U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Regional Medical Center 4/21/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2761

April 21, 2011

WARNING LETTER

CIN-11-174032-13

Via United Parcel Service

Mr. Justin Sedlak, Laboratory Medical Director
Regional Medical Center
900 Hospital Dr.
Madisonville, KY 42431-1644

Dear Mr. Sedlak:

The Food and Drug Administration (FDA) conducted an inspection of your firm, Regional Medical Center, from January 11 through February 2, 2011. During the inspection, the investigator documented deviations from applicable current Good Manufacturing Practice (cGMP) regulations for blood and blood components, Title 21 Code of Federal Regulations (CFR) Parts 606-680 and current Good Manufacturing Practice for Finished Pharmaceuticals (2 CFR Part 211). 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 determine the suitability of a donor as a source of Whole Blood on the day of collection by a qualified physician or by persons under his supervision and trained in determining suitability [21 CFR 640.3(a)(1)].

For example, approximately one-third of the 100 donor cards reviewed by the FDA investigator were incomplete. Ten donor cards were incomplete due to multiple unanswered donor history questions. Seventeen donors answered "no" to questions that should have been answered "yes." Five donors answered qualifying questions with adverse and/or discrepant responses. All donors were allowed to donate, resulting in fourteen blood products that were distributed and transfused and six products that were distributed for further manufacture.

2. Failure to check input to and output from the computer or related system of formulas or other records or data for accuracy [21 CFR 211.68 (b)].

For example, your firm went live with version 2.0.0 of the Hemocare Lifeline (HCLL) Donor Module on March 2, 2009, however, the validation of Module 15, Product Labeling, was incomplete in that it was not reviewed, accepted, or signed off by a responsible individual. In addition, the old system utilized social security numbers with dashes and the new system utilizes social security numbers without dashes. Therefore, under the new system, duplicate social security numbers are not capable of merging into the social security field, which may result in the creation of duplicate donor records. Your firm was aware of this issue; however, no work- around was implemented.

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, and failure to complete and record a thorough investigation, including the conclusions and follow-up, of any unexplained discrepancy or failure of a lot or unit to meet any of its specifications [21 CFR 606.100(c)]. For example:

a. Thirteen weekly temperature recording charts for 2009 and 2010 were not recording continuous refrigerator and/or freezer temperatures. There were no visible temperature recordings on eleven charts, although the charts were initialed and dated as having been reviewed.

b. Three donor cards did not have documentation that the donor was accepted or rejected and were not signed by the donor screener, although the donors were allowed to donate.

4. Failure to maintain and/or follow written standard operating procedures (SOP) that include all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for transfusion and further manufacturing purposes [21 CFR 606.100(b)]. For example:

a. Your SOP 882, *Blood Donor Phlebotomy Protocol, states*, "Using a vigorous circular motion, scrub skin for thirty (30) seconds with the 7.5% povidone-iodine scrub swabstick #1." However, on January 12 and 25, 2011, phlebotomist T.B. scrubbed two different venipuncture sites for less than 10 seconds and proceeded with the donation process.

b. Your SOP 803, *Error Correction Procedure-Blood Bank*, requires that a single line be drawn through an error and the initials of the person making the correction must be documented along with the date of correction. However, errors on several blood donor records were corrected with scribbled or illegible write-overs and no dates or initials of the person making the correction.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your blood bank. It is your responsibility to ensure that your firm is in compliance with all requirements of the Act and federal regulations. You should take prompt action to correct the current deviations. Your failure to promptly correct these deviations may result in administrative and/or regulatory action without further notice.

We acknowledge receipt of your letter dated February 23, 2011 that provided responses to FDA's inspectional observations. We have reviewed the corrective actions outlined in the responses and have found them generally adequate. However, for Observations #1 and #4 on the FDA Form 483, your response only indicated changes in the prospective card review process and did not address a plan for a retrospective review of donor history cards from 2009 and 2010 to determine if donors were accepted without a complete donor screening. For Observation # 6, you indicated that