DEPARTMENT OF HEALTH & HUMAN SERVICES 93329d

New York District

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

June 6, 2002

WARNING LETTER NYK 2002-35

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Valentino J. Bianchini, M.D.
Kings Highway Center
Kingsboro Medical Group, P.C.
3245 Nostrand Avenue
Brooklyn, New York 11229

RE: Facility ID Number 187393

Dear Dr. Bianchini:

A representative of the New York City Department of Health, acting on behalf of the United States Food and Drug Administration (FDA), inspected your facility on April 18, 2002. This inspection revealed serious regulatory problems involving the mammography at your facility.

Under 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 Repeat Level 2 finding at your facility:

- ***There are no examples of, nor attempts made to obtain, results of biopsies performed outside the facility (see 21 C.F.R. 900.12(f)(1)).***

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 a Repeat Level 2 because it is a deviation from MQSA standards that may compromise the quality of mammography services offered by your facility.

The following additional Level 2 observations, which were also noted on your MQSA Facility Inspection Report, were made during thc inspcction:

- ***One of five mammography reports reviewed at random did not contain an acceptable assessment category (see 21 C.F.R. 900.12(c)(1)(iv)).***

- ***Failure to conduct the medical audit and outcome analysis for the facility as a whole (see 21 C.F.R. 900.12(f)(1))***

- ***Failure to conduct the medical audit and outcome analysis for each individual radiologist at the facility (see 21 C.F.R. 900.12(f)(1))***

- ***Failure to conduct the medical audit and outcome analysis annually (see 21 C.F.R. 900.12(f)(2))***

These conditions represent violations of the law which may result in FDA imposing regulatory sanctions. These sanctions 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 federal mammography standards, or suspending, or revoking your facility's FDA certificate.

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 these violations and to prevent the recurrence of similar violations.

Please submit your response 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 certain 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
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American College of Radiology
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cc: Dorothy Pender
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