DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

CIN WL –02-15041

September 27, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Conrad Lindes, M.D.
Partner
Southwest Family Physicians
7225 Old Oak Blvd.
Middleburg Heights, OH 44130

Facility I.D.#: 175794

Dear Dr. Lindes:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on September 18, 2002. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act (MQSA) of 1992, 42 U.S.C. § 263b, and the regulations set forth in Title 21, Code of Federal Regulations (C.F.R.), Part 900, 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 included on the MQSA Facility Inspection Report that your facility received at the close of the inspection:

Medical records and mammography reports – *Communication of mammography results* (21 C.F.R. § 900.12(c)(2))

Your records revealed that your facility failed to provide adequate results in the lay summary letters to patients for the mammography examinations that were interpreted as "Suspicious" (Category 4) and "Highly suggestive of malignancy" (Category 5). Also your facility's policy does not state that if assessments are "Suspicious" or "Highly suggestive of malignancy", that the serious results are communicated to the patients as soon as possible.

The inspector observed your facility's policy and records and found your facility provided to patients with serious assessments (Categories 4 & 5) lay summary letters that read: "the results of your recent mammograms were inconclusive. If you have not already spoken to your physician regarding your mammogram, it is critical that you call your doctor's office as soon as possible during regular office hours". Also your facility's policy reads: "All patients are sent a

'Lay Summary Report'. Patients that are a category 4 or 5 are instructed to call their referring physician for further evaluation. Reports are mailed within 30 days of service."

The inspection also revealed the following repeated violation as identified on your inspection report:

Quality Assurance – *Mammography Medical Outcomes Audit* - 21 CFR 900.12(f)(3)

Your records revealed that your facility conducted the medical outcome audit analysis inappropriately. Your facility failed to have a designated and qualified audit interpreting physician. Also your facility had an unqualified person review and evaluate your facility's calendar year 2000 mammography medical outcome audit data.

In addition, we found other deficiencies that were listed as Level 2 findings on your inspection report:

1. **Quality Assurance – *Mammography Medical Outcomes Audit* - 21 CFR 900.12(f)(3)**

There is no designated audit (reviewing) interpreting physician for your facility.

This item is mentioned in the previous section of this letter.

2. **Quality Assurance – *Equipment* - 21 CFR 900.12(e)(8)(i)&(ii) & 21 CFR 900.12(e)(2)**

Your records revealed that your facility failed to conduct and document corrective action on a mammography unit for which density difference optical density reading for the unit was charted outside the regulatory limits before further mammography examinations.

During the inspection, the inspector observed the weekly phantom quality control (density difference) result was out of limits on one occasion in August 5, 2002 for the [redacted] mammography unit located at your facility. Your records showed that mammography examinations were performed on August 5, 2002 with no documentation of corrective actions taken.

The other items listed in your September 18, 2002 inspection report identified, as Level 3 should also be corrected. We will verify corrections of these items during our next inspection. You are not required to address the Level 3 items in your written response.

These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and represent serious violations of the law that may result in FDA initiating regulatory action. 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; 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 the MQSA Standards; seeking suspension or revocation of your facility's FDA certificate; or seeking a court injunction against performing further mammography (see 42 USC §§ 263b(h) through (j) of the MQSA).

It is necessary to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and

- Each step your facility is taking **to prevent the recurrence** of similar violations.

Please also provide the following in answering this letter: (Note: Patient names or patient social security numbers should be deleted from any copies submitted)

- A copy of your corrected written procedure for communication of mammography results. The written procedures shall cover any and all serious (Categories 4 & 5) mammography results for patients. Also include a copy of a sample lay summary letter for the serious mammography result reports.

- A copy of your corrected written procedure for the medical outcome audit analysis with a statement of the qualified designated audit interpreting physician. Please include a complete copy of the personnel qualification documents of the designated audit interpreting physician.

- A copy of the your written standard operating procedure covering the phantom control chart operation and a copy of the phantom control chart covering the time period just prior to and after the September 18, 2002 inspection.

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Also, please **send a copy** to the State radiation control office:

Mr. Dwight Leeseberg
Ohio Department of Health
Radiological Technology Section
161 South High St., Suite 400
Akron, OH 44308-1616

Finally, you should understand that 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, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700, extension 138.

Sincerely yours,

John W. Thorsky
Acting District Director
Cincinnati District Office