

Office of the Chief Counsel Food and Drug Administration 5600 Fishers Lane, GCF-1 Rockville, MD 20857

June 20, 2008

VIA FIRST CLASS & CERTIFIED MAIL AND FACSIMILE TO 410-788-2843

NOTICE OF DEFAULT

Amile A. Korangy, M.D. Korangy Radiology Associates, P.A. d/b/a Baltimore Imaging Centers 724 Maiden Choice Lane, Suite 102 Catonsville, MD 21228

Dear Dr. Korangy,

On March 10, 2008, after extremely protracted negotiations, you entered into the attached agreement (Agreement) with the United States Food and Drug Administration (FDA) on behalf of yourself and your company, Korangy Radiology Associates, P.A. (KRA). The Agreement was executed on FDA's behalf by Daniel Schultz, M.D., Director, Center for Devices and Radiological Health (CDRH), on March 14, 2008.

Pursuant to the Agreement, you and KRA are jointly and severally liable for the full \$1.158 million civil money penalty assessed against you both for your violations of the Mammography Quality Standards Act of 1992, 42 U.S.C. § 263b. Agreement, ¶ D. You and KRA agreed to pay FDA the sum of \$579,000 within 90 days from the date of the Agreement's execution. Agreement, ¶ C. Because the Agreement was fully executed on March 14, 2008, your first payment of \$579,000 was due to FDA on June 12, 2008.

On June 9, 2008, your lawyer Timothy Lynch contacted Marci Norton, an attorney on my staff, to notify her that you would not make the payment as you had agreed and to suggest a revised payment plan in which you would pay \$150,000 on June 12, 2008, and \$100,000 a month until the initial \$579,000 was paid in full. On June 10, 2008, Ms. Norton e-mailed Mr. Lynch that any change in the terms of the Payment Agreement was unacceptable to FDA. Ms. Norton told Mr. Lynch via e-mail on June 11, 2008, that FDA's position was final.

The Agreement provides that if you or KRA fail to make any of the agreed upon payments, FDA may send you a notice declaring you to be in default, at which time the full remaining unpaid balance shall become immediately due and payable without demand, process, notice, or other formality, judicial or otherwise, of any kind, all of which you expressly waived. Agreement, ¶ D.

Amile A. Korangy, M.D. Korangy Radiology Associates, P.A. d/b/a Baltimore Imaging Centers June 20, 2008 Page 2

The Agreement further provides, "interest on any unpaid amount shall accrue at the rate of 7.5% per annum compounded daily from the date of default on the full remaining unpaid balance." <u>Id.</u>

This letter serves as FDA's notice of your default. The entire \$1.158 million owed by you, plus interest, is now immediately due and payable. Please remit a certified check and/or money order made payable to the "United States Treasury," and sent via express mail to: Nikol Echols, 5600 Fishers Lane, HFA-121, Room 11-64, Rockville, Maryland 20857, and include with your payment a copy of this letter and the Judgment issued by the Court of Appeals for the Fourth Circuit on August 17, 2007. Please be advised that FDA is referring this matter to appropriate authorities to ensure enforcement of the agreement and collection of the entire amount, plus all interest due upon collection.

Sincerely

Eric M. Blumberg

Deputy Chief Counsel for Litigation United States Food and Drug Administration

Attachment

cc: Timothy Lynch, Esq. (via Fed Ex, facsimile, and e-mail)