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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

**WARNING LETTER**
**2003- DT -22**

September 23, 2003

**Certified Mail**
**Return Receipt Requested**

Re: MQSA Inspection ID # 2214340005

Mr. Mike Bruns, Office Manager
Universal Imaging, Inc.
3100 Cross Creek Parkway, Suite 120
Auburn Hills, Michigan 48326

Dear Mr. Bruns:

On August 28, 2003, a representative of the State of Michigan, acting on behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA") which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report (copy enclosed) that the inspector left with your facility at the close of the inspection. The violations are again identified below.

**Level 1:** Your facility failed to produce documents verifying that the interpreting physician, [redacted] is certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography, and that [redacted] has had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. [See 21 CFR 900.12(a)(1)(i)(B), (a)(4).]

**Level 2:** Your facility failed to produce documents verifying that the interpreting physician, [redacted] has interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that he qualified as an interpreting physician. [21 CFR 900.12(a)(1)(i)(D), (a)(4).]

**Level 2**: Your facility failed to produce documents verifying that the interpreting physician, [redacted] had at least 60 hours of documented category I medical education in mammography. [21 CFR 900.12(a)(1)(i)(C), (a)(4).]

**Level 2:** Your facility failed to produce documents verifying that the interpreting physician, [redacted] has interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that he qualified as an interpreting physician. [21 CFR 900.12(a)(1)(i)(D), (a)(4).]

**Level 2**: Your facility failed to produce documents verifying that the interpreting physician, [redacted] had a minimum of 60 hours of documented category I medical education in mammography. [21 CFR 900.12(a)(1)(i)(C), (a)(4).]

Because the failure to resolve these violations 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 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

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

You should respond in writing to FDA within fifteen (15) working days from the date you receive this letter. Your response should address the findings listed above and include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

Please submit your response to this letter to:
Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
300 River Place, Suite 5900
Detroit, MI 48207

Please send a copy of your response to:
Mr. James F. Camburn, Chief
Radiation Safety Section
Department of Consumer and Industry Services
P.O. Box 30664
Lansing, MI 48909

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspections 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, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Dennis E. Swartz, Radiological Health Specialist, at 313-393-8156.

Sincerely yours,

Joann M. Givens
District Director
Detroit District

cc:
Mr. James F. Camburn, Chief
Radiation Safety Section
Department of Consumer and Industry Services
P.O. Box 30664
Lansing, MI 48909

Priscilla F. Butler, M.S., FAAPM
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