



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Los Angeles District
Pacific Region
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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 1, 2003

WL 32-03

Mr. Mathew Abraham
President
Antelope Valley Healthcare District
1600 West Avenue J
Lancaster, CA 93534

Dear Mr. Abraham:

During an inspection of your blood collection facility located in Lancaster, California conducted on December 17-18, 20, 26-27, 2002, and January 2, 2003, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR), Parts 210-211 and 600-680 as follows:

1. Your facility used human blood and blood components from a donor who had not been shown to be suitable by a requalification method or process found acceptable for such purposes by FDA after such donor had a previous record of a reactive screening test for antibodies to human immunodeficiency virus, types 1 and 2 (anti-HIV-1/2). (21 CFR 610.40(h)(1))

Specifically, a donor who tested reactive to anti-HIV-1/2 and who had an indeterminate licensed HIV-1 Western Blot result in 1994 was inappropriately re-entered as a suitable donor in 2002. The current requalification method accepted by FDA does not allow for donors with an indeterminate licensed Western Blot result to be considered for requalification. (21 CFR 610.41(h)(2)(iv)). Two whole blood units were subsequently collected and the red cell components transfused.

2. The standard operating procedures (SOPs) fail to include a written description of all steps of the donor suitability and donor deferral process. (21 CFR 606.100 (b)(1) and 21 CFR 211.100(a))

Specifically, the procedure "Donor Registration and Medical Interview," which includes instructions for entering deferral information into the computer system based on disqualifying information provided during the donor screening process, does not provide details concerning the documentation of information (such as exposure dates) so that an appropriate time-dependant deferral can be calculated. The attempted donation by [REDACTED] on 5/20/02 documents skin piercing "5 weeks ago." The attempted donation by [REDACTED] on 6/6/02 only documents "skin piercing." There are no instructions or a standardized method of documenting information so that the next eligibility date can be accurately determined.

3. Equipment used in the collection of blood is not calibrated on a regularly scheduled basis as prescribed in the SOP manual to assure that it performs in the manner for which it was designed. (21 CFR 606.60 (a) and 211.68(a))

Specifically, the donor center performs daily quality control checks of automated equipment used in determining donor temperature, blood pressure, and pulse by comparing the readings from an ear thermometer and manual blood pressure cuff with the automated [REDACTED] and [REDACTED] machines.

- a. The donor center, blood bank, and biomedical department could not demonstrate that the [REDACTED] or ear thermometers were calibrated to a standard. These thermometers were not included on the biomedical department's calibration schedule.
 - b. The [REDACTED] and/or [REDACTED] readings for blood pressure were out of range when compared to the manual blood pressure results on 8/29/02, 9/19/02, and 11/21/02.
 - c. The [REDACTED] and [REDACTED] readings for temperature were out of range when compared to the ear thermometer results on 10/22/02.
 - d. The manual blood pressure results were not recorded on 9/11/02.
4. Your facility failed to maintain complete and accurate records. For example:
 - a. Failure to maintain a record from which unsuitable donors may be identified, including donors testing reactive by a screening test for evidence of infection with a communicable disease agent listed in 21 CFR 610.40(a). (21 CFR 606.160(e) and 21 CFR 610.41(a))

Specifically, at least three autologous donors that tested reactive for screening tests for hepatitis B or hepatitis C were not appropriately deferred from future allogeneic donation. While you did enter the donors' deferral status in your manual index card system, the donors' deferral status was not appropriately updated in your computer system. The manual index card system is only checked when the computer system flags the donor as deferred, therefore, the lack of deferral information in the computer system would prevent you from identifying the donors as deferred if they attempted an allogeneic donation.

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- b. Records are not available to determine the lot numbers of supplies and reagents used for specific lots or units of the final product. (21 CFR 606.160 (a)(2) .

Specifically, the lot number of the venipuncture arm preparation solution is not documented so it is not traceable to units collected. On 12/17/02, four different lot numbers of the arm scrub solutions were available for use on the donor collection floor.

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

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.

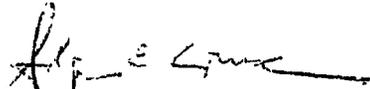
Please notify this office in writing within fifteen (15) days from your receipt of this letter. Your response should describe each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and the date by which each such item will be corrected and documented.

Your reply should be addressed to:

Director Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

If you have any questions regarding any issue in this letter, please contact MaryLynn Datoc, Compliance Officer at telephone number 949-798-7628.

Sincerely,


Alonza E. Cruse
District Director

CC: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320