DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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April 4, 2007

ADVERSE DETERMINATION LETTER

BY FACSIMILE & CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John F. McGuire
President and CEO &
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 IV.B.17.a. of the amended Consent Decree of Permanent Injunction (Decree) dated April 15, 2003, requires that the American National Red Cross (ARC) must ensure that its regional blood service facilities (regions) notify the Food and Drug Administration (FDA) "in writing within 5 *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." Ensuring traceability of blood and blood components is critical to protect public health. For example, 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.

For the period September 1, 2005, through December 31, 2006, ARC reported to FDA that it failed to locate 200 blood or blood component items within 72 hours of initially learning that they were not in their assigned locations. 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 $650 for each of 53 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. See Attachment 1 (List of Lost Products -- Penalty Assessed).

Attachment 2 is a list of 147 instances reported by ARC, but excluded from penalty assessment by FDA at this time. According to ARC's reports, thirty six of these instances involved either: the amount of blood collected was insufficient; no blood was collected from the donor; or the container was broken or leaking, none of which could be further processed. Because such problems prevent any blood collected

from being processed and distributed, they would be expected to present a low risk to public health. For that reason, we are not assessing a fine for these instances this time. Nevertheless, these occurrences reflect problems in the blood inventory management system that should be prevented. FDA reminds ARC that it must maintain a record of the disposition of such instances in accordance with FDA regulations and that it should strengthen its efforts to reduce their occurrence.

Additionally, FDA is exercising its regulatory discretion in not assessing a penalty for each of the 111 lost blood products listed in the June 21, 2006 report for the Lewis and Clark Region. ARC reported that all of these products were part of one incident involving biohazardous waste disposal on that day. Although ARC failed to follow certain of its own standard operating procedures in documenting and verifying boxes of material picked up, the disposal control records show that ARC properly designated the units for disposal. We therefore believe this incident involved a low risk to public health and will not assess a fine on this occasion, without restricting our ability to assess a fine in the future for similar failures to follow standard operating procedures.

Paragraph IV.B.17.a. further states that "[w]ithin 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 five reports (covering seven products) 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. In the exercise of its enforcement discretion and without committing to whether or not similar future events will result in fines, FDA is not assessing a penalty for two of these late reports, which were four and seven days late. However, FDA is assessing a penalty of $500 for one report that was 24 days late and $10,000 for each of two reports that were 676 days and 206 days late. See Attachment 3.

The total fine that FDA is imposing is $54,950. 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., MPH, Director, Center for Biologics Evaluation and Research, 1401 Rockville Pike, Suite 200 N, Rockville, Maryland 20852.

Sincerely yours,

Evelyn Bonnin
Director, Baltimore District

ATTACHMENTS