DEPARTMENT OF HEALTH AND HUMAN SERVICES

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July 27, 2006

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:

The United States Food and Drug Administration (FDA) inspected the manufacturing and distribution facility of the Greater Chesapeake and Potomac Region (GCPR) of the American National Red Cross (ARC), located at 4700 Mount Hope Drive, Baltimore, Maryland 21215, on a number of days between September 13, 2005 and January 30, 2006. During the inspection, FDA investigators observed many violations of the law, FDA regulations, and the Amended Consent Decree of Permanent Injunction entered on April 15, 2003 (Decree). In this letter we discuss only the observation that GCPR failed to thoroughly investigate and correct a significant training record irregularity. FDA is still reviewing ARC's response to the other issues listed in the Form FDA 483 Inspectional Observations (FDA 483) issued at the conclusion of the inspection.

FDA investigators notified GCPR of the violation verbally on January 19, 2006 and in writing on January 30, 2006, in the Form FDA 483 (copy attached). FDA has reviewed ARC's March 30, 2006 response regarding the training record irregularity and finds it inadequate. Pursuant to Paragraph VIII of the Decree, FDA is now notifying ARC of its determination that ARC has violated the law, regulations, and the Decree.

On August 9, 2005, a GCPR [redacted] and her supervisor both signed the employee's training record indicating that she had been trained and was competent to perform twelve separate blood collection tasks, even though the employee had been trained to perform only seven of those tasks.[1] According to GCPR's problem report, the employee only performed one of the five tasks for which she

[1] The Decree requires ARC employee training files to include a "list that identifies each procedure for which the employee is responsible" and a statement "signed by the employee and that employee's supervisor attesting to the fact that the employee . . . has received, successfully completed, and understands the training specified in the [Decree], and that as a result of the foregoing, the employee is qualified, competent, and ready to perform each such procedure." Paragraph IV.C.5.f.

had not been trained, Whole Blood Collection Set Preparation, before the problem was discovered two months later by GCPR, on October 11, 2005.[2] The report does not state how many times the employee performed the task, which, if not performed correctly, could have resulted in whole blood number mix-ups. Whole blood number mix-ups pose a significant potential health risk, *e.g.*, communicable disease test results could be associated with the wrong donor, and/or a unit of blood could fail to be correctly associated with its donor in the donor deferral database. The first situation places both recipients and donors at risk: an unsuitable donor, such as an HIV-positive donor, would not be prevented from making subsequent donations because test results have been associated with the wrong donor record, which would also result in the donor not being contacted about the HIV-positive test results. The second situation places recipients at risk because a unit of blood from an unsuitable donor may be distributed (even when a donor's deferral status is later detected).

On October 11, 2005, GCPR became aware of the problem with the training record, and a GCPR Education Coordinator initiated an investigation and notified the Regional Quality Director. GCPR classified the incident as a problem requiring a [redacted] investigation (moderate risk). ARC's [redacted] requires [redacted] investigations to [redacted], requires the problem manager to determine root causes of the problem.

On November 1, 2005, a Problem Manager, a Quality Assurance representative, the Education Coordinator, and a blood collection supervisor met to determine and document the root cause of the problem and develop a corrective action and an effectiveness check. The group concluded that the root causes were that the employee [redacted] and the Education Coordinator failed to compare the employee's previous training transcript with the training requirements for GCPR whole blood collections staff[3], and that the employee signed the training record without realizing that she had not been trained for certain tasks. The proposed corrective action was to fully re-train all employees [redacted], and the proposed effectiveness check was to ensure that the re-training occurred.

On January 3, 2006, GCPR Quality Assurance approved the results of the effectiveness check and closed the problem, ending its investigation. However, the problem file contains no documentation that GCPR conducted a thorough investigation to discover why the employee and supervisor both signed the erroneous training record, even though the first page of the record explains the scope of the training reflected by a signature.[4] As a result of the incomplete investigation, GCPR failed to determine all root

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[2] The Decree further requires ARC employees to be trained and competent in procedures before performing them. Paragraph IV.C.6.

[3] As ARC's March 30, 2006 response clarified, the Education Coordinator's failure to compare the employee's training transcript [redacted] with training requirements for GCPR whole blood collection staff resulted in the failure to inform the employee's supervisor about the need for training.

[4] The first page of the training record states:

[redacted]

...

causes of the problem, in violation of ARC's SOPs (standard operating procedures) and [redacted] As mentioned above, FDA notified GCPR of this violation on January 19 and 30, 2006, and ARC provided its response to FDA on March 30, 2006.

