DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

93176d

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

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-35

March 27, 2002

FACILITY ID # 218644

David Taylor, Administrator
Putnam Diagnostic Imaging Center
6905 Old Wolf Bay Road
Palatka, Florida 32177

Dear Mr. Taylor:

We are writing to you because, on February 15, 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 a 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 assuring that a facility can perform quality mammography. The February 15, 2002 inspection revealed the following violations at your facility:

1. Failure to adjust and maintain film processors used to develop mammograms to meet the technical development specifications for the mammography film in use. A processor performance test is required to be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference as required by 21 CFR 900.12(e)(1)(i), (ii), (iii). For example, mammograms were processed when the X-OMAT Kodak processor (Mammo Room) was out of limits on twenty- three days. Specifically, the speed and contrast indices were out of limits from April 26 through May 30, 2001 and new AIMS were repeatedly established without documenting that the facility physicist was consulted.

2. Failure to identify and correct the source of problems discovered during the comparison of the test results, for the tests specified in 21 CFR 900.12(e)(1) through (7), to the corresponding specified action limits, or to the manufacturer's recommended action, before further exams or within thirty days, as required by 21 CFR 900.12 (e)(8)(i) and ii(A). For example, corrective actions were not documented for: (1) processor QC failures at least once for processor 01, Kodak, RP X-OMAT M6B, 6AN, Mammo room; and (2) for a failing image score, a phantom background optical density, or a density difference outside the allowable regulatory limits before further exams were performed for unit 1, Bennett X-Ray Corp., CONT., Mammo room. More specifically, phantom QC contrast index was out of limits on March 1, 8, 10, 13, and 17, 2001. Phantom QC specks score failed on July 20, and 27, 2001. Mammograms were performed on these days and no corrective actions were 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. 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 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 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, U.S. Food & Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (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, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact D. Janneth Caycedo at 561-338-5236 ext 23.

Sincerely,

for Emma R. Singleton
Director, Florida District