DEPARTMENT OF HEALTH AND HUMAN SERVICES

937174

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–03-15556

November 18, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

George K. Adams, D.O.
Partner
Cooper Foster Family Practice
1959 Cooper Foster Park Rd.
Amherst, OH 44001

Facility I.D.#: 176727

Dear Dr. Adams:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on October 2, 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 (identified on your inspection report):

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 lay summary letters to patients that included the results of each mammography examination in which addendum mammography reports were produced based on the interpretation of the past mammography films. According to your facility's lead mammography technologist, your facility does not issue an addendum lay letter to patients when these addendum reports show that there is no change in the final assessment category or the recommended course of action.

The inspection also revealed the following Level 2 repeated violation at your facility (identified on your inspection report):

Quality Assurance – *Mammography medical outcome audit* - 21 CFR 900.12(f)(3)

Your facility failed to produce documentation that a medical audit and outcome analysis was completed according to the regulatory requirements.

The inspector observed that your facility failed to produce a medical audit and outcome analysis report that included an indication that all interpreting physicians have been notified of their individual results and the facility aggregate results. In addition, your facility failed to include in the report a discussion of any follow-up actions taken and the nature of these follow-up actions

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

1. Quality Assurance – *Equipment* - 21 CFR 900.12(e)(10)

During the inspection, the inspector observed that your facility installed a new [redacted] mammography processor on September 18, 2002 and failed to have an equipment evaluation performed by a medical physicist.

2. Quality Assurance – *Equipment* - 21 CFR 900.12(e)(1)

Your facility's mammography processor records in September 2002 were missing for at least 10% but less than 30% of the operating days in that month.

3. Personnel – *Radiologic technologists* – 21 CFR 900.12(a)(2)(iii)(A)

Your facility failed to produce documents verifying that the radiologic technologist, [redacted] met the continuing education requirement of having taught or completed at least fifteen (15) continuing education units in mammography in 36 months.

The inspector observed that your facility provided documents that [redacted] has only taught or completed 12 continuing education units in mammography in the past 36 months.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they 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:

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

2. 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)

3. A copy of your corrected written procedure for communication of mammography results. The written procedures shall cover any and all addendum mammography results for patients. Also, include a copy of a sample lay summary letter for an addendum report.

4. A copy of the annual medical audit and outcome report with an indication that the medical audit interpreting physician has notified the staff of interpreting physicians of their individual results and the facility aggregate results. The report must also list any follow-up actions taken, and the nature of the follow-up actions. Also, please provide assurances that your facility will correct **permanently** the medical audit and outcome analysis reporting requirement.

5. A copy of the amended medical physicist's report demonstrating that the [redacted] processor used for mammography has been evaluated.

6. A copy of your written standard operating procedure covering the processor quality control chart operation and a copy of the processor control chart covering the time period just prior to and after the October 2, 2002 inspection.

7. A copy of [redacted] certificates covering at least 15 continuing education units in mammography earned within the last 36 months period prior to the current date.

On November 4, 2002, this office received a letter, dated October 24, 2002, from [redacted] of your facility. Your facility's October 24, 2002 letter was in response to the Post Inspection Report that was provided to your staff at the close of the October 2, 2002 inspection. [redacted]'s letter is inadequate in answering this Warning Letter. Your staff letter did not provide the information requested in the above items numbered 1, 2 , 3 , 6 and 7.

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,

Mary S. Womack
Acting District Director
Cincinnati District Office

c.
OH/DWLeeseberg

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