DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5707

July 13, 2004

CONSENT DECREE CORRESPONDENCE

BY FACSIMILE &
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John F. McGuire
Executive Vice President
Biomedical Services
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

RE: United States v. American National Red Cross, Civil Action No. 93-0949 (JGP)

Dear Mr. McGuire:

FDA has reviewed the American National Red Cross' (ARC) submission that was received by the Food and Drug Administration's (FDA) Baltimore District Office on June 22, 2004. That submission includes ARC's third revisions to the Problem Management standard operating procedure (SOP) and associated procedures. Following its review of ARC's Problem Management SOP and associated procedures submitted on April 30, 2004, and the modification submitted on May 5, 2004, FDA issued a letter dated June 2, 2004, directing ARC to make specific changes to the SOP, requesting additional information, and providing comments. ARC's June 22, 2004 submission is its response to that letter. Under Paragraph IV.B.1. of the Amended Consent Decree of Permanent Injunction (Decree), entered on April 15, 2003, ARC is required to establish and submit to FDA the Problem Management SOP. Once FDA notifies ARC that it appears adequate, ARC must implement the SOP.

During its review of the June 22, 2004 submission, FDA identified several concerns and raised those with ARC by telephone on July 1, 2004. In response, ARC modified two work instructions in the SOP and sent evidence of those modifications to the FDA Baltimore District office by electronic mail on July 7, 2004. Based on its review of the above-mentioned submissions, FDA finds that, contingent upon incorporation of the May 5, 2004, June 22, 2004, and July 7, 2004 modifications into the April 30, 2004 version, the Problem Management SOP appears adequate.

ARC has 90 days from receipt of this letter to implement the SOP. FDA will verify adequacy of the SOP and its implementation during future inspections of ARC facilities.

If you have any questions regarding this letter, please contact me at (410) 779-5424.

Sincerely yours,

Lee Bowers
Director, Baltimore District

cc: Marsha Johnson Evans
President & CEO
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

C. William Cherry
Senior Vice President
for Quality and Regulatory Affairs
2025 E Street, N.W.
Washington, D.C. 20006

Mary Elcano
General Counsel
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006

Bonnie McElveen-Hunter
Chairman, Board of Governors
American National Red Cross
2025 E Street, N.W.
Washington, D.C. 20006