



Food and Drug Administration  
Denver District Office  
Building 20 - Denver Federal Center  
P. O. Box 25087  
Denver, Colorado 80225  
TELEPHONE: 303-236-3000  
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December 20, 1996

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ms. Jean Lauderdale  
Responsible Head  
DCI Biologicals, Inc.  
1706 South 2nd Street  
Gallup, New Mexico 87301

Ref. # - DEN-97-08

Dear Ms. Lauderdale:

During an inspection of DCI Biologicals, Inc., located at 753 West Broadway, Farmington, New Mexico, between October 30 and November 15, 1996, Ms. Betty K. Baxter and Barbara J. White documented violations of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, CFR Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure of the designated qualified person to exercise control of the establishment in all matters relating to compliance with the regulations [21 CFR 606.20] in that performance of assigned functions by employees engaged in the collection, processing, storage, and distribution of source plasma was not adequately directed or disciplined, as evidenced by the shipment of incompletely tested units, inadequate records, and not following standard operating procedures.
2. Failure of the personnel responsible for the collection, processing, storage, and distribution of source plasma to have adequate training and experience to assure competent performance of their assigned functions [21 CFR 606.20(b)] as evidenced by the shipment of incompletely tested units, inadequate records, and not following standard operating procedures.

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3. Failure to maintain concurrent, detailed and/or accurate records [21 CFR 606.160(a)] in that records were not maintained concurrently with the performance of each significant step of the collection, processing, storage and distribution of each unit of plasma, including logs not written in chronological order, and logs with skipped units and entries.
4. Failure to maintain complete and accurate records from which unsuitable donors may be identified so that products from such individuals will not be distributed [21 CFR 606.160(e)] in that repeatably hepatitis/HIV reactive donors were not placed on a list of unsuitable donors until four to ten weeks after the donor was found to be unsuitable. Examples include
5. Failure to follow written standard operating procedures [21 CFR 606.100(b)] in that procedures for plasma packing, plasma shipping, the destruction and disposition of unsuitable blood products, and processing of donors were not always followed.
6. Failure to adequately determine the suitability of persons to serve as the source of Source Plasma [21 CFR 640.3(a); 21 CFR 640.63 (c)(6)] in that the weight of Donors was not recorded or monitored.
7. Failure to maintain a complete record for each donor [21 CFR 640.72(a)(2)] in that neither final weights nor Plasma No Bleed (PNB) indications were recorded for donor

In addition, there were numerous instances of no record of the final disposition of red blood cells from bleeds between July and October 1996.

We are concerned that your establishment shipped an HCV positive unit labeled as negative non-reactive, and shipped several units prior to having the HIV-1 Ag test performed (testing was never completed on units and units and were shipped prior to the completion of the test). Current FDA guidance recommends that HCV positive units not be shipped, and that HIV-1 Ag testing be completed before shipment. I have attached a copy of the following Memos to Blood Establishments (MBE) to aid you in understanding our concerns:

April 23, 1992 and August 5, 1993 memos, both entitled "Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)"

August 8, 1995 memo entitled "Recommendations for Donor Screening with a Licensed Test for HIV-1 Antigen"

March 14, 1996 memo entitled "Additional Recommendations for Donor Screening With a Licensed Test for HIV-1 Antigen"

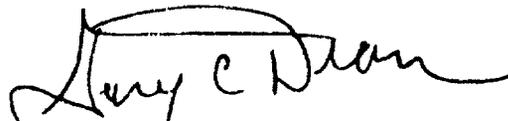
The above violations are not intended to be an all- inclusive list of deficiencies at your facility. It is your responsibility as Responsible Head to assure that your establishment is in compliance with all requirements of the federal regulations.

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 license suspension and/or revocation, seizure and/or injunction.

We acknowledge your response of November 27, 1996 to our Form FDA 483, Inspectional Observations. If you have additional information to provide us, please respond within 15 working days, including any additional steps you have taken or plan to take to correct the noted violations and to prevent their recurrence. If this 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 U. S. Food and Drug Administration, Denver District Office, P.O.Box 25087, Denver, Colorado, 80225-0087, Attention: Shelly L. Maifarth, Compliance Officer.

Sincerely,

  
Gary C. Dean  
District Director

Enclosures  
As Stated

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