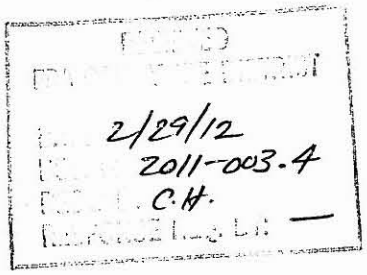
American Red Cross

Biomedical Services
2025 E Street, NW
Washington, DC 20006

February 27, 2012



Ms. Evelyn Bonnin
District Director
Baltimore District
Food and Drug Administration
6000 Metro Drive, Suite 101
Baltimore, MD 21215

Re: Adverse Determination Letter dated January 13, 2012

Dear Ms. Bonnin:

This is a follow-up letter to the initial response letter dated February 13, 2012 associated with the concerns raised in the Food and Drug Administration (FDA) Adverse Determination Letter (ADL) dated January 13, 2012.

This letter includes the following items in response to the ADL.

- Attachment 1 – FDA Orders – Response Status Report – this attachment provides FDA with a status report of the Red Cross' response to each FDA Order.
- Attachment 2 – Response to 45 day Orders (Order 4 and Order 16).

If you have any questions regarding this submission, please contact my office at 202-303-5300.

Sincerely,

Kathryn Waldman for

J. Chris Hrouda
Executive Vice President
Biomedical Services

cc: Karen Midthun, M.D., Director, CBER
Mary Malarkey

Attachments:

Attachment 1 – FDA Orders – Response Status Report
Attachment 2 – Response to 45 day Orders (Order 4 and Order 16)

ATTACHMENT 1

FDA Orders – Response Status Report

Order 1:
Within 60 days of receipt of this letter, provide a status report of each issue noted during internal audits of the DCSC since the beginning of consolidation in May 2008 and whether each issue has been effectively corrected. Please provide a justification for any open problems created as a result of an internal audit. Explain why they were not addressed promptly when the auditors found each issue.

Status: Red Cross will provide a response within 60 days of receipt of the ADL.

Order 2:
Within 30 days of receipt of this letter, provide a list and a complete description of each functional team in the DCSC, including a complete list of all supplemental sites assisting with Philadelphia and Charlotte DCSC activities. Provide a status report of the staff hiring plan described in your 12/15/10 response to the Philadelphia DCSC FDA 483 issued on 10/29/10.

Status: Red Cross' response was provided in the February 13, 2012 submission.

Order 3:
Within 90 days of receipt of this letter, re-examine the DCSC response to the ARC BHQ audit observations related to training. Report to FDA what ARC is doing to strengthen its DCSC training program given the audit observation and the lack of a corrective action plan to address training at that point in time. Explain why obvious training deficiencies were not addressed promptly and adequately at the time of their discovery by the auditors. Also, explain ARC's methodology for evaluating the adequacy of its DCSC training program.

Status: Red Cross will provide a response within 90 days of receipt of the ADL.

Order 4:
Within 45 days of receipt of this letter, provide a thorough description of ARC's system for determining the staffing levels for the mobile collection drives and submit the written procedure that describes this system.

Status: Red Cross' response is provided in this submission, dated February 27, 2012.

Order 5:
Within 60 days of receipt of this letter, provide a thorough description of the DCSC's operation for answering donor eligibility calls from collection sites, including the number of staff assigned to this function. Explain the use of inexperienced DCSC personnel answering donor eligibility

calls from collections sites. Describe what controls ARC has implemented to ensure DCSC personnel provide accurate answers to donor eligibility calls.

Status: Red Cross will provide a response within 60 days of receipt of the ADL.

Order 6:

Within 45 days of receipt of this letter, establish and implement a time frame for the Medical Director' s review of DRIRs. A timely review is critical to donor safety due to the seriousness of some donor reactions. In order to ensure that the safety of the donor is not compromised, the Medical Director's review should be completed prior to allowing a donor who has experienced a donor reaction to return for additional donations.

Status: The DCSC and Medical Directors have discussed appropriate ways to address this concern. System 14, Donation Recruitment and Qualification Management, documents are currently being revised under Document Change Request (DCR) #14647 to ensure that a standard process for managing donor reaction evaluations is effectively implemented throughout the organization. Red Cross anticipates document development to be completed by February 29, 2012 and will fully implement the revised procedures no later than May 7, 2012.

