DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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June 17, 2010

BY FACSIMILE & CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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. 93-0949 (JGP)

Dear Mr. Hrouda:

On October 30, 2009, the Food and Drug Administration (FDA) issued the American National Red Cross (ARC) an Adverse Determination Letter (ADL) citing significant violations of the law, regulations, and the Amended Consent Decree of Permanent Injunction (Decree), entered on April 15, 2003. The violations were observed during inspections of twelve ARC Blood Services facilities conducted in 2008. In that ADL, FDA notified ARC that it had determined that ARC did not comply with the law, ARC SOPs, and the Decree; that it regards the violations discussed in the ADL to be significant; that FDA was continuing to evaluate assessing fines and alternate or additional regulatory measures; and that its decision on those matters would be communicated to ARC separately. The purpose of this letter is to notify ARC of FDA's decision.

As stated above and in the October 30, 2009 ADL, FDA has determined that ARC did not comply with the law, ARC SOPs, and the Decree. Pursuant to Paragraph IX of the Decree, FDA is fining ARC $10,000 for each day from May 11, 2007, through February 8, 2009 (639 days). This period begins on the date that is 270 days before an FDA Investigator issued an FDA 482 Notice of Inspection at BHQ on February 5, 2008, continues through the FDA inspection conducted at ARC's New England Region, which concluded on November 24, 2008, when FDA issued the FDA 483 Inspection Observations, and ends ten days after FDA reviewed ARC's January 29, 2009 response to the FDA 483 that was given to ARC at the conclusion of the inspection of the New England Region. The subtotal for the fine, before including a fine amount yet to be determined for the number of days it takes ARC to submit its compliance plan, is $6,390,000. If the compliance plan is not adequate, additional penalties may be assessed.

We have fined ARC $10,000 for each day during the relevant period described above (May 11, 2007, to February 8, 2009) because FDA investigators documented that ARC was significantly and consistently violating the law and the Decree before February 8, 2008, as shown by the violations discussed in the October 30, 2009 letter, up to and including January 29, 2009, the date on which ARC filed its last

response to the FDA 483. In addition, we are fining ARC for the first ten days of FDA's response period.

Please note that under the Decree there are other methods of calculating the fine. First, because many of the violations continued for an extended period of time, there were many days on which several violations occurred simultaneously. Thus, FDA could have charged for more than one violation on a single day instead of the single per diem charge. Second, under paragraph IX.A. of the Decree, FDA could have penalized ARC "up to $10,000 for each violation and (emphasis added) for each day described in FDA's [ADL]." Third, under paragraph IX.F.4 of the Decree, FDA could have penalized ARC not only for the initial violations of each line employee but also for each subsequent ARC failure to detect and correct the violations (e.g., by downstream supervisors and BHQ). FDA did not impose these cumulative fines here and instead chose to impose a single per diem fine. If FDA had chosen to cumulate the fines, the total amount would have been far more than $6,390,000. Please also note that our decision to not cumulate the fines for these twelve inspections may not be followed in subsequent ADLs.

Paragraph IX.F.5. of the Decree states that "All penalties assessed under this Order shall be based on the year in which the violative conduct occurred. The annual cap amounts described in paragraph IX.F.1. of this Order shall also be attributed solely to the year in which the violative conduct occurred." The penalty period described in this letter includes violations that occurred in 2007, 2008, and 2009. The penalty amounts assessed as a result of the violations for each of those years is $2,350,000 in 2007, $3,650,000 in 2008, and $390,000 in 2009.

After evaluating the compliance plan, FDA has elected not to assess an additional penalty amount for the period between ARC's receipt of the ADL and submission of its compliance plan. Pursuant to Paragraph IX .F.6 of the Decree, payment of the $6,390,000 is due no later than thirty days after ARC notifies FDA that it will not dispute FDA's adverse determination. In this instance, payment is due no later than thirty days after receipt of this letter.

In accordance with paragraph IX.F.7. of the Decree, we are attaching instructions for the electronic transfer of this payment to the United States Treasury. ARC must, contemporaneously 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 Nancy Rose, Compliance Officer, at (410) 779-5415, or Linda Mattingly, Consumer Safety Officer, at (410) 779-5443.

Sincerely yours,

Evelyn Bonnin
Director, Baltimore District

Enclosure

cc:

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