

DECREE CORRESPONDENCE

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Sensitive Proprietary Information Provided Under Amended Consent Decree
Entered in U.S. v. American National Red Cross, U.S.D.C., D.C.
93 CIV. 0949

MASTER INDEX

<i>Document:</i>	<i>Subject:</i>	<i>Date:</i>	<i>Bates:</i>
1.	Decree Correspondence To: Evelyn Bonnin, FDA From: J. Chris Hrouda, ARC cc: Karen Midthun, M.D. Mary Malarkey This letter responds to the Food and Drug Administration's (FDA) Adverse Determination Letter dated October 30, 2009 related to Problem Management (the PM ADL). The Suspect Product Monthly Report per Order #1 is included in this submission.	March 24, 2010	090629
2.	Response to FDA Orders		090630- 090632
3.	Exhibit: Suspect Product Monthly Report		090633- 090934



Biomedical Services
2025 E Street, NW
Washington, DC 20006

March 24, 2010

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

RECEIVED
FDA BALTIMORE DISTRICT
DATE: 3/25/10
DOC # 2009-009.6
FILED BY: L. Matthews/ly
SOURCE REQ. BY: —

Re: Problem Management Adverse Determination Letter
Dated October 30, 2009

Dear Ms. Bonnin:

This letter responds to the Food and Drug Administration's (FDA) Adverse Determination Letter dated October 30, 2009 related to Problem Management (the PM ADL). The Suspect Product Monthly Report per Order #1 is included in this submission.

As indicated in the February 25, 2010 submission, the retrospective review for selective Chagas testing, as required in Order #3, will be provided to the FDA in the April 30, 2010 submission along with the next monthly suspect product report per Order #1.

If you have any questions regarding this submission, please contact my office at 202-303-4155.

Sincerely,

A handwritten signature in black ink, appearing to be "J. Chris Hrouda".

J. Chris Hrouda
Executive Vice President
Biomedical Services

cc: Karen Midthun, M.D.
Mary Malarkey

Attachments

This response contains confidential commercial information and trade secrets that belong to the American Red Cross.

Response to FDA Orders

FDA Order #1

Commencing with the first full calendar month following receipt of this letter, provide FDA each month thereafter a summary of problems involving failure to control suspect blood products. Such reports shall identify the responsible Region; provide a factual description of the occurrence, the dates of occurrence and discovery, the number of affected blood products, and the corrective action plan; state whether and when consignees were notified; and include a copy of the corrective action plan.

Order #1 Response

Attached is the *Suspect Product Monthly Report*, which includes data through March 5, 2010 (Exhibit 1).

Suspect Product Monthly Report Summary

This report has a total of [REDACTED] open problems. Of the [REDACTED] open problems there are 49 violative biologic product deviation (BPD) problems and [REDACTED] non-BPD problems. These problems are in various phases of completion:

Phase	Number of Open Problems
Investigation	[REDACTED]
QA Review	[REDACTED]
Implementation	[REDACTED]
Effectiveness Check Review	[REDACTED]
Other ¹	[REDACTED]
Total	[REDACTED]

Please inform the Red Cross if FDA requests any changes to the *Suspect Product Monthly Report*, and the requested changes will be made, where possible. The next monthly report will be submitted to FDA by April 30, 2010.

How to Use the Report

This report contains two sections: newly reported problems and previously reported problems. The report lists the Problem Number, Description, Date Occurred, Date Discovered, the Violation Indicator that shows whether it is a BPD or not, the associated Issue Number, and the Actions and Effectiveness Checks contained in the Corrective Action Plan. For problems where the Corrective Action Plan has not been developed, the page will contain a table header with no information other than [REDACTED] for the QA

¹ These problems do not yet have an associated issue created in [REDACTED]

Approval Status and [REDACTED] for the Action Plan Due Date. The report also lists Consignee Notified (Yes, No, N/A), First Date Notified (if Consignee Notified = Yes), and Total Affected Products.

On the header, of the Action Plan the report indicates the phase the problem was in at the time the report was run. These phases include INVESTIGATION, IMPLEMENTATION, EC REVIEW, and QA REVIEW.

Exhibits

Exhibit 1 Suspect Product Monthly Report: data through March 5, 2010