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
FAX: 214-655-8130

August 2, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

02-SWR-WL-51/8

James D'Agostino
Hospital Administrator
Roosevelt General Hospital
14121 US Hwy. 70
P.O. Box 868
Portales, NM 88130

Dear Mr. D'Agostino:

Re: Inspection ID - 2265540001

We are writing to you because on June 5, 2002, a representative of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed serious regulatory problems involving the mammography at your facility. Under the Mammography Quality Standards Act of 1992 (MQSA or the Act), 42 U.S.C. § 263b, and its implementing regulations set forth in Title 21, Code of Federal Regulations (CFR), Part 900, 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 violation at your facility:

- The system to communicate results is not adequate because there is no system in place to provide timely lay summaries (See 21 CFR 900.12(c)(2))

- Your facility failed to produce documents verifying that the interpreting physician [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months (See 21 CFR 900.12(a)(1)(ii))

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection

These conditions represent a violation of the law that may result in FDA's instituting regulatory action against your facility. Possible actions include, but are not limited to, placing your facility under a Directed Plan of Correction and/or charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA

standards, seek suspension or revocation of your facility's FDA certificate, or seek a court injunction against further mammography (see sections 263b(h) through (j) of the Act).

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**).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which corrections will be completed. 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 certain findings of your inspection and does not necessarily address other obligations you have under the law, including, but not limited to, correcting the other violations cited on your MQSA Facility Inspection Report. 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, ext. 138.

Sincerely yours,

Gary L. Pierce
Regional Food and Drug Director