DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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
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September 11, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Martin E. Hickey, MD
President/CEO/CFO
Lovelace Health Systems, Inc.
5400 Gibson SE
Albuquerque, New Mexico 87108

Ref. # DEN-00-37

PURGED

Dear Dr. Hickey:

On July 26 through August 8, 2000, Investigators Cynthia Jim and Mitzi Schwab-Schwertferger of our office, conducted an inspection of Lovelace Health Systems' blood bank. Our inspection documented deviations from the Current Good Manufacturing Practice Regulations, Title 21, Code of Federal Regulations (21 CFR), Parts 211 and 600 – 680. These deviations cause your blood products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). Deviations noted include:

Failure to assure the Model 143 Irradiator is performing in the manner for which it was designed, as required by 21 CFR 606.60. For example, our inspection revealed that your firm has not made periodic adjustments to the timer in order to assure that a minimum of 2500 cGy of radiation is delivered to the center of the irradiator container. Records reviewed show that your firm has incorrectly calculated the exposure time needed to adequately irradiate your products. Also, you have failed to perform leak testing on the Irradiator every six months, as required by the manufacturer.

Failure to maintain complete and accurate records of each unit of blood or blood components' preparation as required by 21 CFR 606.160. For example, units were documented as irradiated up to one hour prior to actual irradiation of the units. Instances of units irradiated out of date sequence or out of time sequence were also noted.

Failure to assure all automatic, mechanical or electronic equipment used in the manufacture, processing, packing and holding of blood products will perform satisfactorily, as required by 21 CFR 211.68. For example, proper operation of the Irradiator's timer has never been verified against a calibrated timer. Multiple units of blood were irradiated in one cycle although a maximum acceptable dose and loading pattern was never established for each product and packaging type. You have failed to assure that the [XXXXXXXX] used to monitor the temperature and humidity of your lab freezers, refrigerators and

rooms, is performing as intended. Although your firm developed a new procedure to document verification of the electronic temperature sensors, review of records indicate that your firm has not consistently completed this requirement. Also, your facility has failed to calibrate the [XXXX XXXXXXXXX] as required by the manufacturer's manual, and to consistently document the calibration of scales used to weigh autologous and therapeutic units.

Failure to follow standard operating procedures to ensure the proper quarantine, storage, handling and disposition of therapeutic units, as required by 21 CFR 606.100. For example, therapeutic units collected in the Oncology Department were not placed immediately in the biohazard bin but were retained by the Department for one or two days after they were drawn. Also, drawn therapeutic units were left unprotected on counter tops in the patient area before being disposed of in the biohazard bin. Review of patient files also revealed that required review by a supervisor or medical director was not performed.

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 requirements of the Federal regulations.

Many of the above deficiencies have been brought to your attention during prior inspections of your facility in 1997 and 1999. These include the inadequate operation of your irradiator, the failure to validate the [XXXXXX], the failure to ensure the proper quarantine, handling and disposition of therapeutic units and the failure to perform therapeutic bleeds in accordance with your SOPs. During these previous inspections your firm was advised of these findings and corrections were promised. We are disappointed that you have failed to make corrections and are concerned that these deficiencies continue. Therefore, 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.

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 violations 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,

Karen S. Kreuzer
for
Thomas A. Allison
District Director

PURGED

cc: Dr. Lee Gates III
Technical Director
Lovelace Health Systems, Inc
5400 Gibson SE
Albuquerque, New Mexico 87108