American Red Cross

Together, we can save a life

June 12, 2003

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

RE: Bar Code Label Requirement for Human Drug Products and Blood; Proposed Rule.
[68 FR 12500-12534, March 14, 2003; Docket No. 02N-0204]

Dear Docket Officer:

The American Red Cross (Red Cross) appreciates this opportunity to provide public comments concerning the Food and Drug Administration's (FDA or Agency) proposed rule titled "*Bar Code Label Requirement for Human Drug Products and Blood*" (Hereafter, referred to as *The Proposed Rule*).

The Red Cross is committed to the safety of donors and patients, and to meet the best interests of 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 whole blood and further processed or fractionated into plasma derivatives. Red Cross is also a major supplier of human tissue including bone and skin for transplantation.

The Red Cross fully supports the intent of *The Proposed Rule* to establish a new requirement for machine-readable bar codes on blood and blood products including human-derived plasma derivatives. Red Cross has voluntarily applied bar coded information on our blood and blood products for many years. Red Cross is actively considering application of bar codes to tissue products.

While we agree with many of the stated requirements given in *The Proposed Rule*, we offer the following comments for your consideration.

02N-0204 C89

The Red Cross strongly endorses the mandatory use of ISBT 128 as a unifying bar code standard for blood and blood products. No other step could help bring about improvements in patient safety as immediately, and as effectively, as the use of standardized bar coding technology. ISBT 128, a technology independent standard based on data structures, describes all the essential information needed to help assure patient safety such as: (1) the blood's identification number, (2) blood group and Rh type, (3) product code, (4) expiration date and time, and (5) special testing results. Although "machine-readable bar codes approved by the CBER Director" will further efforts to minimize errors and improve safety, one unifying standard will provide additional benefits to providers, hospitals and patients by lowering the cost of implementation and allow exchange of inventories so that the needs of patients everywhere can be more easily met. Moreover, a unifying bar code standard may help to expedite investigations of unforeseen events.

The Red Cross endorses the proposal to amend 21 CFR 606.121 (c) (13) to add a new requirement to use "machine-readable information" approved by the director of the Center for Biologics Evaluation and Research (CBER). Red Cross believes the new requirement is the appropriate mechanism by which to begin requiring usage of bar code labels and associated technology for biological products. Red Cross recognizes the complexities that would be created by specifying ISBT 128 in the final rule. Red Cross applauds the Agency's foresight to provide flexibility in the regulation so that new rulemaking would not be required as technology evolves. Therefore, in harmony with the American Association of Blood Banks (AABB) and other blood bank organizations, Red Cross supports implementation of ISBT 128 through control of approval by the CBER Director as stated in *The Proposed Rule.*

Red Cross believes that mandating a unified bar code standard such as ISBT 128 would positively affect a hospital's decision to purchase a machine reader (e.g., scanner) that can properly identify: (1) the intended recipient of the blood and blood component and (2) the machine-readable information encoded on the blood or blood component label. Red Cross understands that modern bedside scanners can automatically discriminate between the symbols used on blood and blood components and those on other FDA-regulated products. The ISBT 128 bar code system is solely maintained by the International Council for Commonality in Blood Bank Automation (ICCBBA) which provides essential management and oversight including revising, enhancing, and maintaining associated databases for a reasonable licensing fee. One comment in *The Proposed Rule* suggests that licensing fees may deter hospitals from using the ICCBBA system. Red Cross disagrees with the comment and would like to clarify that the licensing policy published by ICCBBA provides a license fee exemption to transfusion-only facilities. Red Cross believes that ISBT 128 system provides numerous benefits over ABC Codabar System including reduction of "reused" numbers.

In the blood collection process, Red Cross believes recipient safety can be further enhanced by applying bar codes to certain medical devices such as blood bags, filters, and apheresis kits. As an end-user of such medical devices, Red Cross would positively benefit by furthering our efforts to: (1) expedite lookbacks, (2) expedite suspected transfusion transmission disease (STTD) investigations, (3) expedite retrievals, (4) assure reconciliation and (5) mitigate errors. A unifying bar code standard may help to expedite investigations into unforeseen events potentially affecting the safety of recipients. Red Cross would welcome a public workshop to have this matter further discussed.

The Red Cross appreciates this opportunity to provide public comments on *The Proposed Rule*. If you have any further questions or require follow-up, please contact Joel C. Harder, Senior Associate, Technical Policy and Promotions at 202-303-5942 (phone), 202-303-0103 (fax) or HarderJ@usa.redcross.org (e-mail).

Sincerely,

Kathryn Waldman

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