

STATEMENT: American Red Cross Receives Adverse Determination Letter, Fines, from U.S. Food and Drug Administration

WASHINGTON, Thursday, February 07, 2008 On Wednesday, February 06, 2008, the American Red Cross received an Adverse Determination Letter (ADL) from the U.S. Food and Drug Administration (FDA) assessing penalties for product recalls during the time period from April 15, 2003 through April 15, 2006. In accordance with established procedure, we will review the letter and respond to the Agency within 20 days.

Penalty assessments were negotiated as part of the Consent Decree.

The top priority of the American Red Cross is the safety and availability of nearly half the nation's blood supply. The Red Cross has many layers of safety in place to help protect the blood supply, which include completion of the blood donation record, health history screening, testing, deferrals and post-donation information.

The American Red Cross takes this ADL very seriously and is committed to full FDA compliance. Moreover, the Red Cross and the FDA agree that the nation's blood supply is safer today than it has ever been. The Red Cross acknowledges the important role of the FDA and remains dedicated to its mission and to the millions of people in this country who rely on us to provide lifesaving blood and blood components each year.

We would like to express our gratitude to our generous blood donors and volunteers without whom our blood program would not be possible.

The American Red Cross provides relief to victims of disasters at home and abroad, collects and distributes nearly half of the nation's blood supply, teaches lifesaving skills, and supports military members and families. The American Red Cross, a charity and not a government agency, depends on voluntary contributions of time, money and blood to perform its humanitarian mission.