



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

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Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

January 30, 2004

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 No. 2003H-0432

Dear Sir or Madam:

Enclosed for filing in the above-captioned matter is the original and one copy of Joint Notice And Agreement To Resolve Discovery Dispute.

If you have any questions, please call me at (301) 827-7138. Thank you.

Sincerely yours,

Douglas A. Terry
Assistant Chief Counsel
for Enforcement

Enclosures

cc w/enc.:

Hon. Daniel J. Davidson, A.L.J.
Henry E. Schwartz
Karen Schifter, OCC

2003H-0432

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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.,)	ADMINISTRATIVE COMPLAINT
trading as BALTIMORE IMAGING CENTERS,)	<u>FOR CIVIL MONEY PENALTY</u>
a corporation,)	
and)	FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D.,)	
an individual.)	

**Joint Notice And Agreement To
Resolve Discovery Dispute**

Pursuant to 21 C.F.R. § 17.32(c), Complainant, the Center for Devices and Radiological Health, United States Food and Drug Administration (FDA), and Respondents, Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers, and Amile A. Korangy, M.D., by their undersigned counsel, file this Joint Notice And Agreement To Resolve Discovery Dispute And agree to the terms contained herein.

Agreement To Resolve Discovery Dispute

On January 13, 2004, Complainant served Complainant's First Request for Production of Documents (Complainant's Document Request) on Respondents. On January 26, 2004, Respondents served upon Complainant Respondents' Request for Protective Order (Respondents' Request) objecting to certain document requests made by Complainant.

In order to resolve the objections raised by Respondents, Complainant and Respondents agree as follows:

1. Complainant's Document Request Number 1 is modified as follows:

All documents relating to (i) the creation and formation of Korangy Radiology Associates, P.A., and any predecessor or successor of Korangy Radiology Associates, P.A.; and (ii) all official corporate acts taking place between January 1, 1998 to the present, including corporate formation and dissolution, name change, shareholders' meetings, directors' meetings, and corporate resolutions of the persons identified below; and (iii) the composition of the corporation, its management, owners, and employees, including lists of directors, officers, and shareholders of:

- (A) Korangy Radiology Associates, P.A.;
- (B) Any person employing, using, or conducting business or operating under, or that has employed, used, conducted business or operated under, the name Baltimore Imaging Center or Baltimore Imaging Centers;
- (C) Any predecessor or successor, parent or subsidiary, of Korangy Radiology Associates, P.A.

2. Complainant's Document Request Number 2 is withdrawn, subject to the following. Respondents acknowledge that they asserted in the Answer of Respondents, Korangy Radiology Associates, P.A., T/A Baltimore Imaging Centers, and Amile A. Korangy, M.D., that civil money penalties should be reduced in accordance with the Small Business Regulatory Fairness Act of 1996 (SBREFA) and the Presidential Memorandum of April 21, 1995 (the Memorandum). See Respondents' Answer at Mitigation Asserted ¶ 4. Respondents also acknowledge that their assets and ability to pay may be a relevant consideration in

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determining whether penalties should be reduced in accordance with SBREFA and the Memorandum. See FDA Regulatory Procedures Manual (RPM), Chapter 5, Administrative Actions, Civil Money Penalties, Reduction of Civil Money Penalties for Small Entities. Finally, Respondents acknowledge that they have not decided whether to claim entitlement to a reduction of civil money penalties in any motion, proposed finding of fact, hearing, or other event scheduled to occur in this proceeding.

Respondents agree that they will respond to Complainant's Document Request Number 2 no later than sixty days prior to (1) filing any motion, proposed finding of fact, evidence, or any other written document in this proceeding in which all or either of them claim entitlement to a reduction of civil money penalties based on their inability to pay; or (2) the hearing in this proceeding if all or either of them claim, or offer evidence in support of a claim, during such hearing, that they are entitled to a reduction of civil money penalties based on their inability to pay. If Respondents fail to respond to Complainant's Document Request Number 2 sixty days prior to filing such motion, proposed finding of fact, evidence, other written document, or the hearing, as described above, Respondents agree that the Presiding Officer should exclude any evidence of their inability to pay or entitlement to reduction of civil money penalties that is submitted in support of such

motion, proposed finding of fact, written document, and/or hearing. See 21 C.F.R. §§ 17.19(b)(11), 17.25(b)(1).

