DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Baltimore District Office
Central Region
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Baltimore, MD 21215
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February 27, 2012

BY ELECTRONIC AND CERTIFIED MAIL
RETURN RECEIPT REQUIRED

Mr. J. Chris Hrouda
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. 93-0948 (JGP)

Dear Mr. Hrouda:

This letter is the Food and Drug Administration's (FDA) response to the American Red Cross' (ARC) February 13, 2012 letter that was received in FDA's Baltimore District Office on the same day. The letter includes ARC's compliance plan and responses to a January 13, 2012 Adverse Determination Letter (ADL), pursuant to Paragraph IX.A. of the Amended Consent Decree of Permanent Injunction (Decree) entered on April 15, 2003. ARC's response and compliance plan remain under review by FDA. Once that comprehensive review is completed, FDA will notify ARC in writing of the results.

In the February 13, 2012 letter, ARC requests extensions of the time frames that FDA established for completion of ADL Orders 6, 7, 8, 9, 13 and 17. FDA has reviewed the request and grants the extensions for ARC to complete its corrective actions for Orders 6, 7, 8, 9, 13 and 17. FDA understands implementation of the corrective actions for Orders 6, 7, 8, 9 and 13 will be completed by May 14, 2012, and by April 13, 2012 for Order 17.

In the January 13, 2012 ADL, FDA informed ARC that it was being fined $9,592,200 for violating the law, ARC standard operating procedures, and the Decree. Pursuant to Paragraph IX.F.6 of the Decree, payment of the $9,592,200 is due no later than thirty days after ARC notified FDA that it will not dispute FDA's adverse determination; that is by March 14, 2012.

In accordance with Paragraph IX.F.6 of the Decree, we are attaching instructions for the electronic transfer of this payment to the United States Treasury. ARC must, contemporaneous with the electronic transfer, provide written notification to the FDA Director, Baltimore District, and the Associate Commissioner of Regulatory Affairs that payment has been made.

If you have any questions regarding this response, please contact Cherlita Honeycutt, Compliance Officer, at (410) 779-5412, or Linda Mattingly, Investigator, at (410) 779-5443.

Sincerely yours,

Evelyn Bonnin
Director, Baltimore District

Enclosure

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