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October 17, 2003

RETURN RECEIPT REQUESTED

Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: In Re: Korangy Radiology Associates, P.A., et al.
FDA Docket: 2003H-0432

Dear Sir/Madam:

Enclosed please find the Response of the Respondents to the Complaint issued in the above-referenced matter. An original and two copies are enclosed. A hearing is requested.

Please enter my appearance on behalf of both Respondents. My contact information appears above.

Thank you for your attention to this matter. Please let me know if anything is currently needed from us.

Sincerely,

Henry E. Schwartz

Enclosure

Cc: Amile A. Korangy, M.D.
Douglas A. Terry, Esquire

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2003H-0432

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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., Trading as BALTIMORE IMAGING CENTERS, A corporation,	*	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY
And		FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D., An individual	*	

* * * * * * * * * * * *

ANSWER OF RESPONDENTS, KORANGY RADIOLOGY ASSOCIATES, P.A., T/A BALTIMORE IMAGING CENTERS, AND AMILE A. KORANGY, M.D.

Now come Respondents, Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers ("BIC") and Amile A. Korangy, M.D. ("Dr. Korangy"), by their attorneys, Henry E. Schwartz, and Henry E. Schwartz LLC, and answer the Complaint in the above-captioned matter as set forth below. All responses are applicable to both Respondents, unless specifically indicated to the contrary.

RESPONSE TO ALLEGATIONS

Respondents respond as following to the allegations contained in the numbered paragraphs of the Complaint:

1. Admit.
2. Admit.
3. Admit.
4. Deny.
5. Admit.
6. Admit.
7. Admit.
8. Admit.
9. Deny.
10. Deny.
11. Deny.
12. Deny.
13. Deny
14. Deny
15. Deny.

16. Admit.
17. Admit.
18. Deny.
19. Deny.
20. Deny.
21. Deny.
22. Admit
23. Deny.
24. Admit.
25. Admit.

DEFENSES ASSERTED

Respondents assert the following defenses to the charges contained in the Complaint:

1. Respondents did not receive a written communication from FDA indicating that they would be in legal violation to continue to perform mammography during the time period in question.

2. Complainant has inappropriately utilized 42 USC 263b(h)(3) to levy fines totaling $20,000 per "incident," when the statute limits any such fines to $10,000 per "incident."

3. Complainant has inappropriately utilized 42 USC 263b(h)(3)(D) as a basis for levying fines that are based solely on alleged violations of 42 USC 263b(h)(3)(A), and are therefore limited by statute to a total of $10,000 for "failure to obtain a certificate."

4. Complainant has inappropriately utilized 42 USC 263b(h)(3)(D) to levy fines upon the corporate entity that is the facility providing and billing for the services in question, when that section of the law can, at best, only apply to the "owner, operator, or any employee" of the "facility."

5. Complainant, in determining to levy one or more fines at the statutory maximum level of $10,000, has failed to appropriately consider the various reasons for mitigation set forth below.

MITIGATION ASSERTED

Respondents seek consideration of the following mitigative factors in respect to the charges contained in the Complaint:

1. Respondents did not receive a written notice from FDA indicating the legal impropriety of performing mammography procedures during the time period in question. Respondents were unaware that they were allegedly in violation of the law in the manner

in which they immediately replaced the equipment questioned by the American College of Radiology.

2. Respondents received a confusing notice from the American College of Radiology, which led them to believe that they could continue testing pending the installation of the newly ordered replacement machine.

3. No patients were harmed by Respondents' conduct in this matter.

4. Penalties should be reduced in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 and the Presidential Memorandum of April 21, 1995 (60 FR 20621, April 26, 1995).

5. The alleged violations took place over a brief period of time.

6. Respondents resolved the subject matter of the Complaint expeditiously.

7. Respondents have not been charged with, or found guilty of, any prior violations.

8. The extreme amount of total penalties requested would be more than punitive in nature, both against the corporation and the individual. The effects of fines at such levels would be financially disastrous. Such impact is not in accord with Congress' intent that the Secretary's first priority be restoring a facility to compliance, and imposing intermediate sanctions to that effect, in lieu of revoking, suspending or limiting a certificate.

9. Respondents perform mammography procedures only for the benefit of their patients, and not for financial gain, as BIC effectively loses money on each mammography procedure performed.

Respectfully submitted on behalf of Respondents, by:

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Towson, MD 21204
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henryeschwartzllc@verizon.net

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 17 day of October, 2003, a copy of the foregoing Answer of Respondents was mailed, first class, postage prepaid, to Complainant's Counsel, as follows:

Douglas A. Terry, Esquire
The Center for Devices and Radiological Health
United State Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
Telephone: 301.827.1141

Henry E. Schwartz