DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

935/3d

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

WARNING LETTER

September 20, 2002

Via Federal Express

MQSA Facility ID: 170779
CFN: 2952004

Inspection ID: 1707790005

David Campa, Medical Director
Golden Valley Health Centers
727 West Childs Avenue
Merced, CA 95340

Dear Dr. Campa:

We are writing to you because on August 29, 2002, 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. Phantom QC records were missing for at least 4 weeks for unit 2, [redacted] room Mammo.

2. Mammograms were processed in processor 0000000001, [redacted] or [redacted] room Dark Rm at site Golden Valley Health Centers, when the parameters for density difference and mid density were out of limits on at least 5 days, specifically July 10, 11, 12, 15, 16, 17, 18, and 19, 2002.

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 informal 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 seeking a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 finding is:

Two (2) of six (6) random reports reviewed did not contain an acceptable assessment category for site Golden Valley Health Centers.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

1. the specific steps you have taken to correct all of the violations noted in this letter;

2. each step your facility is taking to prevent the recurrence of similar violations;

3. equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

4. sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

Please submit your response to:

Russell A. Campbell, Compliance Officer
U. S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of the inspection of your facility 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.

* - *This notice is not applicable for letters which also address patient notification.*

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, at 510-337-6861.

Sincerely yours,

Dennis K. Linsley
District Director