DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6007

July 8, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Peter Rodriguez
CEO/President
Bergenline X-Ray Diagnostic Center Corp.
402 43rd Street
Union City, New Jersey 07087

FILE NO.: 02-NWJ-25
Inspection ID NO.: 027130007

Dear Mr. Rodriguez:

A representative from the State of New Jersey under contract to the Food and Drug Administration (FDA) inspected your facility on June 6, 2002. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA) 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 inspection revealed the following violation(s) of Section 354(f) of the Act [42 U.S.C. 263b(f)] at your facility (identified on your inspection report):

- **Your facility failed to document that phantom image quality control testing was performed. See 21 CFR §900.12(e)(2). Phantom image quality control records were missing for the following weeks:**
  - **June 3-9, 2001**
  - **June 17-23, 2001**
  - **July 22-28, 2001**
  - **December 16-22, 2001**

- **Your facility failed to either have or to follow adequate procedures for infection control. See 21 CFR 900.12(e)(13).**

- **Your facility failed to either have or to follow adequate procedures for collecting and resolving consumer complaints. See 21 CFR 900.12(h).**

- **Your facility did not perform an annual medical audit and outcome analysis for your facility as a whole, or for each individual radiologist reading mammograms for Bergenline X-Ray Diagnostic. See 21 CFR 900.12(f).**

- **Five of five random mammography reports reviewed during your annual inspection failed to contain an acceptable assessment category. See 21 CFR 900.12(c)(1)(iv).**

- **Your facility failed to have a qualified medical physicist perform a survey of your mammography unit within one year of the date of your previous survey. The previous survey was conducted on December 22, 2000, and the current survey conducted on March 9, 2002. See 21 CFR 900.12(e)(9).**

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, they could compromise the quality of mammography at your facility. They represent serious violations 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 (see Sections 354(h) through (j) of the Act, 42 U.S.C. 263b(h) through (j)).

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct 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.

Please submit your response to Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings disclosed during 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, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely,

Douglas I. Ellsworth

DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office