



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

d1084b

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Facility ID# 113290

WARNING LETTER

FLA-98-51

June 5, 1998

Dr. Wayne Windham
Lead Interpreting Physician
Franz Lucas & Bernstein, M.D., P.A.
1925 Mizell Avenue
Winter Park, Florida 32792

Dear Mr. Windham:

Your facility was inspected on May 13, 1998, by a representative of the State of Florida, on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

1. Failure to have documentation that the following interpreting physicians, [REDACTED] and [REDACTED] meet the requirement of being licensed by a State to practice medicine.
2. Failure to have documentation that the following interpreting physicians, [REDACTED] [REDACTED] [REDACTED], meet the requirement of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms.

Level 2

3. Failure to have documentation that the following interpreting physicians, [REDACTED], meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per 24 months.
4. Failure to have documentation that the following interpreting physicians, [REDACTED], meet the initial training requirement of having 40 hours of continuing medical education in mammography.
5. Failure to have documentation that the following interpreting physicians, [REDACTED], meet the requirements of having read and interpreted mammograms from the examinations of at least 240 patients in six months.
6. Failure to have documentation that the following interpreting physicians, [REDACTED], meet the requirements of having read and interpreted mammograms from the examinations of at least 240 patients in six months.
7. The radiologic technologist, Penelope W. Cloud, did not meet the continuing education in mammography over a 3-year period (an average of 5 credits/year).

These specific deficiencies appear on the List of Observations which was issued to your facility on May 21, 1998. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

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:

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- 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.

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 Timothy J. Couzins, Compliance Officer, U. S. Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4728. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Carlos I. Medina, Compliance Officer, at (305) 526-2800, ext. 921.

Sincerely,



Douglas D. Tolen
Director
Florida District

cc: State of Florida