DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

93541d

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

FEDERAL EXPRESS

WARNING LETTER

FLA-02-62

October 3, 2002

FACILITY ID # 170134

Robert Hall, Radiologist
DeSoto Memorial Hospital
900 North Robert Avenue
Arcadia, Florida 34266

Dear Dr. Hall:

We are writing to you because on July 18, 2002 a representative of the State of Florida, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed serious regulatory problems involving the mammography at your facility.

Under United States Federal law, the Mammography Quality Standards Act of 1992, 42 USC § 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 REPEAT violations at your facility.

Your facility failed to produce documents verifying that all interpreting physicians taught or completed at least 15 category I continuing medical education units in mammography during the 36 months immediately preceding the inspection or the last day of the calendar quarter preceding the inspection, or any day in between the two as required by 21 CFR 900.12(a)(1)(ii)(B). For example, your facility failed to produce documents verifying that the interpreting physician [redacted] met the continuing education requirement of having taught or completed 15 CMEs in 36 months. This is a Repeat violation identified during the previous inspection of your facility dated on July 12, 2001.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection on July 18, 2002. Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents 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 $10,000.00 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or seeking a court injunction against further mammography.

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 receive this letter:

- the specific steps you have taken to correct the violation noted in this letter.
- each step your facility is taking to prevent the recurrence of similar violations;
- 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 Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone no. (407) 475-4728.

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, Maryland 21045-6057, telephone no. (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 contact D. Janneth Caycedo, Boca Raton Resident Post, Food and Drug Administration, Interstate Plaza, 1499 W. Palmetto Park Rd., Suite 110, Boca Raton, Florida 33486, telephone no. (561) 338-5236, ext. 23.

Sincerely,

for Emma R. Singleton
Director, Florida District