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August 26, 2004

VIA OVERNIGHT MAIL

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1051
Rockville, Maryland 20852

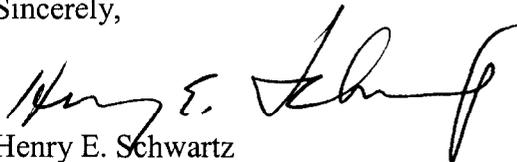
RE: In re Korangy Radiology Associates, P.A., *et al.*
FDA Docket No. 2003H-0432

Dear Sir/Madam:

Enclosed for filing in the above-referenced matter please find an original and one copy of Respondents' Objections to Complainant's Proposed Findings of Fact

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
Hon. Daniel J. Davidson, ALJ

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' OBJECTIONS TO COMPLAINANTS' PROPOSED FINDINGS
OF FACT**

Respondents, by their undersigned attorneys, hereby respectfully submit the following objections, with accompanying explanations, to Complainants' Proposed Findings of Fact:

10. Respondents disagree with the characterization that they were advised by the FDA letter of April 1, 2002, as Dr. Korangy has testified that he never received that letter.

11. Respondents disagree with the characterization that the FDA letter of April 1, 2002 was properly addressed, for the reasons set forth in Respondents' Proposed Findings of Fact. Dr. Korangy will testify to the fact that communications addressed to the prior operating corporation were not opened, but were forwarded by KRA.

12. Respondents disagree with the characterization that the ACR letter of April 29, 2002 informed Respondents that they were to stop performing mammography, either temporarily or permanently.

13. Respondents disagree with the characterization that Respondents deemed the mammograms performed by their prior machine to be "acceptable," for the reasons stated in Respondents' Proposed Findings of Fact.

14. Respondents disagree with the characterization that Respondents received FDA's letter of May 1, 2002, for the reasons set forth in Respondents' Proposed Findings of Fact, and because notices of the critical importance of the FDA's letter of April 1 and May 1, 2002, should have been delivered only through certified mail requiring the

signature of the addressee. Such a method would have provided Dr. Korangy with proper notice, and forestalled any issues regarding the delivery of the documents.

15. Respondents disagree with the characterization that they were aware of the content of FDA's letter of May 1, 2002, for the reasons set forth in Respondents' Proposed Findings of Fact.

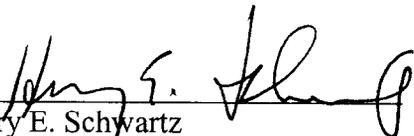
19. Respondents disagree with the characterization that they received notice that were conducting mammograms unlawfully, for the reasons set forth above and in Respondents' Proposed Findings of Fact.

20. Respondents disagree with the characterization that they knew that they were operating mammography equipment without approval, for the reasons set forth in Respondents' Proposed Findings of Fact.

21. Respondents disagree with the characterization that the exhibits submitted by Respondents do not make their financial circumstances clear.

25. Respondents disagree with the characterization that they have failed to demonstrate their inability to pay fines in the millions of dollars.

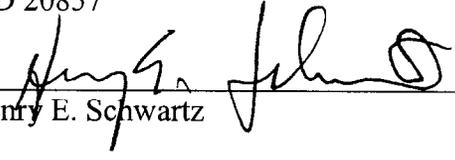
Submitted by:


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Attorneys for Respondents

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 26 day of August, 2004, a copy of the foregoing Respondents' Objections to Complainants' Proposed Findings of Fact was mailed, postage prepaid, to:

Jennifer E. Dayok, Esquire
Associate Chief for Enforcement
Office of the General Counsel
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, GCF-1
Rockville, MD 20857


Henry E. Schwartz