



4052 National Headquarters
Washington, DC 20006

May 18, 1999

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

RE: Docket No. 99N-0386 – Comments on the FDA Plan for Statutory Compliance with §406(b) of the Food and Drug Administration Modernization Act

Dear Docket Officer:

The American Red Cross (ARC) is pleased to provide comments to the Food and Drug Administration (FDA) regarding consultation with stakeholders as it moves forward to modernize the agency. The American Red Cross is the nation's largest supplier of blood services in the United States. Throughout our 37 Blood Service regions, the American Red Cross collects almost 6 million units of whole blood each year from volunteer donors, representing approximately 45 percent of the nation's blood supply. In addition, the American Red Cross Tissue Services (ARCTS) supplies approximately 20-25% of the nation's tissue needs for transplantation. The American Red Cross Tissue Services supplies cardiac tissues (aortic and pulmonic valves, conduits, etc.) as well as skin, bone and associated connective tissue to physicians and dentists for patient treatment.

On March 22, 1999, the FDA published a notice in the **Federal Register** which informed industry about the FDA initiative, Talking With Stakeholders About FDA Modernization, to re-visit the Agency's plan for compliance with §406(b) of FDAMA. As part of this effort, the FDA has solicited public comment on five questions outlined in the notice. The American Red Cross wishes to endorse the comments submitted by the Coalition for Regulatory Reform (CFRR), both at the public meeting and in written form. The CFRR's membership consists of the American Association of Blood Banks (of which ARC is a member), America's Blood Centers, and the American Blood Resources Association.

In this letter, the American Red Cross, as a large processor of human tissue for transplantation, provides an additional comment on the implementation of FDAMA that was not covered by the CFRR Testimony.

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Specifically, it appears as though the regulation of tissue products and processing has become a relatively lower priority within the Agency. We recommend a second evaluation of the resources constraints which underlie this concern, and urge the FDA to continue with its plans for regulation of tissue products without slowing the process. We understand the Agency's need to make difficult choices as it evaluates resource allocations. However, the current priorities could be reconsidered to enable the FDA to maintain the momentum initiated over the last few years.

As early as 1991, the American Red Cross testified in support of the regulation of human tissue, including a recommendation to register tissue banks¹. In 1993, the FDA published the Interim Rule. Additional actions have taken place since then, including workshops and proposed guidance to discuss such aspects as donor screening and testing, and the Interim Rule, was made final in 1997. The FDA also published, *A Proposed Approach to the Regulation of Cellular and Tissue-Based Products* in February of 1997. Although commentators noted the need for additional definitions and re-focusing of some areas within the "Proposed Approach", most (including the American Red Cross) indicated their strong support for the "Approach's" overall direction. The tissue-banking community has also identified and discussed with the FDA, other potential actions to appropriately regulate tissue for human transplantation. One major recommendation was the petition to change jurisdiction for human heart valve regulation from the Center for Devices and Radiological Health (CDRH) to the Center for Biologics Evaluation and Research (CBER).

Among the reasons the American Red Cross supported the above activities, was that they reflected such risk-based concepts as acknowledging that products developed using emerging technologies need more scrutiny than established products. These activities also recognized that streamlined approaches could more than adequately ensure appropriate level of Agency oversight, without adding unduly burdensome or unnecessary requirements.

The FDA has taken steps to implement its tissue regulatory plan. In January of 1998, the FDA issued a Federal Register Notice "requesting submission of comments proposing product standards intended to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells..." [63 Fed. Reg. 2985, Jan. 20, 1998]. The FDA also proposed requirements for registration and listing of establishments involved in any phase of the tissue

¹ September 9, 1991, Senate Labor and Human Resources Committee.

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manufacturing process [63 Fed. Reg. 26744, May 14, 1998]. However, the resource constraints noted above, may slow the issuance of further proposals, guidance, and final regulations.

The American Red Cross believes it is in the best interest of public health for the FDA to ensure timely fulfillment of the 1997 "Proposed Approach" and other plans. Delay may raise its own form of risk. For example, until the proposed regulation for registration and listing is finalized, the FDA does not have a mechanism to directly and quickly communicate with all parties currently involved in the procurement, recovery, or manufacture of cells or tissues about a newly identified public health risk. The American Red Cross also asks consideration of the length of time since we testified regarding the need for facility registration and other regulatory approaches (i.e., 8 years), and cautions against further delay.

Moreover, the science and engineering associated with stem cells and tissue products are developing at a very rapid pace. It may appear expedient to slow the current process. However, there is a risk that greater resources may be required to "catch up" than would have been required to keep up with developments as they occur.

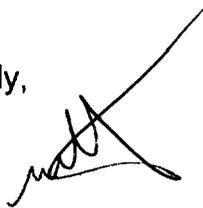
Finally, we believe that the FDA's "Proposed Approach" for the regulation of tissue represents exactly the type of "risk-based" approach the FDA encouraged the regulatory community, consumers and other Stakeholders to consider in its March 22nd Federal Register Notice and at the recent Stakeholders' meeting. The American Red Cross believes it would be a considerable gain for the FDA if the plan for implementing FDAMA recognized the regulation of tissue as such, and potentially, used the "Proposed Approach" as a model for other FDA risk-based programs.

In conclusion, the American Red Cross urges a slight but important re-focusing of the Agency's efforts on its Tissue regulatory program. The actions we've seen to date reflect considerable work on the part of the Agency staff, the regulated community, and the public at large. We encourage the Agency to continue to apply appropriate resources to a program that has, so far, shown considerable promise.

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Thank you for allowing us the opportunity to comment. If you have any questions, please contact Anita Ducca Director, Regulatory Relations at the American Red Cross 703-312-5601.

Sincerely,

A handwritten signature in black ink, appearing to read 'Glenn M. Mattei', with a long, sweeping horizontal stroke extending to the right.

Glenn M. Mattei, Esq.
Senior Director, Quality Assurance
And Regulatory Affairs
American Red Cross