



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
Atlanta District
Southeast Region
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Atlanta, Georgia 30309

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May 6, 2003

WARNING LETTER
(03-ATL-19)

VIA OVERNIGHT DELIVERY

Ms. Linda Jubinsky
Vice President, Chief Operating Officer
Children's Healthcare of Atlanta at Scottish Rite
1001 Johnson Ferry Road
Atlanta, Georgia 30342

Dear Ms. Jubinsky:

During an inspection of your blood transfusion service, located at 1001 Johnson Ferry Road Atlanta, Georgia, on March 19-20 and April 1 & 3, 2003, our investigators documented serious deviations from Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 351(a)(2)(B)] and the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components under Title 21, Code of Federal Regulations (CFR), Parts 600-680 (21 CFR 600- 680). Most biological products are included in the definition of a drug under the FD&C Act, Section 201(g)(1). You can find the Act and Title 21, Code of Federal Regulations, through links in the FDA's home page at <http://www.fda.gov>

The deviations documented include the following:

- Your facility failed to submit biological deviation reports to FDA's Center for Biologics Evaluation and Research (CBER) within 45 calendar days from the date you acquired information reasonably suggesting that a reportable event has occurred [21 CFR 606.171] and failed to follow your SOP titled "Return and Reissue of Blood Products" [21 CFR 606.100(b)]. Specifically, on 10/14/02 and 9/22/02, two patients experienced a transfusion reaction during the transfusion of a unit of volume reduced irradiated platelets. Your investigations revealed possible bacteriological contamination during your volume reduction procedure. Another reportable event occurred on 5/14/02 when an aliquot of Red Blood Cells (RBC) was made from an A negative unit, but was mislabeled as A positive. The unit was subsequently released to the operating room. The mislabeled unit was not used during surgery and was returned to the blood bank on 5/15/02. The error was discovered on 5/16/02 when the RBC aliquot was being reissued. The aliquot was then put back into the primary mother bag and the aliquot was discarded from the computer.

- Your Blood Bank Manager does not have adequate knowledge concerning the daily operations to ensure that compatibility testing and daily blood bank operations are performed accurately. In addition, the technicians responsible for compatibility testing of blood or blood components are not adequately trained and experienced to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess [21 CFR 606.20(b)]. For example:

A) Conflicting test results for antibody screening were obtained on more than one occasion:

1. On 2/15/03, an antibody screen for patient [REDACTED] was reported as negative. An antibody screen for this same patient was then repeated by the [REDACTED] and by a second technician at your facility and was confirmed to be positive.

2. On 1/29/02, one of your technicians reported an antibody screen in [REDACTED] for patient [REDACTED] as negative, and later that same evening the antibody screen cells (sample tubes) were found in the cell washer. On 1/29/02, one of your technicians performed a retype and another antibody screen on patient [REDACTED]. The results of the antibody screen were subsequently reported as positive.

B) Contradictory ABO typing results were obtained on more than one occasion:

1. On 7/24/02, a technician typed patient [REDACTED] as B positive and typed patient [REDACTED] as A positive, however, patient [REDACTED] was later retyped as A positive and patient [REDACTED] retyped as B positive.

2. On 1/29/02, patient [REDACTED] was typed as B positive by one of your technicians, however, this patient was subsequently retyped as A positive during crossmatching.

In addition, your facility had no documentation to show whether the technicians in the aforementioned examples received retraining.

- Your facility failed to perform thorough investigations and make a record of the conclusions and follow-up of any unexplained discrepancies [21 CFR 606.100(c)]. For example:

A) The daily temperature logs document temperatures that are not consistent with the actual temperatures depicted on the recorder charts during the period of 2/25 – 4/5/02.

B) Review of the temperature recorder charts for the period of 4/29/02 – 2/10/03 found that the refrigerator recorder charts were placed on the platelet rotator and vice versa, however, acceptable temperatures were documented on the blood bank Temperature Log Sheet for both the refrigerator and platelet rotator. The refrigerator charts and platelet charts have different temperature measurement scales.

C) Discrepancies noted in the quarterly QC/Maintenance logs from June 2001 through March 2003 were not investigated and corrected prior to final management approval, specifically:

- a. Quality Control was routinely performed on two out of [REDACTED] centrifuges in use.
- b. The [REDACTED] centrifuge (lab equipment # [REDACTED]) was routinely outside of the manufacturer’s specified range of [REDACTED] RPM.
- c. A technician changed the high alarm set point of the freezer from -18.5° C to -18.6° C and -15.0° C on numerous occasions, without justification.
- d. The established temperature range for the plasma thawer was changed from [REDACTED]° C to that of [REDACTED]° C, without justification.

The records in the above examples were reviewed and signed by the Blood Bank Manager without noting these discrepancies or providing justification for the hand written changes made to the established set points and/or ranges.

- Records are not concurrently maintained with the performance of each significant step in the 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)]. Specifically, your facility failed to maintain records titled “Surgery Blood Bank Sign Out Record” which document the time that blood units and components are checked out of the blood bank, time placed in the Operating Room (OR) refrigerator, time removed from the OR refrigerator, and the time the unit was returned to the OR refrigerator. In addition, your facility routinely discards these records.
- Your facility failed to have written standard operating procedures for the operating room personnel on the proper utilization of the blood bank refrigerator temperature recorders, located in the operating room, to include maintenance of the recorder charts and documentation of blood storage temperatures [21 CFR 606.100(b)(10)].

We acknowledge receipt of your response letter dated May 3, 2003. Your response letter will be reviewed by Investigator Edecia Richards and Compliance Officer James MacLaughlin and comments regarding the adequacy of your corrective actions will be provided at a later date.

The above deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood products issued by your facility are in compliance with the Act and the CGMP regulations. You should take prompt action to correct these

deviations. Your failure to correct these deviations may result in regulatory action being taken by FDA without further notice. Possible actions include seizure and/or injunction.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these deviations, including examples of any documentation such as employee training records, written standard operating procedures, or other records demonstrating corrective action. If you cannot complete corrections within 15 working days, state the reason for the delay and the time period within which corrections will be completed.

Your reply should be directed to James C. MacLaughlin, Compliance Officer, at the address noted in the letterhead.

Sincerely,



Mary H. Woleske
District Director
Atlanta District