



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

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

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January 13, 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 Complainant's First Request for Production of Documents.

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
Thomas Jakub, CDRH
Heyward Rourk, CDRH
Michael Divine, CDRH

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,) FOR CIVIL MONEY PENALTY
a corporation,))
))
and) FDA Docket: 2003H-0432
))
AMILE A. KORANGY, M.D.,))
an individual.))
_____)

COMPLAINANT'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS

Pursuant to 21 C.F.R. § 17.23, Complainant, the Center for Devices and Radiological Health, United States Food and Drug Administration ("FDA"), requests that Respondents, within 30 days after service of this request, produce for inspection and copying at the offices of the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland, 20857, the documents requested herein.

DEFINITIONS AND INSTRUCTIONS

As used herein,

1. "Respondents" means Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers (collectively "BIC") and Amile A. Korangy, M.D., and any person acting on behalf of them, including, but not limited to, employees and independent contractors.

2. "You" and "your" refers to Respondents.
3. "Person" means any individual, partnership, corporation, association, trust, store, franchise, sole proprietorship, or other legal or business entity.
4. "Documents" is defined in 21 C.F.R. § 17.23.
5. "Communication" means the transmittal of information from one person to another person or persons whether written or oral, including, but not limited to, telephone conversations, meetings, letters, telexes, facsimiles, electronic messages and email, and all other documents relating to such communications.
6. "Receipts" is defined in 13 C.F.R. § 121.104.
7. The terms "relating to" and "regarding" mean that which constitutes, comprises, contains, consists of, sets forth, proposes, shows, discloses, describes, discusses, explains, summarizes, concerns, reflects, authorizes, or refers to, directly or indirectly.
8. Use of the singular shall be deemed to include the plural and use of the masculine shall be deemed to include the feminine, as appropriate, and vice versa. As used herein, the terms "and" and "or" should be interpreted liberally, as conjunctive, disjunctive, or both depending on the context, so that the fullest disclosure of information is achieved.
9. These document requests are intended to be continuing in nature so as to require supplemental or amended responses or

productions by Respondents. Such supplemental or amended answers should be furnished within ten days of the date on which the additional information is obtained.

10. If you withhold from disclosure any requested documents on the basis of any asserted privilege, including the attorney-client privilege and the work product doctrine, state the nature of the privilege or protection claimed and the basis for the claim as to each specific document request. Each document and all information claimed as privileged shall be unambiguously described by setting forth at least:

a. the identity of all persons who initiated, received, or were privy to such information, communications, or documents;

b. whether any such persons were counsel to you and were acting in such capacity, and if so, which ones;

c. the date of such information, communication, or document;

d. its subject matter; and

e. a concise statement of the reasons for the assertion of privilege as to such information, communication, or document.

11. If you object to any part of a document request, set forth the basis for your objection and respond to all parts of the document request to which you do not object.

12. If you believe there to be an ambiguity in construing a document request, definition, or instruction, set forth the

matter you find ambiguous and the construction selected in responding to the document requests.

DOCUMENT REQUESTS

Please produce the following:

1. All documents relating to (i) all official corporate acts, including corporate formation and dissolution, shareholders' meetings, directors' meetings, and corporate resolutions; (ii) the composition of the corporation, its management, owners, and employees, including lists of directors, officers, and shareholders; and (iii) all financial records of:

(A) Respondents;

(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.;

(D) Any other person, in which any of the Respondents, and/or any immediate family member of any of the Respondents, and/or any predecessor or successor, parent or subsidiary, of Respondents, individually or collectively, held ten percent or more of the ownership interests.

2. All documents reflecting any or all of the assets, including any ownership interests in any business entity, of

each of the Respondents and any of Dr. Amile Korangy's immediate family members.

3. All documents relating to all financial transactions between Respondents, including all contracts, or other indicia of employment or ownership relationships, and all records of payments.

4. All documents relating to the annual receipts and number of employees of:

(A) Respondents;

(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.;

(D) Any affiliate, as that term is used in 13 C.F.R. § 121.103, of any Respondent, including, but not limited to, (i) any person in which any Respondent controls or has the power to control; (ii) any person in which any Respondent is an officer, director, or partner, or is otherwise able to control the board of directors or management of such person; (iii) any person that controls or has the power to control any Respondent; and (iv) any other person, in which any of the Respondents, and/or any

immediate family member of any of the Respondents, hold fifty percent or more of the ownership interests.

5. All documents relating to the identity and duties of the person(s) responsible for the operations of BIC on a day-to-day basis.

6. All documents relating to the identity and duties of the person(s) responsible for conducting mammography examinations and procedures, and ensuring mammography quality and compliance with the Mammography Quality Standards Act of 1992, 42 U.S.C § 263b, on a day-to-day basis at BIC.

7. All documents relating to the duties, responsibilities, supervision of, and communications between, Amile A. Korangy, M.D., Barry J. Henderson, and Irfan S. Shafique, M.D.

8. Any and all documents relating to any communications between any of the Respondents and Complainant, and any of the Respondents and the American College of Radiology, including, but not limited to, logs, journal entries, telephone records, and receipts of delivery.

9. All documents relating to any certificates and/or accreditation received by Respondents from the FDA, the American College of Radiology, or any other entity.

10. All documents reflecting the identities and locations of each facility, as defined in 42 U.S.C. § 263b(a)(3), that is

owned or operated by, or that employs, directly or indirectly, any Respondent, or that conducts business or operates under the names Baltimore Imaging Center or Baltimore Imaging Centers.

11. Any documents relating to your alleged defense in paragraph 4 of the "Defenses Asserted" Section of Answer of Respondents, Korangy Radiology Associates, P.A., T/A Baltimore Imaging Centers, and Amile A. Korangy, M.D., filed October 17, 2003 ("Respondents' Answer"), which suggests that Korangy Radiology Associates, P.A., is merely the entity responsible for "providing and billing for the services in question" and is not the "owner or operator" of a mammography facility.

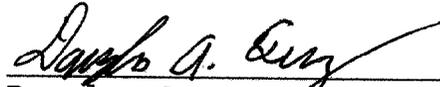
12. Any documents relating to your alleged defense in paragraph 5 of the "Mitigation Asserted" Section of Respondents' Answer, which alleges that "[p]enalties should be reduced in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 and the Presidential Memorandum of April 21, 1995."

13. Any documents relating to your alleged defense in paragraph 9 of the "Mitigation Asserted" Section of Respondents' Answer, which alleges that "BIC effectively loses money on each mammography procedure performed."

14. All documents that you have obtained in your investigation of this matter.

15. All documents that you may introduce into evidence in connection with the hearing or any dispositive motions in this matter.

Respectfully submitted,

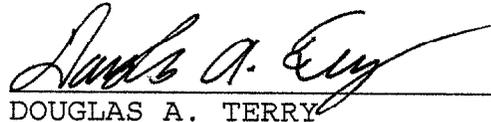


Douglas A. Terra
Attorney for Complainant
CDRH, United States Food and Drug
Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 827-7138

CERTIFICATE OF SERVICE

I certify under penalty of perjury that on this 13th day of January, 2004, I have caused a copy of the foregoing Complainant's First Request for Production of Documents to be served by regular United States mail on the following:

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



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