DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Baltimore District Office
Central Region
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Baltimore, MD 21215
Telephone: (410) 779-5454
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April 2, 2004

ADVERSE DETERMINATION LETTER

BY FACSIMILE &
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Alan McCurry
Executive Vice President and CEO
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. McCurry:

Paragraph IV.B.17.a. of the amended Consent Decree of Permanent Injunction (Decree) dated April 15, 2003, requires that within 30 days of entry of the Decree, the American National Red Cross (ARC) must modify its standard operating procedure to ensure that its regional blood service facilities (regions) notify the Food and Drug Administration (FDA) "in writing within five business days after a region has failed to locate any blood or blood component within 72 hours of the time that the region initially learned that such blood or blood component was not in its assigned location." For the period May 15, 2003, through December 31, 2003, ARC reported to FDA that it failed to locate 47 units of blood or blood components within 72 hours of initially learning that such blood products were not in their assigned locations. (See Attachment 1.)

Ensuring traceability of blood and blood components is critical to protecting public health. Any unit of blood or blood component, even one initially deemed suitable for distribution, could become subject to retrieval or lookback based on subsequent information regarding donor suitability or infectious disease test results for subsequent donations from the same donor. ARC's failure to maintain traceability for 47 units of blood or blood components during the period May 15, 2003, through December 31, 2003, reflects a failure to maintain adequate inventory control.

Paragraph IV. B. 17.a. of the Decree states that "FDA may assess a penalty of up to $1,000 for each unit of blood and each blood component that ARC fails to locate within 72 hours after a region initially learned that such blood or blood component was not in its assigned location." In this instance, FDA is assessing a penalty of $750 for each of the 47 units of blood or blood components that ARC failed to locate within 72 hours after a region learned that the blood or blood component was not in its assigned location. Those lost products are listed in Attachment 1.

Additionally, Paragraph IV.B.17.a. states that "within 5 business days thereafter, ARC shall notify FDA in writing of each such lost unit of blood or blood component and if such timely notification is not made, FDA may assess a penalty of up to $10,000 for each such notification failure." FDA identified two ARC reports that were not submitted to FDA within five business days of the day that ARC initially learned that the blood or blood components were not in their assigned locations. Those late reports were from one region and were substantially late, specifically, 14 and 82 days. (See Attachment 2.) In this instance, FDA is assessing a penalty of $10,000 for the report that was 82 days late and $5,000 for the report that was 14 days late.

The total fine that FDA is imposing is $50,250. As provided in Paragraph IX of the Decree, if ARC agrees with this adverse determination, it must within 20 days of receipt of this letter, notify FDA of its agreement and its intent to pay the fine. If ARC disagrees with FDA's adverse determination, it must respond in writing within 20 days of receipt of this letter, explaining its reasons for disagreeing with FDA's determination. Your response must be submitted to me at the Food and Drug Administration, Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, with a copy to Jesse Goodman, M.D., Director, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200 N, Rockville, Maryland 20852.

Sincerely yours,

Lee Bowers
Director, Baltimore District

ATTACHMENTS

cc: Marsha Johnson Evans
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2025 E Street, N.W.
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