Inspections, Compliance, Enforcement, and Criminal Investigations

Community Blood Centers of Florida, Inc. 4/27/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
555 Winderley Place, Ste. 200
Maitland, Florida 32751
Telephone: (407) 475-4700
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
FLA-12-31

April 27, 2012

George H. Scholl, Chief Executive Officer
Community Blood Centers of Florida, Inc.
1700 N. State Road 7
Lauderhill, FL 33313-5097

Dear Mr. Scholl:

The Food and Drug Administration (FDA) conducted an inspection of your firm, Community Blood Centers of Florida, Inc., from September 1, 2011 - December 19, 2011. During the inspection, FDA investigators documented deviations from applicable current Good Manufacturing Practice for Finished Pharmaceuticals (21 CFR Part 211) and current Good Manufacturing Practice (cGMP) regulations for blood and blood components, Title 21 Code of Federal Regulations (21 CFR) Parts 600, 610 and 640. These deviations cause your blood products to be adulterated within the meaning of Section 501 (a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act), [21 U.S.C. 351 (a)(2)(B)]. These deviations include but are not limited to the following:

1) Failure to maintain records that include, but are not limited to, records to relate the donor with the unit number of each previous donation from that donor [21 CFR 606.160(b)(1)(vii)]. At least thirteen ABO discrepancies were noted during the previous inspection in July, 2007 and the discrepant units were still found to be associated with the wrong donor records during the current inspection. For example:

a) Registration information for a donor was entered over the existing record of another donor. The discrepant record was registered under "John Doe" and your firm failed to update the donor records to relate the unit number to the actual donor.

i) Registration information for an O Positive donor (unit # **(b)(6)** was entered over an existing A Positive donor record resulting in an ABO discrepancy. The O Positive donor donated again on January 13, 2010 but his previous donation information dated January 25, 2009 was registered under "John Doe."

ii) Registration information for an A Positive donor (unit # **(b)(6)**was entered over an existing O Positive donor record resulting in an ABO discrepancy. Your firm assigned the donation information for unit # **(b)(6)**to "John Doe."

iii) Registration information for an A Positive donor (unit # **(b)(6)** was entered over an existing 0 Negative donor resulting in an ABO discrepancy. Donation information for unit # **(b)(6)** was assigned to "John Doe."

b) Registration information for a donor was entered over the existing record of another donor. Your firm failed to identify the donor of the unit and it was discovered during the inspection that the discrepant unit was still associated with the wrong donor record.

i) Registration information for an A Positive donor (unit # **(b)(6)** entered over an existing 0 Positive donor record resulting Discrepancy.

ii) Registration information for an O Positive donor (unit # **(b)(6)** was entered over an existing A Positive donor record resulting in an ABO discrepancy.

iii) The initial donation for donor **(b)(6)** on November 16, 2009 (unit # **(b)(6)** tested A Positive. The donor's second donation on April 13, 2010 (unit # **(b)(6)** tested O Positive, resulting in an ABO discrepancy. The donation information for the second unit was assigned to "John Doe." · · collected from the same donor on February 9, 2011 (unit # **(b)(6)** tested O Positive and also resulted in an ABO discrepancy. Information obtained by your firm during subsequent donations indicated the donor was O Positive; however the donation records for donor **(b)(6)** had not been updated at the time of the inspection.

2) Failure to notify consignees of the results of the supplemental (additional more specific) test results for human immunodeficiency virus (HIV) within 45 calendar days after the donor tests reactive for evidence of HIV infection under 21 CFR 610.40(a) and (b) [21 CFR 610.46(a)(1)(ii)(B) and (3)]. Specifically:

Donor # **(b)(6)** on November 2, 2008 and tested initially reactive for anti-HIV. Your firm received the positive confirmatory HIV test results on December 10, 2008. According to your records, unit # **(b)(6)** was collected from the same donor on February 1, 2008. However, your firm did not notify the consignee of the unit of the HIV positive status of the donor until January 28, 2009, 87 days after the initially reactive test for HIV antibody was reported.

3) Failure to review all records pertinent to a lot or unit maintained pursuant to these regulations before the release or distribution of a lot or unit of final product [21 CFR 606.100 (c)]. Specifically:

Acrodose® pooled platelet unit **(b)(6)**. ed to meet product specifications. It was manufactured on December from four single donor units, using a sterile docking device. The following day, staff was unable to process the pooled platelet unit in your computer system due to the volume in the pool bag being insufficient. One of the single donor platelet units **(b)(6)** which had not drained completely, was retrieved from the biohazardous waste bin, sterile docked to the pool bag and added to the pooled unit. The single donor unit had not been in a temperature controlled environment with agitation for over 21 hours. The pooled platelet unit was distributed and transfused on December 23, 2007.

4) Failure to use supplies and reagents in a manner consistent with the instruction provided by the manufacturer [21 CFR 606.65 (e)].

