

HPI-35



DEPARTMENT OF HEALTH & HUMAN SERVICES

M2237N
New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

WARNING LETTER

November 30, 1998

REF: NYK-1999-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Facility Cert. No. 221455

Mr. Joseph Paul
President
U.S. Diagnostics
777 South Flagler Drive, Suite 1201E
West Palm Beach, FL 22401

Dear Mr. Paul:

On November 3, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving mammography at your facility, Queens Medical Imaging P.C. located at 69-15 Austin Street, Forest Hills, New York 11375.

Under a Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility is required to have a valid FDA MQSA certificate to perform mammography. Only facilities that have applied to an approved accreditation body and either (1) are being evaluated for accreditation by that body or (2) have been accredited by that body are entitled to a certificate. The accreditation process is a necessary requirement of the law for every facility that performs mammography. This process helps to protect the health of women by ensuring that a facility can perform quality mammography.

Your facility performed mammography without a valid FDA MQSA certificate. Although management at this facility initiated procedures to obtain a certificate on July 23, 1998, the FDA certificate was not actually effective until September 15, 1998. Nevertheless, mammography was conducted on 228 patients in July of 1998, 170 patients in August of 1998 and 117 patients in September of 1998 up until the 14th of that month.

Performing mammography without a valid certificate is 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, assessing civil money penalties up to \$10,000 or obtaining a court injunction against further mammography.

The current certificate for this facility expires on March 15, 1999. You should take the necessary action(s) to assure the certificate is renewed; and prevent further operations without a valid certificate.

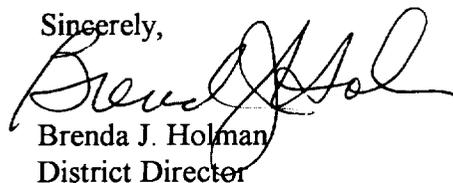
It is necessary for you to act on this matter immediately. Please inform this office in writing within fifteen (15) working days from the date you received this letter as to what measures your facility has taken to prevent this violation from recurring.

Please submit your response to the attention of Lillian C. Aveta, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn NY 11232, Tel. (718) 340-7000, ext. 5142.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to the issue of the performance of mammography under a valid FDA MQSA certificate 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, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely,



Brenda J. Holman
District Director

- cc: Mr. Alan Winakor
Vice President
Northeast Region
Medical Marketing
2001 Marcus Avenue
New Hyde Park, New York 11042
- cc: Mr. Christopher J. DeMeglio
Director of Technical Operations
Queens Medical Imaging P.C.
69-15 Austin Street
Forest Hills, New York 11375
- cc: Pamela A. Wilcox-Buchalla, RN, MBA
Director, Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091
- cc: Ms. Dorothy Pender
New York City Bureau of Radiological Health
2 Lafayette Street
New York, New York 10007