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Food and Drug Administration
New Orleans District
Nashville Branch Office
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Nashville, TN 37217

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September 26, 2003

WARNING LETTER

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Nancy E. Eckert, President and CEO
LifeSouth Community Blood Centers, Inc.
1221 NW 13th Street
Gainesville, Florida 32601

Warning Letter No. 03-NSV-30

Dear Ms. Eckert:

On June 18 - July 2, 2003, the Food and Drug Administration (FDA) conducted an inspection of your facility, located at 396 West Oxmoor Road, Birmingham, Alabama. Our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, *Code of Federal Regulations* (21 CFR), Parts 211, 600-680 as follows:

- You failed to restrict from distribution blood products collected by apheresis that did not meet label specifications as required by your standard operating procedures [21 CFR 606.100(b)(16) and 21 CFR 211.100(b)]. For example:
 - You erroneously labeled and distributed two triple platelet apheresis products as leukoreduced platelet apheresis products after confirmatory lab reports clearly identified the products as “***NOT LEUKOREduced!!!” due to elevated white blood cell counts.
 - You erroneously labeled and distributed one leukoreduced platelet apheresis product as a standard leukoreduced product instead of a non-standard leukoreduced product, since the single unit from which it was prepared failed to meet minimum platelet counts.
- You failed to maintain a written standard operating procedure requiring the investigation of products that fail leukoreduction specifications during routine sampling. In the 12 months prior to the inspection, 28 apheresis platelet units failed leukoreduction specifications [21 CFR 606.100(b) and 21 CFR 211.100(a)].
- You failed to perform investigations concerning apheresis products that failed to meet specifications as required in your written standard operating procedures. For example, no investigations have been conducted concerning 110 single apheresis products that failed to

meet minimum platelet counts. All of the failures occurred in the twelve months prior to the inspection [21 CFR 606.100(c) and 21 CFR 211.192].

- You failed to file Biological Product Deviation Reports on components prepared from 13 units of blood that failed quality control testing. For at least seven of the 13 units, the failed quality control test results were available prior to distribution, yet the Quality Control Unit failed to exercise its authority to reject these products [21 CFR 606.171(b) and 21 CFR 211.22(a)].
- Records intended to document the control of operations at your firm are not maintained adequately and discrepancies in records are not investigated adequately. These records include, but are not limited to, Complete Unit Disposition Listings, Split Apheresis Calculation Sheets, Sterile Docking Records, Non-Therapeutic Apheresis Flowsheets, and Apheresis Instrument Alarm and Reaction Tracking records [21 CFR 606.160, 21 CFR 606.100(c), and 21 CFR 211.192]. Examples of deviations include the following:
 - Failure to maintain Split Apheresis Calculation Sheets for all split products;
 - Failure to document the collection of Therapeutic Concentrate Platelets (TCP) samples on at least 64 occasions during the time period January 2003-May 2003;
 - Failure to maintain complete documentation of the collection of TCP samples on at least 155 occasions during the time period January 2003-May 2003; and,
 - Failure to completely document forty-five equipment alarms and four donor reactions on the Apheresis Instrument Alarm and Reaction Tracking records of four apheresis machines.
- You failed to follow your written procedures regarding your requirement to use the [REDACTED] accessory bag for Spectra and Trima drawn apheresis products when preparing the third part of the split. The [REDACTED] bag was used instead on at least 12 separate occasions during the time period April 16, 2003 to June 21, 2003 [21 CFR 606.100(b)(17) and 21 CFR 211.100(b)].

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your Birmingham, Alabama facility. It remains your responsibility as the Responsible Official to assure that your establishment is in compliance with all requirements of the federal regulations.

We are in receipt of the letter dated July 29, 2003, from Jill Evans, Director of Quality Assurance, that provided a preliminary response to the inspectional observations. We have reviewed the corrective actions outlined in the response, and have determined that the response is inadequate to address our concerns. The response provides a general commitment to correct the deviations identified during the inspection, however, sufficient detail concerning the implementation of the proposed corrections is not provided. For example, the response includes commitments to quarantine products pending quality control testing and to immediately quarantine products that fail routine testing for platelet count and white blood cell count. However, the response does not address whether employees will be trained on the revised standard operating procedures that include these new responsibilities. In addition, the response

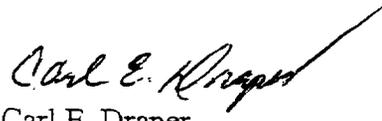
does not address the methods your firm will use to determine the effectiveness of the corrective actions. In your response to this letter, we request that you provide complete documentation to demonstrate that the promised corrective actions have been implemented appropriately.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in initiation of regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Nashville Branch, 297 Plus Park Boulevard, Nashville, TN 37217, to the attention of Kari L. Batey, Compliance Officer.

Sincerely,


Carl E. Draper
District Director
New Orleans District

CED:klb

cc: Tyrone Franklin
Branch Director
LifeSouth Community Blood Centers, Inc.
396 West Oxmoor Road
Birmingham, AL 35209