



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

August 22, 2000

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Randy Middlebrook
Chief Executive Officer
Aspen Valley Hospital
0401 Castle Creek Road
Aspen, Colorado 81612

Ref. #: DEN-00-35

Dear Mr. Middlebrook:

On July 21, 2000, Investigator Michael J. Kuchta of our office, conducted an inspection of Aspen Valley Hospital's blood bank. Our inspection revealed that your blood bank collects autologous units for transfusion and ships the units in interstate commerce. Since January 1999, your records indicate that units of autologous blood were collected for transfusion at facilities located in other states. Shipment of blood in interstate commerce by an unlicensed facility is a violation of the *Public Health Service Act*, Subchapter II, Part F, Subpart 1, Section 351 (42 U.S.C. 262(a)).

Our inspection also found that your facility has collected and shipped these units in violation of your own procedures. Specifically, your Blood Bank Procedure for Interstate Autologous Shipping acknowledges that your facility is not licensed to ship blood outside the State of Colorado and states, "This lab **CANNOT ship** blood out of state."

The above-identified deviation is 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 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.

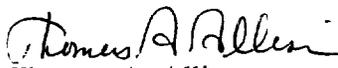
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You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violation and to prevent their recurrence. If corrective action cannot be completed within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

Your response should be sent to Regina A. Barrell, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, Colorado 80225-0087. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,


Thomas A. Allison
District Director

cc: Brent Ford
Chief Technologist
Aspen Valley Hospital Blood Bank
0401 Castle Creek Road
Aspen, Colorado 81612

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