

M3849M
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 30, 2000

WARNING LETTER
SJN- 00- 13

FACILITY ID # 3003017106

Gamaliel Bermudez, M.D.
Interpreting Phycician
German Chavez, M.D. & Gamaliel Bermudez M.D.
P.O. Box 501
Coto Laurel, Puerto Rico 00780

Dear Dr. Bermudez:

Your facility was inspected on December 14, 1999 by a representative of the Puerto Rico Department of Health, Radiological Health Division, on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standard for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Noncompliance Level 1

Processor QC records were missing 20 out of 20 days of operation in month May, 1999. Processor QC records missing 100%, for processor #1, Kodak, x-omat M35 or M35A-M, room x-ray at site German Chaves, M.D. & Gamaliel Bermudez M.D.

Noncompliance Level 2

There is no written procedure for handling consumer complaints at site German Chaves, M.D. & Gamaliel Bermudez M.D.

There is no written procedure for infection control at site German Chaves, M.D. & Gamaliel Bermudez M.D.

The specific deficiencies noted above appeared on the List of Observations, which was issued to your facility on December 14, 1999. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

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It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Carlos I. Medina, Compliance Officer, U.S. Food and Drug Administration, 466 Fernandez Juncos Avenue, San Juan, Puerto Rico 00901, telephone (787) 729-6894, extension 2110.

Sincerely,

Mildred R. Barber
District Director

cc: Puerto Rico Department of Health, Radiological Health Division