

Cutter Laboratories, Inc.

OAKLAND PLASMA CENTER
630 E. 14th STREET • OAKLAND CA 94606 • (415) 465-6404

May 19, 1981

Mr. Robert Barden
Plasma Procurement Manager
Cutter Laboratories, Inc.

cc. Jan Miller
Bill Tarleton

Dear Mr. Barden:

This facility was inspected today by Mr. Donald McClelland, Department of Health Services Examiner for the State of California.

Mr. McClelland found the center to be in compliance in all areas except for the practice of accepting donors into the program who have a past history of illegal IV drug use. The standard operating procedure at this facility is to accept these prospective donors if they meet all other requirements and if the drug use was more than six months prior to their plasma donation.

Mr. McClelland felt that this procedure is not in compliance with both the State Regulations 1002^(b)(9) and the CFR 640.3 (?).

This procedure is allowed by the Cutter SOP 4.0.4 (e), so conforming to Mr. McClelland's interpretation would result not only in a manual change, but would also adversely effect many plasma donors.

No response will be made until further notification.

Cordailly,


David Ichikawa
Manager

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