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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May 16, 2005

ADVERSE DETERMINATION LETTER

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:

Paragraph X of the Amended Consent Decree of Permanent Injunction (Decree) entered on April 15, 2003, permits the Food and Drug Administration (FDA) to assess a penalty for "…each unit of unsuitable blood or blood component that the [American Red Cross (ARC)] distributes after entry of [the Decree] for which FDA determines that the release was preventable by ARC...". Paragraph X.A.2. of the Decree provides that "[i]f FDA determines that use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote, FDA may assess a penalty of up to $5,000 for each such unit of blood or each such blood component. Notwithstanding the foregoing, FDA shall not assess ARC under this subparagraph (X.A.2) for the improper release of more than 100 units in any one event."

FDA reviewed its database and files to identify classified[1] ARC-conducted recalls. We identified 136 events in which ARC reported to FDA that they retrieved unsuitable blood components that were distributed during the period, April 15, 2003 through April 15, 2004. FDA determined that these events were preventable by ARC, that they meet the health hazard criteria of Paragraph X.A.2. of the Decree, and that no penalty exception listed in Paragraph X.B. of the Decree applies. These events involved 9,946 unsuitable blood components. Nine of the events involved more than 100 unsuitable blood components but were limited for penalty purposes to 100 units as provided by Paragraph X.A.2. of the Decree. The total number of unsuitable blood components for which FDA assessed a penalty under Paragraph X.A.2. of the Decree is 1,443. The unsuitable blood components are listed by event in the attachment to this letter. The events are identified by FDA-assigned recall numbers and are arranged by

[1] Recall classification is the numerical designation assigned by FDA to particular product recalls to indicate the relative degree of health hazard presented by the recalled product. See 21 CFR 7.3(m).

ARC Regions. The attached list does not include all events that occurred during the specified time period; only those events classified by FDA as of May 3, 2005, are included. Based on FDA's final review and classification of each event not included herein, additional penalties may be assessed for other events occurring during this aforementioned time period.

Additionally, Paragraph X.C. of the Decree permits FDA to "…assess an additional penalty of up to $50,000 for each unit of unsuitable blood or blood component that was returned by a consignee and re-released for distribution by ARC, if ARC had the ability to determine that the blood or blood component was unsuitable, and failed to do so." FDA identified one unsuitable "Platelets Pheresis Leukocytes Reduced" component that was re-released for distribution by ARC's Central Plains Region in September 2003 after the unit had been held under unacceptable storage conditions for approximately 50 hours. This event (#B-1132-4) is described in the attached list under ARC's Central Plains Region.

After considering the three factors in Paragraph X.A.2. of the Decree, FDA has assessed a total penalty of $3,407,000. The amount assessed for each unsuitable blood component is specified per event on the attached list. Additionally, for the re-release of the unsuitable blood component by ARC's Central Plains Region, FDA is assessing a penalty of $10,000.

As provided in the Decree, if ARC agrees with this adverse determination, they shall within 20 days of receipt of this letter, notify FDA of its intent to come into compliance with the Decree and submit a plan to do so. If ARC disagrees with FDA's adverse determination, they shall respond in writing within 20 days of receipt of this letter, explaining the reason(s) 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., M.P.H., Director, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200 N, Rockville, Maryland 20852.

Sincerely yours,

/s/

Roberta F. Wagner
Acting Director, Baltimore District

Attachment

cc: Marsha Johnson Evans
President and Chief Executive Officer
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2025 E Street, N.W.
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C. William Cherry
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