UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES P1:36

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

SUPPLEMENT TO 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 supplement their answer to the Complaint in the above-captioned matter as set forth below. All responses are applicable to both Respondents, unless specifically indicated to the contrary.

Respondents' Answer indicated that the extreme amount of the total penalties in the instant case is more than punitive, and more severe than revocation, the punishment intended to be supplemented by "intermediate sanctions," i.e., civil money penalties. Respondents wish to make clear that they believe that this circumstance is violative of the Excessive Fines Clause of the Eighth Amendment to the United States Constitution, per the criteria set forth by the Supreme Court in <u>United States v. Bajakajian</u>, 524 U.S. 321, 118 S.Ct. 2028 (1998).

Respectfully submitted on behalf of Respondents, by:

Henry E. Schwartz

Henry E. Schwartz LLC

901 Dulaney Valley Road, Suite 400

Towson, MD 21204 Phone: 410.938.8703 Fax: 410.823.6017

henryeschwartzllc@verizon.net

## **CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 2 day of December, 2003, a copy of the foregoing Supplement to 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

## Henry E. Schwartz LLC 901 Dulaney Valley Road, Suite 400

Towson, MD 21204 2 0 \*03 DEC -4 P1 :36 Phone: 410.938.8703 / Fax: 410.823.6017

henryeschwartzllc@yerizon.net

December 1, 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 Supplement to the Response of the Respondents with respect to the Complaint issued in the above-referenced matter. An original and two copies are enclosed.

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