DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

41451

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA CERTIFIED MAIL

WARNING LETTER

FLA-03-35

June 19, 2003

FACILITY ID # 223295

Mike Dinkel, President/Owner
Drew Medical, Inc.
Suite 303
7208 Sandlake Rd.
Orlando, Florida 32819

Dear Mr. Dinkel:

We are writing to you because on April 23, 2003, a representative of the State of Florida, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed serious 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 ensuring that a facility can perform quality mammography. The inspection revealed the following violation(s) at your facility:

- A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day as required by 21 CFR 900.12(e)(1). Your QC records for processor 1 were missing for 30% of the operating days in the month of December 2002 including 5 consecutive days.

- Your facility failed to produce documents verifying that a radiologic technologist either taught or completed at least 15 continuing education units (CEUs) in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two as required by 21 CFR 900.12(a)(2)(iii)(A). Specifically, your facility failed to produce documents

verifying that the radiologic technologist [redacted] met the continuing education requirement of having taught or completed 15 CEUs in 36 months. This is a repeat violation identified during the previous inspection of your facility dated April 26, 2002.

- The optical density of the film at the center of an image of a standard FDA accepted phantom shall be at least 1.20 when exposed under a typical clinical condition as required by 21 CFR 900.12(e)(2)(i). Specifically, the operating level for the background density for processor #1 was found to be <1.20.

The specific problems noted above appeared on the MQSA Facility Inspection Report that was issued to your facility at the close of the inspection on April 23, 2003.

Because these conditions may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- 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 $10,000.00 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards,
- seeking to suspend or revoke 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 you receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone number (407) 475-4728.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to observations made during the most recent inspection of your facility 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, telephone number (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about FDA's mammography facility requirements, or about the content of this letter, please contact D. Janneth Caycedo, Boca Resident Post, Food and Drug Administration, Interstate Plaza, 1499 W. Palmetto Park Rd., Suite 110, Boca Raton, Florida 33486, telephone number (561) 338-5236, ext. 23.

Sincerely,

Emma R. Singleton
Director, Florida District