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ON BEHALF OF 9 1 '98 AUG 26 AM 11:33
THE AMERICAN RED CROSS

**ON PUBLIC MEETINGS ON SECTION 406(b) OF THE FDA
MODERNIZATION ACT OF 1997, DOCKET NUMBER 98N-0339
August 14, 1998**

Good morning, Dr. Zoon, Ms. Suydam, FDA staff, and fellow members of the regulated community. My name is Sharon Leiser, and I am here speaking on behalf of the American Red Cross which supplies approximately one-half of the nation's supply of transfusable blood components, approximately 20 percent of the nation's plasma derivatives, approximately 20 percent of the nation's tissue for transplantation purposes and which is supporting the agency's current effort for the provision of stem and cord cells. Thank you for providing us with the opportunity to speak today.

As a member of the Coalition for Regulatory Reform (CFRR), the American Red Cross fully supports and agrees with the points made today by Mr. Brinser, the representative for the CFRR. American Red Cross also wants to emphasize several points about the implementation of the FDA Modernization Act that I will be touching on today.

The American Red Cross will also provide written comments which will expand on some of the points raised today.

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We wish to commend you, FDA, on your efforts to date. First, we have seen, for example, a substantial improvement in the blood licensure submission review process. The review of ARC submissions has been reduced from a backlog of over 900 open cases in 1995 to a current open caseload of only a few dozen. In addition, the review period for submissions has decreased approximately 50 percent in only a two year time period. These improvements benefit the public by increasing our ability to manufacture better and more efficacious blood components and plasma derivatives and supply them to those in need.

Second, we are encouraged by the information recently presented on the Blood Action Plan. We see this Plan as the start of a potentially beneficial program for the agency, for the regulated community, and for the public which relies on us and on the FDA to provide the safest blood in the world. We are particularly excited by the agency's initiatives to update the regulations and guidances for blood and blood products. We eagerly await publication of the Blood Action Plan and our opportunities for further participation in the Plan's development.

The American Red Cross strongly endorses efforts towards open communication between the FDA, consumer groups, industry, and professional societies such as AABB. There has been considerable headway in this arena, particularly with the

increased use of the web and other electronic communication mechanisms. We also encourage the FDA to expand an effective communication policy to all levels of FDA and CBER by reexamining the current practices for working with the regulated community and other groups.

For example, both the regulated community and the FDA need to work in a more open style of addressing issues by directing our approaches toward resolution as partners. We encourage continued interaction between the FDA and workgroups such as the CFRR to seek resolution of outstanding issues such as those relating to adverse reactions, errors and accidents and product retrievals. We also suggest reevaluation of the requirements for participation, as appropriate, by national FDA staff in professional meetings sponsored by the regulated community and other non-government entities to allow for their participation.

I would like to turn now to some of FDA's specific questions listed in "A Message to FDA Stakeholders." The agency asked what could be done to improve the submission review processes, to sustain an effective, timely, and science-based postmarketing surveillance system, to adequately meet increasing demands, and to eliminate backlogs in the review process. As noted earlier, we have already seen vast improvements in these processes.

One of the innovations about which we are most encouraged is CBER's implementation of the new Comparability Protocol process which will be used in conjunction with the revised system of ranking and grading licensure submissions. This system is the first step in creating a review process which will meet the needs of both the biologics industry and the public's health and safety in the 21st century.

We encourage the rapid development and completion of this and other initiatives. In particular, we would like to see clear guidelines for the use of the Comparability Protocol process. We also encourage the FDA to think even more innovatively in addressing the following:

- Providing clear guidance about the requirements for the new Annual Report Process;
- Improving the ranking and grading of specific blood and blood products as the foundation of the blood licensure review process;
- Without compromising the public input process, creating a system for making quick changes to guidances as scientific and technical knowledge expands;
- Expanding the regulations to directly reference blood and blood products instead of trying to fit them into a system with which they do not harmonize; and,
- Creating an innovative staff incentive/reward system that will foster new ideas and speedier reviews without compromising quality and effectiveness.

I want to specifically talk about improving the ranking and grading of products. First, the agency should define what information is necessary to evaluate the licensure submission reviews. Second, the submissions and reviews should be tiered based on hazard and impact. We believe that, in following this approach, the demands on the agency will be reduced thereby increasing FDA's ability to focus resources on new products. For example, there are many blood products, like Red Blood Cells, Platelets, and Platelets, Pheresis, which have been in the public arena for a long time. Their qualities, including efficacy and manufacturing specifications, are well known. It is reasonable that licensure submission requirements for these well-known products could be placed on the lowest review tier, and compliance confirmation could be based on post-licensure sampling audits instead of licensure. The greatest amount of resources could then be transferred to completely new products like Red Blood Cells, Pheresis. Then, as these new products become mainstream, their ranking and tier of review could be lowered to allow for other new products to absorb review resources.

On the FDA question about what approach the agency should use to assure an appropriate scientific infrastructure, we want to emphasize that we, as well as the rest of the regulated community, wish to work with FDA regarding creative and innovative ways to use scientific expertise. We recommend that there be staff

exchange programs with academia, other government agencies such as NIH, CDC, and the National Science Foundation, and industry research organizations, to share staff, expertise, and research results. The idea is that by fostering better understanding of applicable science in a cross-cultural setting, we can simultaneously assure an appropriate scientific infrastructure which utilizes the most current knowledge and also promotes staff development.

I would like to briefly touch upon a point I mentioned earlier concerning approaches to improving error and accident reporting. This is an example of a regulatory program which might benefit from expanded public input beyond the regulated community. American Red Cross, in developing its own program, consulted with Hal Kaplan from the University of Texas, Southwestern Medical Center at Dallas. Dr. Kaplan has suggested a system modeled after a classification for causal factors with multiple applications including transportation, nuclear power, and the petrochemical industry. Information would be submitted to an independent agency and shared among the regulated community for the mutual benefit of its members and the FDA. We also encourage, as part of its implementation of the Modernization Act, that you search out ideas and innovations from other fields which might be applicable to the FDA system.

We believe the FDA's initial efforts in meeting the requirements and demands contained within the FDA Modernization Action merit considerable recognition and praise. Thank you again for this opportunity to participate, and we look forward to future efforts to partner and build a new system together.