



## FDA Statement

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### Media Inquiries:

301-827-6242

### Consumer Inquiries:

888-INFO-FDA

### FDA Fines American Red Cross \$4.2 Million for Failure to Meet Established Blood Safety Laws

The U.S. Food and Drug Administration (FDA) announced today that the American Red Cross (ARC) is being fined \$4.2 million for failure to comply with requirements under Federal laws and FDA regulations relating to the collection of blood products. These fines were assessed under an amended 2003 consent decree that calls for significant financial penalties when ARC fails to comply with FDA regulations and consent decree provisions designed to ensure the safety of the nation's blood supply.

The fines stem from a recently completed FDA review of recalls conducted by ARC between 2003 and 2005 that found these events were preventable by ARC. The violations include breaches of Good Manufacturing Practice (GMP) such as a failure to ask appropriate donor screening questions and failure to follow manufacturer test protocols. We have no evidence that these violations resulted in serious health consequences.

Because receiving blood products always carries a degree of risk, it is important that the blood industry complies with the full set of safeguards in Federal laws and FDA regulations to minimize that risk. However, any particular breach of the safeguards does not necessarily translate into unsafe blood products, because the safeguards designed to protect the blood supply are to some extent overlapping. The FDA continues to advise care providers and consumers that rigorous protections are in place and that the blood supply is safe. Patients in need of a transfusion should continue to follow the advice of their physicians. The risks of receiving a transfusion are far less than the risk of failing to receive a transfusion when blood treatment is indicated.

Improvements in donor screening procedures and the use of a variety of new tests in the last few years have made the national blood supply safer from infectious diseases and other risks than it has been at any other time. However, because there is always some degree of risk in receiving blood products, each individual safeguard is considered critical to minimizing that risk. Although the failure of an individual safeguard does not automatically translate into the release of unsafe products, it may increase the potential for risk. It is the potential risk that FDA insists the Red Cross Board of Directors prioritize and support its new management's ability to immediately address and work to improve its approach to quality.

The amended consent decree requires ARC to:

- Establish clear lines of managerial control over a newly established comprehensive quality assurance system in all regions;
- To enhance training programs; and
- To improve computer systems, records management, and policies for investigating and reporting problems, including adverse reactions

Since entry of the 2003 consent decree and prior to this action, FDA has issued the American Red Cross seven similar letters and assessed a total of \$5.7 million in penalties.

While achieving a blood supply with zero risk of transmitting infectious disease is the ultimate objective, we recognize based on the available science that this may not be realistic. Therefore, the FDA requires blood processors to adopt and strictly follow a multi-layered safety program to protect and enhance the safety of blood products at each stage of their manufacture. At the blood collection stage, these measures generally include:

1. Accurate and complete educational material for donors so that they can assess their risk and decline to donate if that is appropriate;
2. Administration of donor screening questions to identify safety risks;
3. Checking of lists to prevent use of blood from persons known to be ineligible to donate;
4. Quality controlled infectious disease testing procedures;
5. Inventory controls to prevent the release of units that are unsuitable;
6. Appropriate handling and distribution of blood and blood products for patient use; and
7. Investigation and correction of deviations from standards

ARC is responsible for approximately 45% of the nation's blood supply; other independent community-based blood centers together provide another 45%, and hospitals collect most of the remaining 10%.

Blood donations are critically needed every day to save lives, and blood donation is a safe procedure. FDA encourages persons who are in good health to donate blood and to become regular blood donors.