Red Cross requested an extension for responding to this Order in the February 13, 2012 submission letter and will provide a response within 120 days of receipt of the ADL.

Order 7:

Within 45 days of receipt of this letter, communicate to all collection staff personnel and management the regulatory and procedural requirements for managing and documenting donor adverse reactions. Ensure that all collection staff is adequately trained to perform this task. Report to FDA your plan to accomplish this order.

Status: Staff members were retrained on the donor adverse reactions process and procedures with the implementation of BioArch R1; all regions (except Puerto Rico) will implement BioArch R1 by (b) (4) To supplement this training, Red Cross developed a workshop to present to all collections staff to address this concern. The workshop materials are currently in routing for final review and approval. Red Cross anticipates the completion of the training by b4 (b) (4)

Red Cross requested an extension for responding to this Order in the February 13, 2012 submission letter and will provide a response within 120 days of receipt of the ADL.

Order 8:

Within 60 days of receipt of this letter, develop a work around to assess whether a donor has prior names in the NDDR to ensure that unsuitable blood products are not distributed from donors who have prior names in the NDDR.

Status: A task force has been identified to assess workaround options to address the concern related to donors with prior names when the donor had a record in the NDDR. The task force is

currently identifying different scenarios where this situation may occur and investigating how the Red Cross current and future software systems react when presented with these types of scenarios. Because this is a complex issue that requires a detailed analysis, Red Cross anticipates the analysis to be completed by the end of (b) (4), at which point Red Cross intends to develop an action plan based on the analysis.

Red Cross requested an extension for responding to this Order in the February 13, 2012 submission letter and will provide a response within 120 days of receipt of the ADL.

Order 9:
Within 60 days of receipt of this letter, perform a retrospective review of survey cards, since the time they were first issued to the date of this letter, to identify all complaints or concerns that are related to FDA regulated functions and, as required by the Decree, manage any regulated complaints/concerns as problems. Identify all regions that issue such survey cards. Additionally explain how ARC manages such complaints and concerns that are received through the internet.

Status: Red Cross has received the regional retrospective review responses and is evaluating the data.

Red Cross requested an extension for responding to this Order in the February 13, 2012 submission letter and will provide a response within 120 days of receipt of the ADL.

Order 10:
Within 30 days of receipt of this letter, provide copies of all Quality Process Reviews conducted at the DCSC since the DCSC began merging of the regional donor management operations. This material was requested numerous times during the September-October 2010 Philadelphia DCSC inspection. Provide a detailed explanation why the completed Quality Process Reviews were not provided to the FDA investigators during the inspection.

Status: Red Cross' response was provided in the February 13, 2012 submission.

Order 11:
Within 60 days of receipt of this letter, provide a status report on ARC's 12/15/10 response to the Philadelphia DCSC FDA 483 issued on 10/29/10.

Status: Red Cross will provide a response within 60 days of receipt of the ADL.

Order 12:
Within 30 days of receipt of this letter, provide a copy and complete description of the Modified Compliance Improvement Strategy (MCIS) that the DCSC was placed on in January 2011, as well as the status of the MCIS.

Status: Red Cross' response was provided in the February 13, 2012 submission.

Order 13:
Within 60 days of receipt of this letter, develop and implement an SOP to require complete documentation of all information evaluated during review of any utility report including the soundex reports. Provide a copy of this SOP to FDA and include the effective date of its implementation.

Status: Red Cross is currently developing an enhancement to an existing procedure to ensure a standard process for documenting the review of any utility report including the soundex report. On January 24, 2012, BHQ approved the DCR, #14501, associated with this enhancement. Red Cross anticipates the document development and approval process to be completed by the end of February with an implementation date o(b) (4)

Red Cross requested an extension for responding to this Order in the February 13, 2012 submission letter and will provide a response within 120 days of receipt of the ADL.

Order 14:
Within 30 days of receipt of this letter, provide an explanation for the use of BPD Code QC-90-01-05 [failure to adequately manage potentially non-confirming product (product not released)] when ARC's investigation into problems determined that blood products were actually distributed. FDA noted this during the review of Exception Reports E-0780785 and E-0790730.

Status: Red Cross' response was provided in the February 13, 2012 submission.

