HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-64

September 26, 2002

FACILITY ID # 161737

Danielle Fitzgerald, Director of Radiology
HealthSouth Doctors' Hospital
5000 University Drive
Coral Gables, Florida 33146

Dear Dr. Fitzgerald:

We are writing to you because on August 13, 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 U.S.C. § 263b, your facility must meet specific requirements for mammography. These requirements help protect the health of women by ensuring that a facility can perform quality mammography. The inspection revealed the following REPEAT violations at your facility.

All mammography examinations shall be performed by radiology technologists who have, prior to April 28, 1999, qualified as a radiology technologist under paragraph (a)(2) of this section of FDA's interim regulations of December 21, 1993, or has completed at least 40 contact hours of documented training specific to mammography under supervision of a qualified instructor as required by 21 CFR 900.12(a)(2)(ii). Your facility failed to produce documents verifying that the radiology technologist, [redacted], met the initial requirement of having training specific to mammography under the interim regulations. This repeat violation was identified during the previous inspection of your facility dated August 16, 2001.

In addition, when test results fall outside the action limits, the source of the problem(s) shall be identified and corrective actions shall be taken as required by 21 CFR 900.12(e)(8)(ii). For example, density difference was greater than the 0.05 action level at least on one occasion and corrective action was not documented.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection on August 13, 2002. 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 $10,000.00 for each failure to substantially comply with the mammography quality standards, suspending or revoking your facility's FDA certificate, or obtaining 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 all of the violations noted in this letter.
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and,
- 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 number (407) 475-4728.

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, Maryland 21045-6057, telephone number (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 Resident Post, Food and Drug Administration, Interstate Plaza, 1499 W. Palmetto Park Rd., Suite 110, Boca Raton, Florida 33486, telephone number (561) 338-5236, ext. 23.

Sincerely,

Emma R. Singleton
Director, Florida District