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December 7, 2004

VIA OVERNIGHT MAIL

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1051
Rockville, Maryland 20852

RE: In re: Korangy Radiology Associates, P.A., *et al.*
FDA Docket No. 2003H-0432

Dear Sir/Madam:

Enclosed for filing in the above-referenced matter please find an original and one copy of the Respondents' Reply to Post-Hearing Brief of Respondents.

A draft order is also enclosed.

Thank you for your attention to this filing. Please contact me with any questions.

Sincerely,


Henry E. Schwartz

Enclosures

cc: Amile Korangy, M.D.
Jennifer E. Dayok, Esquire
Marci Norton, Esquire
Hon. Daniel J. Davidson, ALJ

2003H-0432

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

In the Matter of

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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

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RESPONDENTS' REPLY TO POST-HEARING BRIEF OF COMPLAINANTS

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 file the following Reply to Post-Hearing Brief of Complainants. All references herein are intended to apply to both Respondents, unless specified to the contrary.

I. Federal statute requires that FDA develop and apply procedures for the issuance of civil money penalties ("CMPs" or "fines"), and the absence of such procedures invalidates the CMPs issued in the instant case.

Complainants' counsel argues that the mandated procedures exist, despite the clear testimony of their expert witness to the contrary. The document provided through the brief, but not admitted as evidence in the case (i) should be stricken from the record as not having been produced prior to or at hearing; and (ii) in any event does not contradict the testimony of Complainants' witness, as it only briefly attempts to indicate whether CMPs should be considered, and does not attempt to indicate the manner in which the amount of CMPs should be determined.

II. Federal regulations place the burden of proof of the appropriateness of the CMPs on the FDA's Center for Radiologic Health, and the failure of the Center to meet this burden invalidates the CMPs issued in the instant case.

Complainants' counsel argues that the Center has met its burden of proof in this case. The record indicates otherwise. Complainants' expressed rationale(s) for the fines levied in this case was paper-thin and, where it existed, was arbitrary and capricious.

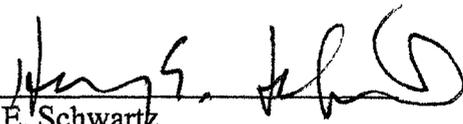
III. FDA issued CMPs in this case that are grossly disproportionate to the offenses charged, and thus are invalid as violative of the 8th Amendment to the United States Constitution.

Complainants' counsel argues that the Constitution does not protect Respondents in this case, because the \$3.8 million dollars in fines levied were "remedial," and not "punitive." The rationale presented for this conclusion is that since Congress allowed maximum fines of \$10,000, no fine of \$10,000 could be "punitive." That this argument is both circular and specious requires no great explanation.

IV. Conclusion.

For the reasons set forth above, the CMPs issued in the instant case violate federal regulation, statute, and the United States Constitution, and therefore must be reversed in total. The Administrative Law Judge has no authority to revise or modify the CMPs in this case, because the (a) the FDA has in place no statutorily mandated guidelines to apply for that purpose, and (b) Federal regulations require the Center to meet the established burden of proof in this case, and it has not done so.

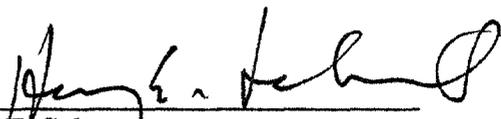
Respectfully submitted on behalf of Respondents, by:


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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 7th day of December, 2004, a copy of the foregoing Respondents' Reply to Post-Hearing Brief of Complainants was mailed, first class, postage prepaid, to Complainant's Counsel, as follows:

Marci Norton, Esquire
Jennifer Dayok, Esquire
The Center for Devices and Radiological Health
United State Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857


Henry E. Schwartz