current Part 11 requirements. Part 11 currently includes an audit trail requirement for each record required by predicate rules, regardless of the criticality of the record or the likelihood that the record could be inappropriately altered. **Red Cross would support a risk-assessment approach to defining which electronic records should be subject to audit trail requirements. For highly critical records, Red Cross would support the inclusion of safeguards designed to deter, prevent and document unauthorized record creation, modification or deletion.**

The blood industry is unique in requiring essentially indefinite retention of records, in spite of changing technology to prepare, store and retrieve them. Red Cross believes that the Agency should include safeguards in Part 11 for the conversion of records to assure that an accurate and complete record is carried forward whenever new technology is used to store records and that records migrated to new technology can be readily accessed, reproduced and read. At the same time, provisions must be made to continue to access, reproduce and read records stored on older media, to prevent the costs of record conversion from becoming prohibitive. Red Cross would encourage the inclusion of appropriate controls and safeguards for record conversion and use of older systems in the revised Part 11 requirements, including a requirement for periodic checks of data integrity while in storage.

Red Cross has used a number of systems since the first introduction of electronic record keeping in our operations in the late 1970s. These systems evolved over time and have continued to evolve since the August, 1997 implementation date of Part 11. Although Part 11 became effective on August 20, 1997, few, if any systems available at that time were capable of meeting Part 11 requirements. Only recently have available systems been truly Part 11 compliant, almost seven years since the regulation went into effect. For this reason, **Red Cross believes that the definition of “legacy systems” should be examined closely and a new definition developed as part of the re-examination of this section. Red Cross urges the Agency to clarify whether and how Part 11 will be applied to systems put into place after August 1997, modified since that date and still in use today.**

Red Cross does not believe the current Part 11 requirements are necessarily a deterrent to innovation; however, any revision of Part 11 should clarify how the Agency will adapt Part 11 to allow the use of new technologies without a burdensome revision of the regulation. This would be true especially in cases like wireless technology, where no predicate device exists. Red Cross fully anticipates the need to use wireless and other direct feed technology to manage certain aspects of our mobile operations in the future; however, Red Cross is also vitally concerned about the integrity and confidentiality of donor records. **Red Cross would support the inclusion in Part 11 of general requirements that would enable the introduction and use of new technologies while providing safeguards for maintaining the integrity and confidentiality of records.**

Finally, Red Cross would encourage the agency not to differentiate requirements for “open” and “closed” systems in Part 11, since we believe that the quality issues for both types of systems are similar.

Red Cross will present remarks concerning these issues at the Public Hearing on June 11, 2004. We appreciate FDA’s interest in obtaining broad public input on this extremely important topic and will look forward with interest to both the presentations on that day and the Agency’s reactions to those presentations.

If you have questions about these comments, please contact me at 202-303-8436.

Sincerely,

A handwritten signature in black ink, appearing to read 'Van C. Sickler', written over the word 'Sincerely,'.

Van C. Sickler
Senior Director
Regulatory Affairs
American Red Cross
Biomedical Services

Comments by
Comments by
The American National Red Cross

Before an Open Public Hearing, June 11, 2004

Part 11: Electronic Records; Electronic Signatures
Food and Drug Administration

Docket Number No. 2004N-0133

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