DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOOD & DRUG ADMINISTRAT
466 FERNANDEZ JUNCOS AV
SAN JUAN, P.R. 00901-3223

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May 12, 2003

WARNING LETTER
SJN-03-09

Certified Mail
Return Receipt Requested

Dr. Gladimiro Dávila-Martínez
Lead Interpreting Physician
Hato Rey X-Ray Office
156 F.D. Roosevelt Avenue # 156
Hato Rey, PR 00918

Re: MQSA Inspection ID # 1839210008

Dear Dr. Dávila-Martínez:

On April 2, 2003, a representative of the Commonwealth of Puerto Rico, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA") which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice 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 the MQSA at your facility:

Level 1: Your Kodak model [redacted] film processor, located in your room 2, had daily quality control test scores outside the appropriate action limits, but the inspector found no documentation that corrective action was taken before the unit was used for further exams. [21 CFR 900.12(e)(8)(ii).]

Level 2: You failed to comply with the requirements for quality assurance-mammography medical outcomes auditing as required by 21 CFR 900.12(f). Specifically, although your facility has been certified for more than 12 months, you did not initiate an analysis of outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report, individually and collectively for all interpreting physicians at your facility.

Because the failure to resolve this violation may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring
- seeking civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- seeking to suspend or revoke your facility's FDA certificate

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

If you choose to respond to the above violation, your response should include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and

3. Sample records that demonstrate proper record keeping procedures.

Please submit your response to this letter to:

Mr. Andres Toro, Acting Compliance Branch Director
466 Fernandez Juncos Avenue
San Juan, PR 00901-3223

Please send a copy of your response to:

Raul Hernandez Doble
Radiological Health Division
Puerto Rico Department of Health
P.O. Box 70184
San Juan, PR 00936-8184

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent 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, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Jose F. Pedro, Acting Compliance Officer, at 787-474-9550.

Sincerely yours,

Donald J. Voeller
District Director

cc:

Mayra Toro
Director, Radiological Health Division
Puerto Rico Department of Health
P.O. Box 70184
San Juan, PR 00936-8184

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