



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

3191 '04 FEB 26 P2:14

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

February 26, 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 Motion For Protective Order.

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
Pamela Schweikert, DCMO
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,)	<u>FOR CIVIL MONEY PENALTY</u>
a corporation,)	
)	
and)	FDA Docket: 2003H-0432
)	
AMILE A. KORANGY, M.D.,)	
an individual.)	

COMPLAINANT'S MOTION FOR PROTECTIVE ORDER

Complainant, the Center for Devices and Radiological Health, United States Food and Drug Administration (FDA), seeks to preserve its objections to "Respondents' First Request for Production of Documents" (Respondents' Document Request) by filing, pursuant to 21 C.F.R. §§ 17.23(d) and 17.28, this Motion for Protective Order.¹ Complainant seeks an opportunity to resolve its objections with Respondents' counsel. Accordingly,

¹Pursuant to 21 C.F.R. § 17.23(d)(1), a party may move for a protective order within ten days of service of a request for production of documents. An additional five days is added to the time permitted to respond when the request is served by mail. See 21 C.F.R. § 17.30(c). Respondents' Document Request was mailed on February 13, 2004. Complainant therefore has until March 1, 2004, to state its objections to Respondents' Document Request and move for a protective order. See 21 C.F.R. § 17.30(a). Although Complainant is diligently determining which responsive documents exist and are subject to production, it does not anticipate being able to resolve all of its objections by March 1, 2004. Complainant is therefore filing

Complainant does not perceive the need for the Presiding Officer to rule on this Motion unless and until, and only to the extent that, the parties are unable to resolve Complainant's objections.

Complainant expressly reserves the right to object to further discovery into the subject matter of these requests and the right to object to the introduction into evidence of any documents produced in response to these requests.

Objections To Respondents' Document Request

DOCUMENT REQUESTS

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.

OBJECTION: Complainant objects to this request on the grounds that it is overly broad and unduly burdensome and seeks documents that are not relevant to the issues before the Presiding Officer and that are protected by the attorney-client privilege, the work product doctrine, and the deliberative process privilege.

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.

this Motion to preserve its objections for later resolution by the Presiding Officer if necessary.

OBJECTION: Complainant objects to this request on the grounds that it is overly broad, unduly burdensome, vague, and ambiguous, and seeks documents that are not relevant to the issues before the Presiding Officer and that are protected by the attorney-client privilege, the work product doctrine, and the deliberative process privilege.

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.

OBJECTION: Complainant objects to this request on the grounds that it seeks documents protected by the attorney-client privilege, the work product doctrine, and the deliberative process privilege.

Respectfully submitted,

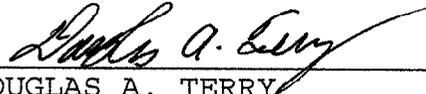


DOUGLAS A. TERESI
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CERTIFICATE OF SERVICE

I hereby certify that, on this 26th day of February, 2004,
I have caused a copy of the foregoing Complainant's Motion for
Protective Order 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



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