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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

April 8, 2003

WARNING LETTER NYK 2003-20

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Philip Gottlieb, M.D.
Guthrie Clinic Steuben
123 Conhocton Street
Corning, New York 14830

RE: Facility ID Number 225728

Dear Dr. Gottlieb:

A representative of the New York State Department of Health, acting on behalf of the United States Food and Drug Administration (FDA), conducted an inspection of your facility on March 20, 2003. This inspection revealed a serious regulatory problem involving the conduct of 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 Level 1 finding at your facility:

- ***Phantom quality control records were missing for four (4) weeks for the [redacted] mammography unit. Specifically, there were no phantom quality control records for the weeks of October 14, October 28, November 25, and December 23, 2002 when the unit was used to perform mammography (see 21 C.F.R. 900.12(d)(2), 900.12(e)(2)).***

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 identifies a failure to meet a significant MQSA requirement.

This condition represents a violation of the law, which may result in FDA taking additional action including, but not limited to, requiring your facility to undergo an Additional Mammography Review, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, seeking 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, seeking the suspension or revocation of your facility's FDA certificate, or seeking a court injunction against your facility.

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 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
1891 Preston White Drive
Reston, VA 22091

cc: Robert P. Snyder
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cc: Gerald O'Connor
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