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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

January 17, 2002

Via Federal Express

MQSA Facility ID: 221533

Inspection ID: 2215330003

Katherine Salazar
P.C.N. Manager
UC Davis Medical Group - Folsom
1370 Prairie City Road
Folsom, CA 95630

Dear Ms. Salazar:

We are writing to you because on December 19, 2001, your facility was inspected by a representative of the State of California, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

1. Processor QC records in the month of 10/2000 were missing for at least 30% of operating days, for processor 1, [REDACTED], room Main at site UCDMG/Folsom.
2. Processor QC records were missing at least 5 consecutive days for processor 1, [REDACTED] room Main at site UCDMG/Folsom.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1, because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further

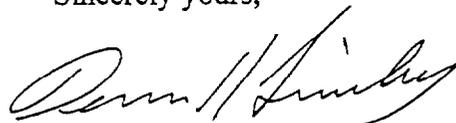
notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

We acknowledge receipt of Carol Blair's, R.T.M., letter dated January 2, 2002 responding to the Level 1 findings discussed above. Ms. Blair's response appears to adequately address the Level 1 findings. Your corrective actions will be verified during the next inspection.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Russell Campbell, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502, telephone #: 510-337-6861.

Sincerely yours,



Dennis K. Linsley
District Director