



Original for release 6/18/98 SP

Food and Drug Administration
St. Louis Branch
12 Sunnen Drive, Suite 122
St. Louis, Missouri 63143-3800

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June 16, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Martin R. Bailey
President
Life Pulse, LLC
11301 Olive Boulevard
St. Louis, Missouri 63141

STL-98-2

Dear Mr. Bailey:

During an inspection of Life Pulse, LLC, located at 11301 Olive Boulevard, St. Louis, Missouri, on May 18-June 4, 1998, our investigators 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 600-680 as follows:

1. Failure to maintain and/or follow adequate written standard operating procedures [21 CFR 606.100(b)] in that:
 - a) [REDACTED] sets of standard operating procedures for donor collections existed, all with variations in them, either handwritten or computer produced, and all of the standard operating procedures were in use. None of the modifications had received authorization from quality assurance or the medical director.

- b) The practice of [REDACTED] blood collection sets, instituted on 7/18/97, was added to the standard operating procedure by a handwritten note, but was not approved by quality assurance or the medical director.
- c) The standard operating procedure revision dated 12/4/96 for operation of the [REDACTED] Cell Separator contained handwritten changes that were initialled but not dated and not approved by quality assurance or the medical director. The handwritten changes were incorporated into the standard operating procedure revision dated 7/7/97 without documentation that approval was given for the changes.
- d) Donor history cards are kept with the daily production records until processing, donation updating, and quality assurance reviews are completed. According to the standard operating procedure, they are to be updated the [REDACTED] and returned to the file. Donor history cards had at least a [REDACTED] filing backlog as of 5/21/98.
- e) Standard operating procedures with handwritten notes and [REDACTED] stickers on them were updated in the computer. All changes were made without approved authorization by quality assurance or the medical director.
- f) The standard operating procedure referencing criteria for donor deferral lacked clear parameters (explanations) when donors should be entered into the donor deferral list.

2. Failure of donor deferral records to be properly maintained as required by 21 CFR 606.160(a) and in accordance with the standard operating procedures [21 CFR 606.100(b)] included:

- a) [REDACTED] different systems actively maintained to identify deferred donors did not contain the same names on all the deferred files. Also names were added to deferral files for reasons not listed in the standard operating procedure and donors were not added to the deferral files when the standard operating procedure required it [super-elevated ALT levels].

- b) Names on the donor deferral file lists were not consistent. Legal names were used in some files while abbreviations or nicknames were used in other files for the same donor.
 - c) Computer formatted donor deferral lists are updated and reprinted every [REDACTED]. All previous copies are destroyed and no archived copies, either hard copy or computer, are retained.
3. Failure of donor history records to be maintained with accuracy and legibility as required by 21 CFR 606.160(b).
- a) Records bore scratch-overs making it difficult to discern what was the correct entry.
 - b) Some donor history record cards were incomplete.
 - c) Duplicate donor history cards were observed for one donor to have different donation dates.
4. Failure to properly review all records associated with units of whole blood before they are released and failure to conduct a thorough investigation, to include conclusions and follow-up, which should include recorded documentation of unexplained discrepancies. [21 CFR 606.100(c)] Examples include:
- a) Drawing a unit of whole blood from a donor who was not eligible to donate because of travel to an area endemic for malaria. The unit was processed and released.
 - b) Incorrectly labeling an A+ unit of red cells as O+ because the laboratory test report was illegible and quality control did not verify accuracy of the test results prior to releasing the unit.
 - c) A unit of whole blood collected at a mobile collection site on 10/25/97 was incorrectly labeled and a handwritten investigation report did not address the failure of production or quality control to address the inconsistency in the blood type of the donor, who had previously donated at your facility.

5. Failure of employees to receive proper training to assure competent performance of their assigned functions and to ensure that the final products have the safety, purity, potency, identity, and effectiveness they purport or are represented to possess, as required by 21 CFR 606.20(b).
 - a) A director of nursing hired 10/1/97 was a phlebotomist at a mobile blood drive the same day and collected units of whole blood.
 - b) A director of nursing hired 10/1/97 according to production records for 10/3/97 was supervisor for the day and collected two units of platelets using an apheresis machine.
 - c) A director of nursing hired 10/1/97 conducted training for collection staff on 10/17/97, covering compliance with standard operating procedures; however, the director of nursing's training profile showed her own training initially occurred on 11/17/97 and 12/15/97. The training she received did not cover the firm's standard operating procedures.

The above violations are not intended to an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes 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 directed to the Food and Drug Administration, 12 Sunnen Drive, Suite 122, St. Louis, Missouri 63143-3800, Attention: Spencer L. Sorenson, Compliance Officer.

Sincerely,


(for)
W. Michael Rogers
District Director
Kansas City District