Order 15:
Within 60 days of receipt of this letter, review the contents of the quarterly and annual QA reports to ensure that such reports adequately convey to ARC' s Biomedical Services senior management that serious problems or deficiencies are developing and/or have occurred. This would enable senior management to be aware of the potential risk of the developing problems/deficiencies to public health and the impact on ARC's compliance with the law and the Decree.

Status: Red Cross will provide a response within 60 days of receipt of the ADL.

Order 16:
Within 45 days of receipt of this letter, provide a list of all facilities using the hand warmers during the blood collection process. Include details regarding: when the facilities began utilizing the hand warmers, what the purpose of their use is, and why they were in use without training and a written procedure.

Status: Red Cross' response is provided in this submission, dated February 27, 2012.

Order 17:

Within 45 days of receipt of this letter, evaluate the process for performing annual competency assessments and determine the reason they consistently fail to identify employees who do not perform tasks in accordance with written procedures or manufacturer' s instructions. Report to FDA what steps you plan to take to ensure the assessments are adequate.

Status: In order to evaluate the competency assessment process, Red Cross is conducting a full task analysis of the process. This analysis will review what is being assessed, how the assessments are conducted, and the qualifications of our instructors. As part of the analysis, Red Cross will also review the current instructor training courses to determine if they appropriately prepare our instructors to effectively perform competency assessments of our employees. The task analysis will be completed by the end of (b) (4) with a full action plan based on the analysis completed by the end of (b) (4)

Red Cross requested an extension for responding to this Order in the February 13, 2012 submission letter and will provide a response within 90 days of receipt of the ADL.

ATTACHMENT 2

Response to Order 4

Order 4:

Within 45 days of receipt of this letter, provide a thorough description of ARC's system for determining the staffing levels for the mobile collection drives and submit the written procedure that describes this system.

Response:

Red Cross uses (b) (4) a Commercial Off-the-Shelf (COTS) scheduling software package developed by (b) (4), to manage blood drive staffing levels and scheduling. Using locally developed staffing plans, the (b) (4) software provides staffing level recommendations based on the staff capacity, anticipated goal of presenting donors, and the length of the blood drive to assist the region in effectively scheduling the number and qualification of personnel needed to perform the blood collection functions. This information is only a recommendation and no requirement exists to staff each collection operation precisely to the recommended level. There is no national standard procedure that describes this system. Although each region makes every effort to staff operations according to the recommendations, illness or other emergencies may occur where it is not possible to have the recommended number of staff members at the blood drive.

Red Cross standard operating procedure (SOP) Reference 15.4.ref208, *Standard Work Guidance – Collection Site Setup*, developed for the BioArch Release 1 implementation, provides guidance for collection site set up. On the day of a blood drive, the on-site supervisor uses this SOP to determine the recommended quantity of equipment to set up based on the number of staff present and working at the site. In addition, the supervisor has the authority to cancel a blood drive, upon consultation with regional management, if the site is unsuitable for the blood collection activities or staff members are unable to provide adequate care to donors. In the event that a blood drive begins with fewer than planned staff, donors may have to wait longer to complete the donation process; however, this situation would not compromise the safety of the donor or the blood supply.

Response to Order 16

Order 16:

Within 45 days of receipt of this letter, provide a list of all facilities using the hand warmers during the blood collection process. Include details regarding: when the facilities began utilizing the hand warmers, the purpose of their use is, and why they were in use without training and a written procedure.

Response:

Staff members are only allowed to use hand warmers for donor comfort in accordance with manufacturer's instructions and are not permitted to use them for any regulated process; therefore, no procedural guidance and/or training is necessary.

The investigation into the incident identified in Southern California revealed that Collections staff members used commercial hand warmers, intended for ALYX apheresis double red cell donor comfort, for whole blood donors in a manner inconsistent with the manufacturer's instruction. The region immediately removed all hand warmers from the supply boxes and hand warmers are no longer used in the facility.

On October 22, 2010, as a global corrective action to the observation cited in Southern California, Red Cross issued Communications Weekly Update (CWU) #874, which reinforced that hand warmers may only be used on an apheresis donor's hands, in accordance with the manufacturer's instructions, as a means of providing comfort.

The Red Cross facilities listed below currently use commercial hand warmers for donor comfort during apheresis procedures only. Based on the information from the Red Cross national purchasing database, these regions have been using hand warmers since at least 2003.

- Arizona Region
- Central Ohio Region
- Midwest Region
- New England Region
- River Valley Region