



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
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WARNING LETTER

WL-CIN-8577-01

July 6, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Edward Roth, CEO
Aultman Health Foundation
2600 Sixth Street SW
Canton, OH 44710

Dear Mr. Roth:

From 6/5-6/15/2001 the an FDA investigator conducted an inspection of the hospital blood bank located at 2600 Sixth Street SW, Canton, OH. The investigator documented deviations from the Current Good Manufacturing Practices (CGMP) in Title 21, Code of Federal Regulations, Part 606 [21 CFR 606]. These deviations cause the biologics products processed 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 investigator's findings include:

The failure to calibrate or properly calibrate equipment used to determine donor suitability. For example the hematastat used in the donor rooms and mobiles was not properly calibrated and the oral thermometer calibration was not documented from September 2000 through May 2001.

[606.160(b)(5)(i)]

The failure to calibrate or properly calibrate equipment used in blood component preparation. For example you prepare components using two different centrifuge speeds and only calibrate the machine to one speed. [606.160(b)(5)(i)]

The failure to follow written SOPs. For example, you do not have records that show that you followed the SOP for the red blood cell quality control for any months other than April and May 2001. Additionally, you cannot document that the refrigerator charts are changed weekly as required by the SOP. Your records also do not indicate that the charts are always changed according to the SOP.

[606.160(b)(5)(i)]

The failure to establish and follow written SOPs for the following areas: calibration of the donomatic weight scale used to weigh units of blood, performance of a quality control check on the speed of the centrifuges used to prepare blood components and a description of the duties and responsibilities of the quality assurance personnel. [606.100(b)]

The failure to review all records and the failure to investigate errors prior to the release of blood products. For example, the QC for the heat blocks was out of range and there was no investigation or corrective action documented. Temperatures recorded in some departments are recorded as decimals when the measuring device only lists whole numbers. The quality control files that contain the temperature records contains a statement that all records in the files have been reviewed and are acceptable, however there is no documentation that deficiencies in the records were noted or investigated. [606.100(c)]

Neither the above-identified deviations nor the list of inspectional observations issued at the conclusion of the inspection is intended to be an all-inclusive list of deficiencies at your blood bank. It is your responsibility to ensure that your blood bank is in compliance with all requirements of the Act and federal regulations.

Thank you for providing the investigator with a written response to the FDA-483, Inspectional Observations that was issued in July 2000. We note that you have made some corrections but are still far from full compliance with the regulations. The investigator documented nine violations continuing from the previous inspection as well as four new violations. We also note that you waited almost one full year before responding to the FDA-483 observations.

You should take prompt action to correct the current deviations. Your failure to promptly correct the deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 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 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please provide evidence that you have corrected the problems such as copies of finalized SOPs or new forms that are implemented to correct the problems.

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097. Attn: Stephen J. Rabe, Compliance Officer.


Henry L. Fielden
District Director
Cincinnati District Office