



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
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May 3, 2001

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jack Bovender
President
HCA The Healthcare Company
One Park Plaza
Nashville, Tennessee 37202

Ref. #: DEN-01-27

Dear Mr. Bovender:

On February 20 through February 23, 2001, Investigators Kelly D. Moore and Brent W. Higgs of our office, conducted an inspection of Mountain View Hospital's Blood Bank in Payson, Utah. Our inspection documented deviations from the Current Good Manufacturing Practices (GMP's) for Blood and Blood Components, Title 21 Code of Federal Regulations, part 606 (21 CFR 606). These deviations cause the blood and blood products manufactured by your firm to be adulterated within the meaning of section 501(a)(2)(b) of the Federal Food, Drug, and Cosmetic Act (the Act).

The deviations noted include:

Record keeping demonstrating the performance of significant steps in the collection, processing, compatibility testing, storage and distribution of each unit of product is significantly incomplete or inaccurate (21 CFR 606.160 (a)(b) (c) and (e)).

For example, unit (X X X) and unit (X X) were determined to be repeatedly reactive for HTLV-1/2. Both the donor cards and the Blood Bank Disposition Record and Processing Record indicated that the plasma and red blood cells were incinerated. However, the Plasma Packing Records indicated that the salvaged plasma was actually shipped to [REDACTED]. Also there was no evidence that your firm followed up on this error, as required by 21 CFR 606.100(c). Another discrepancy noted included the disposition of unit (X X X)

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collected from a repeatedly reactive HTLV-1/2 donor. The Blood Bank Disposition Record states that the plasma was incinerated, however, there is no documentation of the destruction of the packed red blood cells.

Other record keeping deficiencies noted during this inspection include: discrepant or invalid records existing in the computer's donor deferral files that could lead to the release of unsuitable products. Our investigator found numerous discrepancies between your hardcopy permanent deferral list and your computer records. For example, donor (X X) was listed as permanently deferred on your hardcopy list but not in your computer. This donor subsequently married and changed her name to (X X X X X X) was listed as permanently deferred in the computer but not recorded in the hardcopy deferral list.

Your computer records should match the information found in the hardcopy permanent deferral list. Our investigator was informed that your firm created the hardcopy system, as your computer could not generate a list of permanently deferred donors. Our investigator was also told that when a unit is collected from a donor, your firm enters the donor information in the computer. Your personnel rely on the computer to notify them if the donor is an acceptable "Active" donor. If a unit is collected from a permanently deferred donor by accident and the donor is not identified or is not present in the computer, there is a possibility that unsuitable products will be collected and released.

Also, donor (X X) donated on 2/13/01 and was found to be repeatedly reactive for anti-HIV 1/2 on 2/16/01. This donor was not immediately deferred but was listed under "active" status until 2/21/01, when he was permanently deferred. Donor (X X) was not listed on the hardcopy permanent deferral list printed on 2/20/01. As your firm does not re-enter donors, there was no reason to delay permanent deferral of this donor.

Other examples of the inadequacies of your computer system include the lack of traceability of blood units and components from collection to final disposition and the failure to document units collected during mobile blood drives or in the donor room until ABO/Rh and viral marker test results are received. Our investigators found many reactive units entered into your computer system, although in your May 26, 2000 response you stated that it is your policy that positive units are not entered into the computer.

Personnel responsible for the collection, processing, compatibility testing, storage or distribution of blood or blood components are not adequately trained 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, as required by 21 CFR 606.20(b).

For example, our investigator observed discrepancies from your written blood collection procedures by your phlebotomists. Your procedure calls for the donor to apply pressure to the site and to raise his/her arm above their head upon conclusion of the procedure. In two of the four blood collections observed, the

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phlebotomist did not have the donors raise their arms above their heads. Also, in three of seven blood collections observed, your phlebotomists touched the venipuncture site with gauze after preparation, but did not re-prepare the site. This is contrary to your written procedures.

Failure to maintain written standard operating procedures to include methods of component preparation, including any time restrictions for specific steps in processing, as required by 21 CFR 606.100 (b).

For example, your firm did not have a written procedure for the operation of the (XXXXX) used to separate whole blood units into packed red blood cells and plasma. Our investigator observed your technician operating the machine. When asked what settings she used for time, temperature and speed, she replied that she did not know the speed or temperature.

The above-identified violations 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 will all requirements of the Federal regulations.

You should take prompt action to correct these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

We have serious concerns regarding the operation of this facility. Many of the deficiencies were listed as deviations and discussed with your firm during the prior inspections of Mountain View in 1999 and 2000. The 1999 inspection resulted in the issuance of a warning letter on October 5, 1999, a copy of which is enclosed for your information. After both these inspections, your firm made commitments to implement corrective actions. We are dismayed to again find that these deviations continue to exist at your facility.

We are in receipt of Dr. Stanley L. Gibbon's April 17, 2001 response to the FD 483. Our comments regarding this response are attached to this letter as a separate attachment. These deviations are serious and if left uncorrected may result in the release of unsuitable products. Therefore, we are requesting that you contact our office within one week of receipt of this letter to arrange an acceptable time for a meeting to discuss the status of your facility and the corrective actions you intend to undertake.

Please contact Ms. Regina A. Barrell, Compliance Officer, at (303) 236-3043 to arrange this meeting at your earliest convenience.

Sincerely,


Thomas A. Allison
District Director

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