



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

December 14, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20857

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 Opposition to Respondents' Motion to Strike, along with a Proposed Order. If you
have any questions, please call me at (301) 827-5523. Thank you.

Sincerely,


Jennifer E. Dayok
Associate Chief Counsel
for Enforcement

Enclosure

cc w/encl.:

Hon. Daniel J. Davidson, A.L.J.
Henry E. Schwartz, Esq.

2003H-0432

D M O C

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 OPPOSITION TO RESPONDENTS' MOTION TO STRIKE

Complainant, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), hereby opposes Respondents' Motion to Strike filed December 7, 2004. Respondents move to strike two categories of exhibits that CDRH attached to its Post-Hearing Brief on Penalty Amount: (1) Exhibit G-31, which is the FDA Compliance Program Guide (CPG) 7382.014 regarding mammography facility inspections; and (2) Exhibits G-15 to G-25 and G-27 to G-29, which are documents relating to Respondents' assets and ability to pay, some of which were obtained by CDRH from the public record and some of which were provided by Respondents themselves. All of these documents are relevant to rebut the purported mitigating factors set forth by Respondents with respect to the penalty amount. Accordingly, they should not be stricken.

ARGUMENT

Respondents claim that Exhibit G-31, the mammography facility inspection CPG, should be stricken from the record because it was not presented by CDRH prior to the September 20,

2004 oral hearing in this case, “as required,” nor was it presented at the hearing where Respondents could have reviewed it and perhaps cross-examined CDRH’s witness about it. Contrary to Respondents’ argument, CDRH was not “required” to introduce the CPG before or during the hearing. Respondents did not ask for the CPG in discovery, although they certainly could have. Nor did CDRH seek to introduce the document as part of its case-in-chief with respect to either liability or the penalty amount. Therefore, CDRH had no obligation to introduce it into the record or to provide it to Respondents in advance of the hearing under 21 C.F.R. § 17.35 and this Court’s November 13, 2003 scheduling Order.

In fact, it was not until the conclusion of that oral hearing--at which the parties were expected to cross-examine witnesses about the proper penalty amount based on written evidence, testimony, and proposed findings of fact previously exchanged by the parties--that Respondents, for the first time, informed CDRH that they would argue, in their post-hearing brief, that no penalty should be imposed because the Secretary of Health and Human Services supposedly did not develop procedures as required by the Mammography Quality Standards Act of 1992 (MQSA). See Transcript of Oral Hearing, September 20, 2004 (Hearing Transcript), at 44. Under those circumstances, CDRH could not have been expected to anticipate such an argument or the need to respond to it with the CPG. However, because Respondents belatedly introduced the issue of the Secretary's alleged failure to develop procedures, this Court should use its discretion as permitted by 21 C.F.R. § 17.39(g) to allow CDRH to introduce the CPG as evidence to rebut Respondents’ argument.¹

¹ Although Respondents’ counsel questioned CDRH witness Michael P. Divine about FDA procedures during the oral hearing, he did not pose his questions in a manner that would have elicited testimony from Mr. Divine about the CPG at issue. When Respondents’ counsel asked Mr. Divine about FDA procedures with respect to assessing civil money penalties, Mr. Divine

Respondents' motion to strike Exhibits G-15 through G-25 and G-27 through G-29, which have been introduced by CDRH to counter Respondents' claim that they are unable to pay the penalty sought, is nothing short of absurd, given Respondents' adamant refusal to produce financial information to support their claim. Respondents allege that these exhibits should be stricken because they were not presented before or during the oral hearing and, therefore, are "inappropriate and prejudicial" because Respondents could not respond or cross-examine any witnesses about the documents. Respondents' Motion to Strike, at 1.

However, as CDRH has objected, both at the oral hearing and in its Post-Hearing Brief, Respondents should not even have been permitted to argue inability to pay or to present any evidence thereof at the oral hearing due to their breach of the Joint Notice and Agreement to Resolve Discovery Dispute (Joint Notice) filed January 30, 2004. See Hearing Transcript, at 5-6; Complainant's Post-Hearing Brief on Penalty Amount, at 3-4. Because Respondents failed to respond to CDRH's discovery request for financial documents no later than 60 days before the oral hearing, they should have honored the agreement set forth in the Joint Notice that this Court exclude evidence and argument related to their purported inability to pay. Not only have they

set forth a detailed process of evaluation of a proposed civil money penalty action by several components of FDA. See Hearing Transcript, at 11-12. Respondents' counsel characterized that process as "an internal procedural process ... basically describing the people and agencies that develop and review the matter before it goes out" and then asked Mr. Divine if there were "any substantive guidelines that the FDA follows with respect to the issuance of civil money penalties." Id. at 12-13. Mr. Divine then responded that there was no formal guidance specifically with respect to civil money penalty cases, but that there was a draft guidance. Id. at 13. It is evident from his answer that Mr. Divine interpreted counsel's question as referring to a document relating solely to civil money penalty cases and not to the broader CPG addressing mammography facility inspections and the variety of sanctions that can result from a violation. In any event, regardless of any miscommunication at the oral hearing, it is clear that the CPG, along with procedures set forth in 21 C.F.R. Part 17, satisfy the statutory requirement that the Secretary develop and implement procedures with respect to when and how each of those

ignored that agreement and repeatedly argued inability to pay based on a small number of selective financial documents, they now seek to prevent CDRH from rebutting such argument and providing this Court with a more complete picture of their financial situation. Given that it is Respondents' burden to prove a claimed mitigating circumstance such as inability to pay, 21 C.F.R. § 17.33(c), CDRH should at least have an opportunity to present evidence to counter such a claim, especially in light of Respondents' refusal to provide the necessary evidence to meet their burden.

Furthermore, Respondents' claim that the documents at issue are prejudicial because they were not available for cross-examination at the hearing makes little sense, given that Respondents have full knowledge of their own financial position. It is difficult to imagine how the inability to cross-examine other witnesses about this information could have prejudiced them.

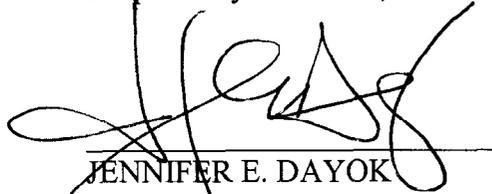
This Court has already indicated its inclination to consider all of the documents available, including those relevant to inability to pay, in its determination of the penalty amount. See Hearing Transcript, at 7. This Court should also exercise its discretion under 21 C.F.R. § 17.39(g) to allow CDRH's rebuttal evidence relating to this issue to remain on the record.

sanctions is to be imposed under the MQSA. See Complainant's Post-Hearing Brief of Penalty Amount, at 13-15.

CONCLUSION

For the foregoing reasons, CDRH respectfully requests that this Court deny Respondents' Motion to Strike in its entirety.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jennifer E. Dayok", written over a horizontal line.

JENNIFER E. DAYOK

Attorney for Complainant CDRH
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CERTIFICATE OF SERVICE

I hereby certify that, on this 14th day of December, 2004, I have caused a copy of the foregoing COMPLAINANT'S OPPOSITION TO RESPONDENTS' MOTION TO STRIKE and PROPOSED ORDER to be served by Federal Express, postage prepaid, on:

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

A handwritten signature in black ink, appearing to read 'J. Dayok', is written over a horizontal line.

JENNIFER DAYOK
Attorney for Complainant
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