DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Southwest Region
7920 Elmbrook Drive
Suite 102
Dallas, TX 75247-4982

Telephone: 214-655-8100
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June 4, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

02-SWR-WL-45/8

Tim Parker
Chief Executive Officer
Colorado Plains Medical Center
1000 Lincoln Street
Fort Morgan, CO 80701

Dear Mr. Parker:

Re: Inspection ID - 1130680011

We are writing to you because on May 5, 2002, a representative of the State of Colorado, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. 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 (MQSA), 42 U.S.C. § 263b, 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 violations of Section 354(f) of the MQSA at your facility:

Level 1: Processor QC records for the month of 09/2001 were missing for at least 30% of operating days, for processor 1, Kodak, X-OMAT. (21 CFR 900.12(e)(1))

Level 1: Processor QC records were missing for at least 5 consecutive days for processor 1, Kodak, X-OMAT. (Id.)

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. A Level 1 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

These conditions represent a serious violation of the law which may result in FDA taking regulatory action against you including, but 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, the mammography quality standards; suspension or revocation of your facility's FDA certificate;

or obtaining a court injunction against further mammography (see Sections 354(h) through (j) of the MQSA).

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 or will take to **correct** all of the violations noted in this letter, any reason that corrective action has not been taken, and the time within which any steps not yet taken will be complete;

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

Please submit your response to:

Deborah M. McGee, Radiation Specialist
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982

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/cdrh/mammography/index.html.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Deborah M. McGee at (214) 655-8100 extension 138.

Sincerely yours,

Gary L. Pierce for
Regional Food and Drug Director

Cc: Mike Boettcher
Director of Radiology
Colorado Plains Medical Center
1000 Lincoln Street
Fort Morgan, CO 80701