3. Complainant's Document Request Number 3 is modified as follows:

All documents relating to contracts and other indicia of an employment or ownership relationship between Respondents that were or are in effect from January 1, 2001 to the present, and all records of payments between Respondents during that same time period.

4. Complainant's Document Request Number 4 is withdrawn, subject to the following. Respondents acknowledge that they may be able to claim a reduction of civil money penalties only upon a showing that one or both of them constitute a "small entity" under SBREFA. See RPM, Chapter 5, Administrative Actions, Civil Money Penalties, Reduction of Civil Money Penalties for Small Entities. Respondents also acknowledge that their "annual receipts" are relevant in determining whether either or both of them constitute a "small entity." See id. Finally, Respondents acknowledge that they have not decided whether to claim in this proceeding that either or both of them constitute a small entity under SBREFA or that they are entitled to a reduction of civil money penalties.

Respondents agree that they will respond to Complainant's Document Request Number 4 no later than sixty days prior to (1) filing any motion, proposed finding of fact, evidence, or any other written document in this proceeding in which all or either

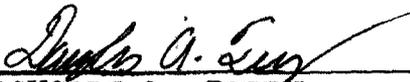
of them claim entitlement to a reduction of civil money penalties based on their status as a small entity or on their annual receipts; or (2) the hearing in this matter if all or either of them claim or offer evidence in support of a claim, during such hearing, that they are entitled to a reduction of civil money penalties based on their status as a small entity or on their annual receipts. If Respondents fail to respond to Complainant's Document Request Number 4 sixty days prior to filing such motion, proposed finding of fact, evidence, other written document, or the hearing, as described above, Respondents agree that the Presiding Officer should exclude any evidence of their status as a small entity, annual receipts, or entitlement to a reduction of civil money penalties that is submitted in support of such motion, proposed finding of fact, written document, and/or hearing. See 21 C.F.R. §§ 17.19(b)(11), 17.25(b)(1).

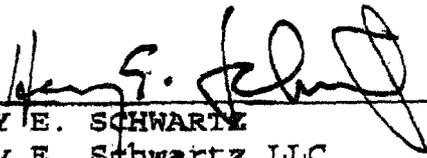
5. Complainant's Document Request Number 7 is modified as follows:

All documents relating to the duties, responsibilities, and supervision of Amile A. Korangy, M.D., Barry J. Henderson, and Irfan S. Shafique, M.D., and all communications between Amile A. Korangy, M.D., Barry J. Henderson, and Irfan S. Shafique to the extent that they relate in any manner whatsoever to the acts and events complained of in the Administrative Complaint for Civil Money Penalty filed by Complainant in this proceeding.

6. Subject to the foregoing, Respondents shall produce for inspection the documents requested in Complainant's Document Request as modified herein within thirty days of service of this Joint Notice And Agreement To Resolve Discovery Dispute.

Respectfully submitted,

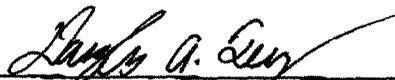

DOUGLAS A. TERRY
Attorney for Complainant
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
(301) 827-7138


HENRY E. SCHWARTZ
Henry E. Schwartz LLC
Attorney for Respondents
901 Dulaney Valley Road, Suite 400
Towson, MD 21204
(410) 938-8703

CERTIFICATE OF SERVICE

I hereby certify that, on this 30th day of January, 2004, I have caused a copy of the foregoing Joint Notice And Agreement To Resolve Discovery Dispute to be served by Federal Express overnight delivery on:

Henry E. Schwartz
Henry E. Schwartz LLC
Attorney for Respondents
901 Dulaney Valley Road, Suite 400
Towson, MD 21204



DOUGLAS A. TERRY
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5600 Fishers Lane (GCF-1)
Rockville, MD 20857