American
Red Cross

Together, we can save a life

April 24, 2003

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

RE: Draft Guidance for Industry: Part 11, Electronic Records; Electronic Signatures- Scope and Application. [68 FR 8775-8776, February 25, 2003; Docket Nos. 003D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539]

Dear Docket Officer:

The American Red Cross (ARC or Red Cross) appreciates this opportunity to provide public comments concerning the Food and Drug Administration's (FDA or Agency) draft "Guidance for Industry Part 11; Electronic Records; Electronic Signatures- Scope and Application." (Hereafter, referred to as *The Draft Guidance*).

The Red Cross is committed to the safety of our donors, our patients, and the public we serve. The Red Cross, through its 36 Blood Services regions, supplies approximately half of the nation's blood for transfusion needs. The plasma donated by Red Cross' volunteers is recovered from blood and further processed or fractionated into plasma derivatives. Red Cross is also a large supplier of human allograft tissue.

Red Cross has several computer systems that contain electronic records heavily relied upon to process over 6 million units of blood and blood products each year. Red Cross acknowledges that our reliance on electronic records will steadily increase and we are committed to ensuring the integrity and quality of our data.

The Red Cross is pleased that the Agency accepted our recommendation to issue *The Draft Guidance* that provides the scope and application of Part 11 and commends the Agency for providing a resource for industry to further interpret the regulatory requirements. Given the size and complexity of the task to implement the rule's requirements, Red Cross encourages prompt release of a comprehensive final guidance.

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The Red Cross fully supports the intent of *The Draft Guidance* to establish controls and safeguards for electronic signatures and electronic records. While we continue to agree with many of the recommendations given in *The Draft Guidance*, we offer the following comments for your consideration.

Red Cross recommends that the Agency issue fewer, more comprehensive Guidance documents that address Part 11 issues so that efforts to implement computer systems can be sustained. The Red Cross utilizes many of the Guidance documents referenced in *The Draft Guidance* including the *General Principles of Software Validation, Final Guidance for Industry and FDA Staff* which provides sufficient guidance on computer systems and integrates well with Part 11 requirements. However, *The Draft Guidance* makes no reference to another computer related Guidance document that Red Cross thinks may be interpreted as conflicting with *The Draft Guidance.* Specifically, Red Cross believes that the *"Draft Guideline for the Validation of Blood Establishment Computer Systems"* needs to be reworked to harmonize the issues of maintenance, storage and the archiving of electronic records, among others. **Red Cross recommends that the Agency withdraw, update or provide clarification for the Validation Guidance in order to streamline computer system implementation and compliance with Part 11 requirements.**

The Red Cross appreciates the Agency's efforts to clarify and communicate their expectations regarding 21 CFR Part 11 rule and this opportunity to provide public comments on *The Draft Guidance.* If you have any further questions or require follow-up, please contact Joel C. Harder, Acting Director, Technical Policy and Promotions at 703-351-5942 (phone), 703-312-5939 (fax) or HarderJ@usa.redcross.org (e-mail).

Sincerely,

Kathryn J. Waldman
Vice President, Regulatory Compliance and Quality Systems
Chief Compliance Officer