The machines your firm uses to collect apheresis platelets (Trima Accel Automated Blood Collection System, Cobe Spectra® and Amicus Blood Cell Separator) are licensed for the collection of products with platelet concentrations between $1 \times 10^6/\mu L$ and $2.1 \times 10^6/\mu L$. From 2002 to June 2011, your firm collected and distributed over 7,000 apheresis platelets with platelet concentrations greater than $2.1 \times 10^6/\mu L$.

5) Failure of the quality control unit to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated and failure to follow written responsibilities and procedures applicable to the quality control unit [21 CFR 211.22 (a) and (d)]. For example:

a) Your blood center personnel responsible for the performance, review, and approval of corrective actions failed to conduct their duties as assigned in that investigations into the causes of product failures, whether found during Quality Control testing or on routine testing of products, were not thoroughly investigated to determine if the problem is related to other system errors that may affect other products that are collected, as evidenced by the inadequacy of the failure of investigations conducted for platelet-pheresis QC failures, ABO discrepancies and the handling of Post Donation Information.

b) Your blood center personnel responsible for conducting internal audits, failed to perform their tasks/functions according to the instructions in SOP QA 1.100, Quality Assurance Internal Inspection Audits. As a result, comprehensive audits of both quality and operational systems that were conducted periodically to assess compliance with regulations, standards and the blood center quality plan, failed to identify deficiencies in the area of donor registration, blood products processing and testing, and investigation of deviations.

c) Your firm's quality control unit failed to conduct a complete investigation of issues related to the interface between your Regulated Software Collections Application (RSA) and BioMerieux Clinical Diagnostics BAC-T Alert computer systems. You therefore failed to ensure the satisfactory transfer of bacterial testing results of platelet products.

6) Failure to maintain records concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced [21 CFR 606.160 (a)(1)]. Failure of your distribution records to contain information to readily facilitate the identification of the name and address of the consignee, the date and quantity delivered, the lot number of the unit (s) the date of expiration or the date of collection, whichever is applicable, or for crossmatched blood and blood components, the name of the recipient [21 CFR 606.165(b)].

a) Your blood center received multiple complaints from a customer regarding discrepancies in shipping records for Recovered Plasma. For example:

i) From August 9. 2010 to January 11, 2011, 42 units of recovered plasma were distributed to the same customer but were not documented on the shipping documents.

ii) From March 7, 2011 to May 17, 2011, 8 units of recovered plasma were documented on the shipping documents but were not included in the shipment to the customer.

b) The information in your irradiation logs does not match the processing records in your RAS computer system. For example:

i) The irradiation log shows unit # **(b)(6)** was irradiated from 13:36 to 3:40 but RAS indicates the unit was labeled as an irradiated product at 13:34.

ii) The irradiation log shows unit # **(b)(6)** was irradiated from 17:10 to 17:14 but RAS indicates the unit was labeled as an irradiated product at 17:13.

iii) The irradiation log shows irradiation was complete for unit # **(b)(6)** at 19:11 but was labeled as an irradiated product at 18:04, one minute prior to the completion of irradiation.

7) Failure to store and maintain Red Blood Cells (RBC) at a temperature between 1°C and 6°C immediately after processing [21 CFR 640.11(a)]. There is no documentation to show that irradiated blood products were placed in controlled temperature storage after irradiation. For example:

a. Unit # **(b)(6)** was irradiated at 10:49 and labeled as an irradiated product at 13:33.

b. Unit # **(b)(6)** was irradiated at 18:50 and labeled as an irradiated product at 19:40.

c. Unit # **(b)(6)** was irradiated at 11:29 and was labeled as an irradiated product at 13:16.

We acknowledge receipt of your written responses. dated January 7, 2012, February 9, 2012 and March 9, 2012 which addresses the inspectional observations on the Form FDA 483 issued on December 12, 2011. Your response is inadequate in that it fails to address corrective actions implemented for all the deviations noted in the FDA 483.

We note in your response that you addressed the issue of donor registration errors prospectively. You did not provide any actions regarding errors that currently exist in your RSA database. We recognized .at least thirteen errors that were identified to have occurred during donor registration which resulted in ABO discrepancies. However, your response provided no assurance that these are the only donor discrepancy errors in your database. We also note that this type of error was brought to your attention at the close of a previous inspection through a Form 483 issued in May 2004.

In addition, your quality control unit was cited in previous inspections in May 2004 and July 2007 for deficiencies related to failure to perform a thorough investigations and failure to implement adequate corrective actions on documented discrepancies. You promised corrective actions in your responses to deviations noted from those inspections; however, we are

concerned that your corrective actions were inadequate to prevent recurrence of these deviations.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your establishment. It is your responsibility to ensure that your establishment is in compliance with all applicable requirements of the federal regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in administrative or regulatory action by the FDA without further notice, including, but not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken or will take to correct the noted violations including an explanation of how you will prevent their recurrence. If the corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your response should be sent to: Winston R. Alejo, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751 If you have any questions about the content of this letter please contact: Mr. Alejo at (407) 475-4731.

Sincerely,

/S/
Emma R. Singleton
Director, Florida District

Page Last Updated: 08/01/2012
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