



DEPARTMENT OF HEALTH & HUMAN SERVICES

3289-1

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

May 21, 2002

WARNING LETTER NYK 2002-30

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Leena Doshi, M.D.
Director
Doshi Diagnostic Imaging Services, P.C.
dba DIA Tribeca Radiology
146 Duane Street
New York, New York 10013-3858

RE: Facility ID Number 215327

Dear Dr. Doshi:

Your facility was inspected on April 3, 2002 by a representative of the New York City Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 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 Level 1 finding at your facility, which is a violation of Section 354(f) of MQSA (42 U.S.C. § 263b(f)):

- *Failure to produce documents verifying the interpreting physician, [REDACTED], met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having two months of initial training in the interpretation of mammograms prior to April 28, 1999 (see 21 C.F.R. § 900.12 (a)(1)(i)).*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it is a deviation from MQSA standards that may seriously compromise the quality of mammography services offered by your facility.

This condition represents a violation 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 MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography (see Section 354(h) through (j) of MQSA, 42 U.S.C. § 263b(h) through (j)).

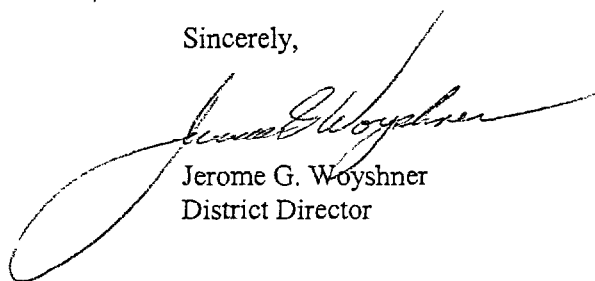
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On April 12, 2002, Jim Owen faxed to FDA letters from the residency programs of Dr. Vaynshelbaum and Dr. Marino and the Mammography Positive Findings Annual Analysis for 1999. The Mammography Positive Findings Annual Analysis for 1999 adequately addresses the Level 2 observation you received. The letter from Dr. Vaynshelbaum's residency program adequately documents his having completed two months of initial training in the interpretation of mammograms. However, the letter from Dr. Marino's residency program does not adequately document Dr. Marino's initial training.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date that you receive this letter each step your facility is taking to correct this violation and to prevent the recurrence of similar violations. Please submit your response to the above issues to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202, telephone (716) 551-4461 ext. 3117.

Finally, you should understand 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, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

Sincerely,



Jerome G. Woyshner
District Director

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Program
American College of Radiology
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Reston, VA 22091

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