



United States Department of Justice

Drug Enforcement Administration
Office of Administrative Law Judges
Washington, D.C. 20537
(202) 307-8188

MAY 15 2007

Honorable Michele M. Leonhart
Deputy Administrator
Drug Enforcement Administration
Washington, D.C. 20537

Re: Lyle E. Craker, Ph.D.
Docket No. 05-16

Dear Deputy Administrator Leonhart:

Pursuant to 21 C.F.R. § 1316.65(c) (2007), I transmit to you herewith my Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision, and I certify and transmit the record in this matter as listed on Enclosure A.

Copies of my opinion were sent to Government counsel by messenger and Respondent's counsel by mail on February 12, 2007.

On March 26, 2007, Government counsel filed exceptions to my opinion, and on May 4, 2007, Respondent's counsel filed a response to those exceptions.

Respectfully,

A handwritten signature in cursive script that reads "Mary Ellen Bittner".

Mary Ellen Bittner
Administrative Law Judge

Enclosure A

cc: Brian Bayly, Esquire
Julie M. Carpenter, Esquire

Enclosure A
In the Matter of
Lyle E. Craker, Ph.D.
Docket No. 05-16

TRANSMITTED RECORD

1. Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge dated February 12, 2007.
2. Docket Sheet.
3. Administrative Law Judge's Exhibits 1-9.
4. Government's Exhibits 1-8, 12-13, 15-22, 24-30, 30A-30B, 31-36, 40, 41 (with stipulation of inclusion only to the extent that November 8, 2005 Order will permit (Item #21 below)), 43-45, 47, 49, 52, 53, 53A, 54-55, 62, 64-71, 74-79, 82-84, 92, 92A, and 93-94.
5. Government's Rejected Exhibits 61, and 63.
6. Respondent's Exhibits 1-9, 11-15, 19 (with stipulation that only relevant parts are page 47 (problems in the Compassionate IND Program)) up to page 51 (Conclusions and Recommendations) and Recommendation Eight, 26 (received by memorandum – Item #25 below), 28-33, 39-43, 49-51, 52A-52B, 53, 54 (stipulation that Judge will only consider two sentences and only to rebut), 55 (parties to stipulate what abbreviations mean), and 57.
7. Respondent's Rejected Exhibits 10, 16-18, 20, 21 (copy included in file for Deputy Administrator, Received, in part, on December 16, 2005), 22-25, 27, and 56.
8. Transcripts of hearing held on August 22 -26, 2005, December 12-14, 2005, and December 16, 2005.
9. Letter to Judge and Law Clerk from Respondent's Counsel filed September 15, 2005.
10. Respondent's Motion to Exclude Some of Government's Proposed Testimony and Exhibits filed September 16, 2005.
11. Letter to Judge from Government Counsel filed September 16, 2005.
12. Memorandum to Counsel dated September 20, 2005.
13. Letter with enclosure to Respondent's Counsel from Judge dated September 27, 2005.
14. Letter to Counsel from Law Clerk dated September 29, 2005.

15. Memorandum to Counsel dated October 7, 2005.
16. Government's Response to Respondent's Motion to Exclude Some of Government's Proposed Testimony and Exhibits filed October 20, 2005.
17. Government's Fifth Supplemental Prehearing Statement filed October 20, 2005.
18. Respondent's Fourth Supplemental Prehearing Statement and Motion for Leave to File It filed November 3, 2005.
19. Memorandum to Counsel dated November 3, 2005.
20. Memorandum to Counsel dated November 7, 2005.
21. Memorandum to Counsel and Ruling on Motion to Exclude Evidence dated November 8, 2005.
22. Government's Response to "Respondent's Fourth Supplemental Prehearing Statement and Motion for Leave to File it" and Government's Motion to Sustain the Government's Objection to Scope and Relevancy of the Cross-Examination of Matthew Strait filed November 14, 2005.
23. Memorandum to Counsel and Ruling dated November 16, 2005.
24. Respondent's Fifth Supplemental Prehearing Statement and Motion for Leave to File It filed November 22, 2005.
25. Memorandum to Counsel and Ruling dated November 29, 2005.
26. Government's Objection and Response to "Respondent's Fifth Supplemental Prehearing Statement and Motion for Leave to File It filed November 29, 2005.
27. Respondent's Motion to Admit Additional Exhibit's in Rebuttal filed January 5, 2006.
28. Government's Reply to Respondent's 'Motion to Admit Additional Exhibits in Rebuttal' filed January 19, 2006.
29. Government's Submission of Affidavit of Kenneth H. Davis, Notification of the Division of Mallickrodt that has Contracted with Dr. ElSohly, Stipulation to Abbreviations in Respondent's Exhibit 55, Stipulation to the Re-dated Letter from Senators Kennedy and Kerry, and Notification that the Government Does Not Plan to Call Any Surrebuttal Witnesses at this Time filed January 23, 2006.
30. Memorandum to Counsel and Ruling dated January 24, 2006.

31. Respondent's Response to DEA Request to Submit Surrebuttal Evidence filed January 31, 2006.
32. Memorandum to Counsel and Ruling dated February 2, 2006.
33. Respondent's Motion to Extend Briefing Schedule filed February 23, 2006.
34. Ruling on Requested Extension dated March 2, 2006.
35. Government's Proposed Corrections to the Transcript filed March 9, 2006.
36. Respondent's Hearing Transcript Corrections filed March 9, 2006.
37. Government's Motion to Request an Extension of Time in Which to File the Parties Briefs filed April 11, 2006.
38. Ruling on Requested Extension dated April 12, 2006.
39. Government's Proposed Findings of Fact, Conclusions of Law and Argument filed May 8, 2006.
40. Respondent's Proposed Findings of Fact, Conclusions of Law and Argument and Non-Record Sources Cited in Respondent's Brief filed May 8, 2006.
41. Letter to Hearing Clerk from Respondent's Counsel filed May 9, 2006.
42. Order for Corrections to the Transcript dated February 12, 2007.
43. Government's Request to Extend the Time to File Exceptions to Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge filed February 16, 2007.
44. Ruling on Requested Extension dated February 22, 2007.
45. Government's Exception to Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge filed March 26, 2007.
46. Respondent's Response to the Government's Exceptions to Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge filed May 4, 2007.