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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
2004-DT-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 1, 2003

Y. Mossa Basha, M.D.
Owner
Basha Diagnostics, P.C.
4045 West 13 Mile Road
Royal Oak, MI 48073

Dear Dr. Basha:

We are writing you because on September 12, 2003, your facility was inspected by a representative of the State of Michigan acting on behalf of the Food and Drug Administration (FDA). The inspection revealed a serious compromise in the quality of the mammography services offered by 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 recent inspection at your facility revealed the following violations of the MQSA:

Level 1: Your facility failed to produce documentation to show that your radiologic technologist, [redacted] met the initial requirement of holding either a valid state license or a valid certificate from an FDA approved board. This is in violation of Title 21, Code of Federal Regulations § 900.12 (a)(4). See also 21 C.F.R. § 900.12 (a)(2)(i).

Level 2: There was no designated audit (reviewing) interpreting physician for review of the medical outcomes audit data. This is in violation of 21 C.F.R. § 900.12 (f)(3).

The specific violations noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility received at the close of the inspection. The first

violation is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

This condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility and represents a violation of the law. Failure to resolve these violations may result in FDA taking additional regulatory action, including, 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, seeking to suspend or revoke your facility's FDA certificate, or seeking a court injunction against performing further mammography.

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 the Level 1 and 2 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;

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

There are many requirements pertaining to mammography including State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. Please note that this letter only concerns the findings of your recent inspection and does not necessarily address other obligations you may have under the law.

You should also send a copy of your response to the State of Michigan radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

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 any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Specialist, at 313-393-8156.

Sincerely yours,

Joann M. Givens
District Director
Detroit District Office

Enclosure (MQSA Facility Inspection Report)