This record discrepancy is significant because it is not an isolated incident, reflects a troubling and recurrent pattern, and presents serious potential health risks. FDA has previously notified ARC of its failure to adequately investigate recordkeeping irregularities, or allegations of such irregularities, at other facilities.[5] Moreover, the erroneous record indicates a problem with the integrity of GCPR's records, and the incomplete investigation does not allow for adequate corrective measures, including measures to address systemic records integrity problems. In fact, the manner in which the incident was coded in ARC's automated problem management system — as a training problem, with no mention of the erroneous information in the training record — would prevent the records integrity issue from gaining the attention of ARC senior management and would have prevented this incident from being reviewed as part of ARC's historical problem with records management.

ARC's March 30, 2006 response states that GCPR took several additional actions to correct and prevent recurrence of the training record irregularity, including management review, with the staff involved in the incident, of the training process and the significance of signatures on training records, and management review of certain SOPs with supervisory staff and collection education coordinators. However, ARC submitted no documentation to support the additional corrective actions.[6] Without documentation of the additional corrective actions, FDA cannot evaluate fully ARC's response. Furthermore, ARC's response does not address GCPR's failure to conduct a thorough investigation of the problem to determine why the employee and her supervisor signed the erroneous record.

The definition of "problem" in the Decree includes "any deviation from the law, ARC SOPs, or this Order . . . . " Paragraph IV.B.1.a.ii of the Decree requires each region "commensurate with the nature of the problem, [to] promptly, thoroughly and adequately investigate, correct, and take steps to prevent the recurrence of each problem . . . ." Here, GCPR failed to adequately investigate, correct, and take steps to prevent the recurrence of this document integrity and training problem, in violation of the Decree.

[redacted]

[5] FDA notified ARC of its failure to follow its own SOPs and failure to adequately investigate recordkeeping irregularities in (1) an FDA 483 issued in December 2002 to ARC's Biomedical Headquarters; (2) in an April 14, 2003 letter to ARC issued under Paragraph VI.A. of the 1993 Consent Decree of Permanent Injunction; and (3) in a May 28, 2005 Adverse Determination letter based on violations observed at ARC's Southern California Region's manufacturing and distribution facility. In fact, precisely because similar recordkeeping irregularities occurred under the 1993 Consent Decree, the United States insisted upon having recordkeeping requirements, including accuracy, incorporated in Paragraph IV.B.9.b of the Amended Decree.

[6] Paragraph IV.B.1.a.ii of the Decree requires ARC to document corrective actions: "Each region and laboratory shall thoroughly and contemporaneously document each step it takes to investigate, correct, and prevent recurrence of each problem . . . ."

Additionally, 21 C.F.R. § 211.22(d) requires that "the responsibility and procedures applicable to the quality control unit shall be in writing . . . [and] shall be followed." Here, GCPR failed to follow its own written procedures, [redacted] in violation of 21 C.F.R. § 211.22(d).

Paragraph VIII of the Decree provides that "[i]n the event that FDA determines, based upon inspection . . . review of ARC records, or other information that comes to FDA's attention . . . that ARC is not following any SOP that may affect donor safety or the purity or labeling of blood or any blood component, . . . has violated the law; has failed to fully comply with any . . . term or provision of this Order . . . then FDA may order ARC to come into compliance with the law, ARC SOPs, or this Order, assess penalties, and/or to take any step that FDA deems necessary to bring ARC into compliance with the law, ARC SOPs, or this Order." For the reasons stated above, FDA has determined that ARC did not comply with the law, ARC SOPs, and the Decree.

Therefore, FDA orders ARC to ensure that all ARC quality assurance staff are informed that they must *promptly* and *thoroughly* investigate, correct, and prevent all recordkeeping irregularities, including irregularities that involve signing records that do not accurately reflect tasks performed or employee training and competency, that quality assurance staff promptly and adequately document such thorough investigations and properly identify recordkeeping irregularities as such, and that quality assurance staff promptly bring any records integrity problem to the attention of ARC senior management.

In addition, pursuant to Paragraph IX of the Decree, FDA is fining ARC $2,000 for each day from August 9, 2005 (the day the violation occurred) through October 11, 2005 (when ARC discovered the violation); $3,000 for each day from October 12, 2005 through January 19, 2006 (when FDA first notified ARC about its inadequate investigation); $4,000 for each day from January 20 through March 30, 2006 (when ARC submitted its inadequate response to FDA); and $1,000 for each day from March 31 through April 13 (the first 10 working days during which FDA reviewed ARC's response). The subtotal for the fine, before including a fine amount to be determined for the number of days for submission of ARC's compliance plan, is $718,000. If the compliance plan is not adequate, additional penalties may be assessed.

As provided in the Decree, if ARC agrees with this adverse determination, ARC shall, within twenty (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, and shall pay the fine no later than thirty (30) days thereafter. If ARC disagrees with FDA's adverse determination, it shall respond in writing within twenty (20) days of receipt of this letter, explaining its reason 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,

Evelyn Bonnin
Director, Baltimore District

ATTACHMENT

cc:

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