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| 4. | Submission of additional 12.85 material if Motion to Modify issues for hearing is granted | 5/20/02 |
| 5. | Exchange of Witness Lists, CV's, and Prior Statements: | 5/20/02 |
| 6. | Objection to witnesses based on qualifications: | 6/03/02 |

Additional Discovery:

During the period between June and September 2003 the participants are free to conduct additional discovery. The office of the Administrative Law Judge will not be involved unless there are disputes that requiring a formal ruling.

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| 7. | Discovery Completed: | 8/30/02 |
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Stipulations:

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| 8. | Exchange of Proposed Stipulations: | 9/09/02 |
| 9. | Submission of Joint Stipulations: | 9/16/02 |

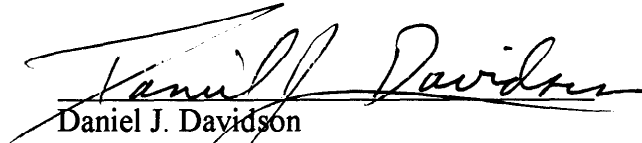
Testimony/Exhibits, Cross Examinations, Dispositive Motions:

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| 10. | Submission of Written Direct Testimony/Exhibits: | 12/09/02 |
| 11. | Motions to Strike Testimony/Exhibits and/or Permission to Conduct Cross-examination: | 1/27/03 |
| 12. | Responses to Motions to Strike Testimony/Exhibits and/or Permission to Conduct Cross-examination: | 2/10/03 |
| 13. | Submission of numbered findings of fact, with record references, based on that which each participant believes the evidence has established. | 3/17/03 |
| 14. | Submission of correspondingly numbered critiques of other participants' numbered findings of fact. | 4/14/03 |
| 15. | Cross Examination of Witnesses: | 4/28/03-5/09/03 |

A schedule for rebuttal, if necessary, and/or the Post-Hearing briefs will be established at the conclusion of the oral phase of the hearing.

Dated this 10th day of April, 2002.

SO ORDERED:

A handwritten signature in black ink, appearing to read "Daniel J. Davidson", is written over a horizontal line.

Daniel J. Davidson
Administrative Law Judge
Food and Drug Administration
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