



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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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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January 26, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Edmund Jacobs
Executive Director
Rocky Mountain Lions Eye Bank
P. O. Box 6026
Aurora, Colorado 80045

Ref. # - DEN-04-04

Dear Mr. Jacobs:

The Food and Drug Administration (FDA) conducted an inspection of your firm, located at 1675 North Ursula Street, EI2049, Aurora, Colorado, between October 2 and 10, 2003. This inspection determined that your firm processes human corneas, sclera, and whole eye globes intended for transplantation. Our investigators documented significant deviations from regulations for human tissue intended for transplantation set forth in Title 21, Code of Federal Regulations (21 CFR), Part 1270, promulgated under the authority of Section 361 of the Public Health Service Act. The deviations include the following:

1. Your firm failed to maintain records documenting the destruction or other disposition of human tissue, as required by 21 CFR 1270.35(d), in that your Tissue Destruction Log was incomplete and/or inaccurate.¹ Examples include:

- A. Your firm could not determine the final disposition of viral marker reactive corneas listed on the Tissue Destruction Log. Your senior staff was unable to locate tissue products listed on the Tissue Destruction Log when they attempted to dispose of them. There is no evidence that these tissues were destroyed. Although your staff stated to our investigator that they were confident that these tissues were not distributed, you have not provided evidence to demonstrate otherwise. Tissues involved included the following: X X X X X X X X

¹ This observation is a repeat of one previously observed during the inspection of your facility in 2000.

research, its final disposition should be recorded when the tissue is placed in a biohazard container. Without proper traceability, the possibility of improper release of unsuitable tissue products remains.

Your procedure states in paragraph 9 that ' X X X X X X X X X X
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' Without a definite time limit, there is no requirement that the tissue be promptly disposed of, potentially permitting unsuitable tissue to be distributed. FDA recommends that your procedure include a timeframe in which to assure the destruction of the tissue and/or language such as "not later than...."

Paragraph 12 of the Biohazardous Waste Disposal procedure includes the provision that the Quality Assurance (QA) staff will review and verify the documentation of destroyed tissue on the Destruction Log is consistent with the record entry in the chart and the computer. The frequency of such QA review is not included in this procedure. Also, the procedure states that if variances are found, the technical staff and management will be informed to resolve the matter. The provision does not address how or if the findings of the QA staff will be documented nor how the variances will be presented to the technical staff and management. Our inspection revealed that your QA staff signed off on the discrepancies found in the Tissue Destruction Log noted above, although there is no indication that any corrective action was taken.

FDA recommends that: (a) Your QA program be designed and implemented to ensure that manufacturing is consistently performed in such a way as to yield a product of consistent quality; (b) QA report independently from production to management and ensure that production personnel follow procedures to control the manufacturing process and to prevent the release of unsuitable products; and (c) when necessary, the QA unit should have the authority to stop release of unsuitable products.

Your response to observation 2 states, "We developed and implemented a more detailed policy to accompany the current risk assessment form and we performed staff training for all technical staff." Our review finds these responses appropriate pending confirmation of compliance during the next inspection.

The above identification of deviations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all tissue products produced and distributed by your firm are in compliance with Section 361 of the Public Health Service Act, and 21 CFR Part 1270. You are responsible for investigating and determining causes of the deviations identified by the FDA. You should take prompt action to correct these deviations. Failure to do so may result in additional regulatory action without further notice. Such action may include, but is not limited to, an Order for Retention, Recall and/or Destruction of Human Tissue.

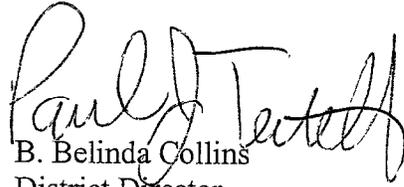
You should notify this office in writing within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted deviations. Include an explanation of each step being taken to prevent the recurrence of similar deviations and documentation showing that

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corrections have been achieved. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the correction will be completed.

Your reply should be sent to the Food and Drug Administration, Denver District Office, P. O. Box 25087, Denver, CO 80225-008, Attention: Regina A. Barrell, Compliance Officer. If you have any further questions, please feel free to contact Ms. Barrell at (303) 236-3043.

Sincerely,


B. Belinda Collins FOR
District Director