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APR 26 P1:35

April 25, 2005

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

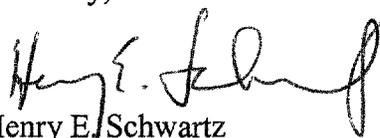
Dear Sir/Madam:

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

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
Marcy Norton, Esquire
Hon. Daniel J. Davidson, ALJ

2003H-0432

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UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES 06/22/05 P1:35

In the Matter of: *
KORANGY RADIOLOGY ASSOCIATES, *
P.A., t/a BALTIMORE IMAGING *
CENTERS, *
And *
AMILE A. KORANGY, M.D. *

ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTY

FDA Docket: 2003H-0432

* * * * *

PROPOSED ORDER

Respondents filed a request for Protective Order, seeking, pursuant to 21 CFR 17.28, that the information pertaining to the instant case, made publicly available by FDA, through its website and otherwise, be limited to protect privileged personal and commercial information. Specifically, Respondents have requested that information relating to their tax returns and financial status and property ownership, as well as property ownership of others that may be imputed to Respondents by FDA, be redacted.

Accordingly, it is ORDERED, ADJUDGED, AND DECREED, that:

Respondents' request for Protective Order is hereby GRANTED, and it is Ordered that future availability of documents to the public be limited in accordance with this Order, and that the information available on the FDA website be modified in conformance with this Order.

The following documents or portions thereof are covered by the terms of this Order:

1. Complainant's Post-Hearing Brief on Penalty Amount (pages 8 and 9; Exhibits G-17, 25, 26 and 30);

Redacted pages 8 and 9 are enclosed herewith. Redacted Exhibit G-26 is also enclosed. Exhibits G-25, 26 and 30 are to be protected in their entirety.

2. Pre-Filed Direct Testimony of Amile A. Korangy, M.D. (Answers 22-24, 27, 28 and 31; Exhibits 2, 3, 5, 6 and 7);

Redacted Answers 22-24, 27, 28 and 31 are enclosed herewith. Exhibits 2, 3, 5, 6 and 7 are to be protected in their entirety.

3. Initial Decision of December 17, 2004 (pages 7 and 8);
Redacted copies of pages 7 and 8 are enclosed herewith.
4. Respondents' Proposed Findings of Fact (Sections 18-23); and
Redacted copies of Proposed Findings 18 - 23 are enclosed herewith.
5. Complainant's Brief in Opposition to Respondents' Appeal and Request for Oral Argument (pages 19, 21 and 22).

Redacted copies of pages 19, 21 and 22 are enclosed herewith.

Daniel J. Davidson
Administrative Law Judge
U.S. Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, Maryland 20857

Proposed by:


Henry E. Schwartz
Attorney for Respondents

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 25 day of April, 2005, a copy of the foregoing Proposed Order 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, Maryland 20857
Telephone: 301.827.1141


Henry E. Schwartz

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., t/a BALTIMORE IMAGING *
CENTERS, *
And *
AMILE A. KORANGY, M.D. *

ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTY

FDA Docket: 2003H-0432

* * * * *

RESPONDENTS' REQUEST FOR PROTECTIVE ORDER

Respondents, by their undersigned attorneys, hereby request that the information pertaining to this case, made publicly available by the FDA, through their website and otherwise, be limited to protect privileged information under (21 CFR 17.23(d)(3) and 21 CFR 17.28(b)), and to avoid an unwarranted invasion of personal privacy (21 CFR 17.28(b)). This request is made pursuant to 21 CFR 17.28(b)(6).

Specifically, Respondents wish to protect information relating to their tax returns and financial status and property ownership, as well as property ownership that the FDA has sought to "impute" to Respondents, though such property may not be held in the name of Respondents.

In particular, protection is sought of the following documents or portions thereof:

1. Complainant's Post-Hearing Brief on Penalty Amount (pages 8 and 9; Exhibits G-17, 25, 26, and 30);

Redacted pages 8 and 9 are enclosed herewith. Redacted Exhibit G-26 is enclosed. Copies of Exhibits G-17, 25 and 30 are also enclosed, but Respondents are requesting that these entire documents be protected.

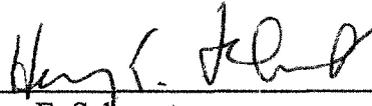
2. Pre-Filed Direct Testimony of Amile A. Korangy, M.D. (Answers 22-24, 27, 28 and 31; Exhibits 2, 3, 5, 6 and 7);

Redacted Answers 22-24, 27, 28 and 31 are enclosed herewith. Copies of Exhibits 2, 3, 5, 6 and 7 are also enclosed, but Respondents are requesting that these entire documents be protected.

3. Initial Decision of December 17, 2004 (pages 7 and 8);
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Redacted copies of Proposed Findings 18 - 23 are enclosed herewith.
5. Complainant's Brief in Opposition to Respondents' Appeal and Request for Oral Argument (pages 19, 21 and 22).
Redacted copies of pages 19, 21 and 22 are enclosed herewith.

For the foregoing reasons, Respondents respectfully request that a Protective Order be issued, limiting the publicly available record in the instant case.

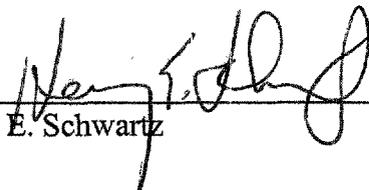
Respectfully submitted,



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 25th day of April, 2005, a copy of the foregoing Respondents' Request for Protective Order was mailed, postage prepaid, to Marci Norton, Esquire, and Jennifer Dayok, Esquire, Office of the General Counsel, Food and Drug Administration, 5600 Fishers Lane, GCF-1, Rockville, Maryland 20857.



Henry E. Schwartz