

Henry E. Schwartz LLC
901 Dulaney Valley Road, Suite 400
Towson, Maryland 21204
Phone: 410.938.8703 / Fax: 410.823.6017
henryeschwartzllc@verizon.net

1101 '04 APR -5 11:32

April 2, 2004

VIA OVERNIGHT MAIL

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

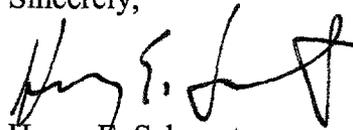
RE: In re Korangy Radiology Associates, P.A., *et al.*
FDA Docket No. 2003H-0432

Dear Sir/Madam:

Enclosed for filing in the above-referenced matter please find an original and one copy of Respondents' Request for Protective Order.

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

Sincerely,



Henry E. Schwartz

Enclosure

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

2003H-0432

MO6

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

1192 04 APR -5 11:32

In the Matter of: * ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTY
KORANGY RADIOLOGY ASSOCIATES, *
P.A., t/a BALTIMORE IMAGING *
CENTERS, *
and * FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D. *

* * * * *

RESPONDENTS' SECOND REQUEST FOR PROTECTIVE ORDER

Respondents, by their undersigned attorneys, having received Complainant's First Request for Production of Documents, hereby seek protection from two of the specific requests contained therein, on the basis that these requests are not relevant to the issues under appeal (21 CFR 17.23(a)), are unduly costly or burdensome (21 CFR 17.23(d)(2) and 21 CFR 17.28), seek privileged information (21 CFR 17.23(d)(3) and 21 CFR 17.28), and constitute an unwarranted invasion of personal privacy (21 CFR 17.28).

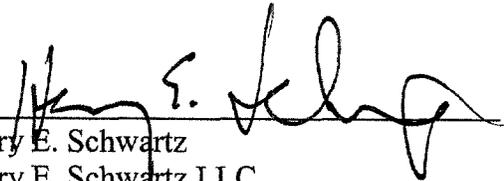
The specific requests herein objected to, and the specific reasons for such objections, follow:

1. Request #2 seeks any document "reflecting" any asset of Respondents and their families. The assets of Respondent Korangy's family members are in no way relevant to the instant matter. This portion of the request also constitutes an unwarranted invasion of personal privacy.

2. Request #4 seeks all documents "relating to" the annual receipts and number of employees of Respondents, as well as any entities unrelated to the instant case in which Respondents may exercise ownership or control interests, or in which Respondents' relatives may hold ownership interests. This request contains no limitations as to scope, subject matter or timeframe. This request, to the extent that it addresses persons in which any Respondent is an officer, director or partner, but is otherwise not controlling such person, does not fall within the scope of the rule defining "annual receipts," and therefore addresses no issue in the instant case, and is overbroad, unduly burdensome and costly, and constitutes an unwarranted invasion of personal privacy and the production of confidential commercial information.

For the foregoing reasons, Respondents respectfully request that a Protective Order be issued, limiting Complainant's Document Production Request to items relevant as to issue and timeframe.

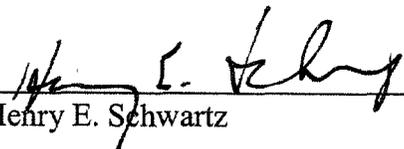
Respectfully submitted,



Henry E. Schwartz
Henry E. Schwartz LLC
901 Dulaney Valley Road, Suite 400
Towson, Maryland 21204
410.938.8703
henryeschwartzllc@verizon.net

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 2nd day of April, 2004, a copy of the foregoing Respondents' Second Request for Protective Order was mailed, postage prepaid, to Douglas A. Terry, Esquire, Office of the General Counsel, Food and Drug Administration, 5600 Fishers Lane, GCF-1, Rockville, Maryland 20857.



Henry E. Schwartz