DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 1, 2002

First Class Mail
FDA MQSA Facility ID#: 110957

Amile A. Korangy, M.D.
Drs. Wityk, Goad, Korangy and Associates
724 Maiden Choice Lane, Suite 102
Baltimore, MD 21228

Dear Amile A. Korangy, M.D.:

I am writing to advise you that your Food and Drug Administration (FDA) Mammography Facility Certificate will expire on 05/06/2002. Under the Mammography Quality Standards Act (MQSA) of 1992, once your certificate expires, you are no longer certified and cannot continue to offer mammography services. This letter constitutes official notice from FDA that performing mammography after your certificate expires is a violation of the MQSA and may result in regulatory action by the agency without further notice.

Specifically, once your certificate expires, you:

1. may no longer perform mammography, and
2. may no longer display your certificate.

Additionally, without a valid FDA certificate, a facility is no longer eligible to receive payment for diagnostic or screening mammography procedures under the Centers for Medicare and Medicaid Services (CMS) (formerly known as HCFA).

If you wish to continue offering mammography services, you must contact your FDA-approved Accreditation Body to pursue your facility's options. If your Accreditation Body has recently notified you that your facility has been re-accredited, this letter does not apply to you, and you can expect a new certificate to arrive shortly. 14 1

I am also enclosing a fact sheet that outlines the steps you must take once your certificate expires. If you have any questions about the status of your accreditation application, please contact your Accreditation Body directly. If you have questions about your FDA certificate or responsibilities associated with certification, you may contact FDA by using one of the following methods:

Baltimore Imaging Center
Baltimore, Maryland
FEI#10005124 17 CFN 1124023
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8/8, 8/12, 8/14, 8/21, 8/22, 9/3, 9/5, 9/6/2002
EAL BAG WLF

FDA Contact Information:

Hotline:	1-800-838-7715
Fax Contact:	Food and Drug Administration 1-410-290-6351
Address:	Mammography Quality Assurance Program Food and Drug Administration P.O. Box 6057 Columbia, MD 21045-6057

Sincerely yours,

CAPT John L. McCrohan, USPHS
Director
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs
Center for Devices and Radiological Health

Enclosure - MQSA Expiration of Certificate Fact Sheet

Baltimore Imaging Center
Baltimore, Maryland
FEI#10005124, CFN 1124028
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Rockville MD 20857

May 1, 2002

Next Day Air - UPS
FDA MQSA Facility ID#: 110957
Amile Korangy M.D.
Baltimore Imaging Center
724 Maiden Choice Lane
Baltimore, MD 21228

COPY

Dear Dr. Korangy:

I am writing to advise you that your mammography Accreditation Body has notified the Food and Drug Administration (FDA) that your facility was denied reaccreditation because it failed to meet the standards required for accreditation. FDA is unable to certify your facility without proof of accreditation. A certificate is required for lawful operation of a mammography facility. Upon receipt of this letter, you must cease performing mammography and you should no longer display your certificate, regardless of the date of expiration. The Mammography Quality Standards Act of 1992 (42 U.S.C. 263b) authorizes FDA to take regulatory action, including suspension or revocation of certification and civil money penalties, against facilities that practice mammography in violation of the law.

Please read the enclosed Denial of Reaccreditation Fact Sheet carefully. If you have any question about your accreditation, please contact your Accreditation Body directly. If you have questions about your FDA certificate or responsibilities associated with certification, you may contact FDA by using one of the following methods:

FDA Contact Information:

Hotline:	-800-838-7715
Fax Contact:	1-410-290-6351
Address:	Mammography Quality Assurance Program Food and Drug Administration P.O. Box 6057 Columbia, MD 21045-6057

Sincerely yours,

John L. McCrohan

CAPT John L. McCrohan, USPHS
Director
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs
Center for Devices and Radiological Health

Baltimore Imaging Center
Baltimore, Maryland
FEI#1000512417 CFN 1124028
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Enclosure - Mammography Quality Standards Act Denial of Reaccreditation Fact Sheet

UPS INDIVIDUAL SHIPPING DOCUMENT
SHIPPING DATE: 5/1/02
UPS Account No. 042231W

5-22-02

FDA ID #/PKG REF 1: JJ 110957
Baltimore Imaging Center
724 Maiden Choice Lane
Baltimore MD 21228
JS

UPS Tracking Number: 1Z64231W0142494861
IDA Ltr $12.75
Pickup Date: 5/1/02
Pickup Record Number: 6206762

Baltimore Imaging Center
Baltimore, Maryland
FEI#1000512417 CFN 1124028
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