DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93743d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

November 26, 2002

Certified Mail
Return Receipt Requested

Miriam S. Wysocki, M.D.
Owner
Miriam Santisteban Wysocki, M.D., Inc.
11100 Warner Avenue; Suite #262
Fountain Valley, CA 92708-7506

W/L Number: 11 - 03
Inspection ID: 1886310008
CFN: 20-30,082
FEI: 1000519197
FACTS: 15505-0

Dear Dr. Wysocki:

On September 19, 2002, a representative of the State of California, 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, your facility must meet specific requirements to practice mammography. These requirements help to protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed a violation of the MQSA at your facility. This violation was noted on the MQSA Facility Inspection Report (*"Important Information about your Mammography Quality Standards Act (MQSA) Inspection"*) that the inspector left at your facility at the close of the inspection on September 19th. The inspection revealed one REPEAT Level 2 finding at your facility:

Medical audit and outcome analysis was not done for the facility as a whole. This is a **REPEAT** violation of Title 21 Code of Federal Regulations section 900.12(f)(1).

Because this repeated violation may be symptomatic 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 ("DPC")
- charging your facility for the cost of on-site monitoring
- seeking civil money penalties of 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
- seeking a court injunction against your facility.

See Title 42, United States Code, Sections 263b(h)-(j) and Title 21, Code of Federal Regulations, Section 900.12(j).

On October 23, 2002 we received your undated letter (the envelope was post marked October 8, 2002) from Ms [redacted] R.T.(M) who was responding, upon your behalf, to the inspectional findings report (noted above).

The response letter is inadequate. We need to see the actual medical audit and outcome analysis for the year 2001. Please submit a copy of this audit and analysis.

Ms [redacted]s letter states in part "The previous technologist at last years inspection did not do any medical outcome analysis.". However, when your year 2001 MQSA inspection (#1886310007; dated July 24, 2001) was performed and a response letter (dated August 28, 2001) was sent to the State agency, Ms [redacted], R.T.(R), M. (Lead Mammography Technologist stated in part "Medical audit and outcome analysis was completed for the facility as a whole and separately for each interpreting radiologist. See attached Medical Audit and Outcome data.".

You should respond, in writing, to FDA within fifteen (15) working days from the date you received this letter. Your response should include:

1. the specific steps you have taken, or will take, to correct the violation 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 implementation of those steps; and,

3. sample records that demonstrate proper record keeping procedures.
   Note: patient names and other information that would likely reveal the patient's identity should be deleted from any copies of records you submit.

Your response should also specifically address the repeat violation which was not corrected from the previous inspection in July 2001. We are requesting why this repeat

violation was not corrected prior to the inspection of September 25, 2002 and who, by name and title, had the responsibly and authority for implementing the correction. Additionally, if you feel that revising your Standard Operating Procedure (SOP) is in order to prevent this repeat problem from recurring, please submit applicable portions of the revised SOP for our review.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
Phone: (949) 798-7600

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, U. S. Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (telephone number: 1-800-838-7715) or through the Internet at http://www.fda.gov

If you have more specific questions about mammography facility requirements or about this letter, feel free to contact Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-798-7644.

Sincerely,

Alonza E. Cruse
District Director