

EXHIBIT G-E

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

_____ )	
In the Matter of )	
KORANGY RADIOLOGY ASSOCIATES, P.A., )	ADMINISTRATIVE COMPLAINT
trading as BALTIMORE IMAGING CENTERS, )	<u>FOR CIVIL MONEY PENALTY</u>
a corporation, )	
and )	FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D., )	
an individual. )	
_____ )	

DECLARATION OF ELIZABETH A. LAUDIG

Elizabeth A. Laudig declares as follows:

1. I am employed as a Compliance Officer in the Baltimore District Office (BLT-DO) of the United States Food and Drug Administration (FDA), United States Department of Health and Human Services. I became a Compliance Officer in July 2003. As a Compliance Officer, I review and process findings and observations that are documented during inspections conducted by FDA investigators. My work address is 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215.

2. I have been employed by FDA since October 1991. From 1991 until 1994, I was employed part-time as a cooperative education student. From 1994 until 1995, I worked full-time as an FDA investigator. In 1995, I attended a six-week training course and became certified to conduct inspections of

mammography facilities. From 1995 until 1998, I served as an FDA investigator, concentrating in the area of radiological health. In this capacity, I conducted inspections of mammography facilities. From 1998 until October 2003, I served as the Mammography and General X-ray Auditor for BLT-DO. In 2000, I also became the Mammography Auditor for FDA's New Jersey District Office. As a Mammography Auditor, I conducted inspections of mammography facilities, audited the onsite performance of state and federal inspectors who performed mammography facility inspections, reviewed inspection reports from state and federal inspectors, reviewed corrective actions submitted by mammography facilities, prepared Warning Letters, and conducted onsite inspector training for mammography facility inspectors.

3. I obtained a Bachelors of Science Degree in Biology from the University of Maryland, Baltimore County, in Catonsville, Maryland, in 1994. In 1995, I received eight weeks of classroom instruction in X-ray testing and FDA's mammography inspection program, which was implemented in 1995. I have also earned approximately forty-five hours of continuing education credits in mammography since 1995.

4. On July 19, 2002, I was contacted by Michael P. Divine, a Compliance Expert for the Inspection and Compliance Branch, Division of Mammography Quality and Radiation Programs,

Office of Health and Industry Programs, Center for Devices and Radiological Health, FDA. Mr. Divine requested that I conduct an inspection of the Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers (BIC), mammography facility, which is located at 724 Maiden Choice Lane, Suite 102, Catonsville, Maryland 21228.

5. I, together with BLT-DO Investigators Barbara A. Gullick and Walter L. Fava, conducted an inspection of BIC during August 8, 12, 14, 21-22, 2002, and September 3, 5-6, 2002. The purpose of the inspection was to determine whether BIC had performed mammography without a valid mammography certificate.

6. On August 8, 2002, Investigator Gullick and I presented our credentials and issued a Form FDA 482 (Notice of Inspection) to Barry J. Henderson. Mr. Henderson stated that he was the Vice President of BIC and the most responsible person present at the time of our arrival.

7. During the inspection, Mr. Henderson stated to me that BIC was known as Drs. Wityk, Goad, Korangy and Associates until 1998. Mr. Henderson stated that Dr. Amile A. Korangy purchased the interests of Drs. Wityk and Goad in 1998 and changed the name of the facility to Baltimore Imaging Centers. Mr. Henderson stated that Dr. Korangy operates eight facilities under the name Baltimore Imaging Centers.

8. Mr. Henderson described Dr. Korangy as the "day-to-day clinical director" of all the BIC facilities. Mr. Henderson stated that he shares certain administrative duties, such as hiring and firing employees, with Dr. Korangy. Mr. Henderson also stated that Dr. Korangy is the lead interpreting physician at BIC and is responsible for submitting accreditation materials to the American College of Radiology (ACR). Mr. Henderson stated that Dr. Korangy and Dr. Irfan S. Shafique perform mammogram interpretations.

9. During the inspection, Mr. Henderson provided to me a copy of BIC's mammography certificate, which expired on May 6, 2002. See Affidavit of Barry J. Henderson, dated September 3, 2002 (Henderson Aff.), Ex. G-11. (A copy of the certificate is attached as Ex. G-4 to the Declaration of Michael P. Divine.)

10. Mr. Henderson also provided to us reports for mammography examinations that BIC performed between May 6, 2002, and July 27, 2002. See Henderson Aff. at 1. (Copies of the reports are attached as Ex. G-10 to the Declaration of Michael P. Divine.)

11. Mr. Henderson stated to Investigator Gullick and me that BIC received a letter dated April 29, 2002, from ACR. See Henderson Aff. at 8. Mr. Henderson acknowledged that ACR strongly recommended in the letter that BIC cease conducting mammography. Id. Mr. Henderson stated that he and Dr. Korangy