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Towson, MD 21204
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5437 '04 FEB 23 09:53

February 13, 2004

VIA CERTIFIED MAIL .
RETURN RECEIPT REQUESTED

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

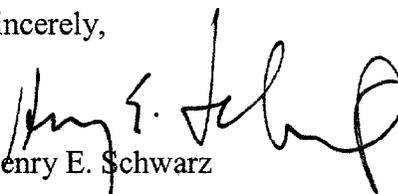
RE: In Re: Korangy Radiology Associates, P.A., et al.
FDA Docket: 2003H-0432

Dear Sir/Madam:

Enclosed please find Respondents' First Request for Production of Documents, for filing in the above-referenced case.

Thank you for your attention to this matter. Please let me know if there are any questions concerning this filing.

Sincerely,



Henry E. Schwarz

Enclosure

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

2003H-0432

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

*

* * * * *

RESPONDENTS' FIRST REQUEST FOR PRODUCTION OF DOCUMENTS

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 request that Complainant produce for inspection and copying, within 30 days after service of this request, at the offices of Respondents' attorney, at 901 Dulaney Valley Road, Suite 400, Towson, Maryland 21204, the documents requested herein.

DEFINITIONS AND INSTRUCTIONS

As used herein,

1. "You" and "your" refers to the Food and Drug Administration, and its employees and agents.
2. "Documents" is defined in 21 CFR § 17.23.
3. "Custody or control" includes documents in the possession of agents of the Food and Drug Administration, or other agencies within the Department of Health & Human Services.
4. "Sanctions" refers to any administrative action taken or threatened in response to alleged or determined violations of statute, regulation or policy, and includes, but is not limited to, the following actions:
 - a. Civil money penalties;

b. Suspension of the ability to (i) provide certain services or (ii) participate in any federally-sponsored health care plan; or

c. Termination of the ability to (i) provide certain services or (ii) participate in any federally-sponsored health care plan.

5. These document requests are intended to be continuing in nature so as to require supplemental or amended responses, to be furnished within ten days of the date on which the additional documents become available to Complainant.

6. If you withhold any requested documents, identify the documents withheld, as well as the reason(s) for withholding any such documents.

DOCUMENT REQUESTS

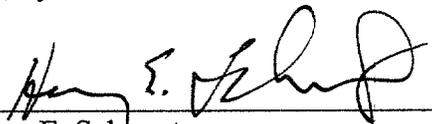
Please produce the following documents in your custody or control:

1. All documents addressing sanctions considered or issued with respect to particular alleged violations of the Mammography Standards Act (MQSA), 42 USC § 263b, regardless of the legal authority cited for the consideration or issuance of such sanctions.

2. All documents relating to appeals, at any level, whether administrative or judicial, of particular sanctions issued for violations of the Mammography Standards Act, regardless of the legal authority cited for the issuance of such sanctions.

3. All documents related to the above-captioned matter indicating consideration given to issuing civil money penalties in any amount less than that which you believed to be the statutory maximum.

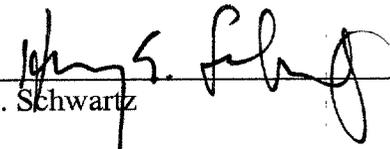
Respectfully submitted on behalf of Respondents, by:


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henryeschwartzllc@verizon.net

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 13th day of February, 2004, a copy of the foregoing Respondents' First Request for Production of Documents, 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