

**Food and Drug Administration  
Center for Drug Evaluation and Research**

**Dermatologic and Ophthalmic Drugs Advisory Committee**

Holiday Inn  
8120 Wisconsin Avenue  
Bethesda, Maryland

**Agenda**

**November 4-5, 2002**

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|-------|---|---|
| 8:30  | Call to Order and Opening Remarks   | Robert S. Stern, M.D.<br>Chair, DODAC                                 |
|       | Introduction of Committee   |   |
|       | Conflict of Interest Statement  | Karen M. Templeton-Somers, Ph.D.<br>Acting Executive Secretary, DODAC |
| 8:45  | Open Public Hearing (Industry)  |   |
|       | Joanne M. Fraser, Ph.D., A.C. Stiefel Research Institute, Inc.  |   |
| 9:15  | Introduction  |   |
|       | Jonathan Wilkin, M.D., Director, Division of Dermatologic and Dental Drug Products, FDA                   |   |
| 9:20  | Overview of Current Approach to Acne Therapy  |   |
|       | Wilma Bergfeld, M.D., Cleveland Clinic  |   |
| 9:35  | Evidence of Effectiveness of Acne Products  |   |
|       | Jonathan Wilkin, M.D., Director, Division of Dermatologic and Dental Drug Products, FDA                   |   |
| 10:00 | FDA Perspective on Global Evaluation  |   |
|       | Brenda Carr, M.D., Medical Officer, DDDDP, FDA  |   |
| 10:15 | Questions to the Speakers (Wilkin, Bergfeld and Carr)   |   |
| 10:45 | Break   |   |
| 11:00 | The American Academy of Dermatology Consensus Conference Report on Acne Classification                    |   |
|       | Peter Pochi, M.D., Boston University  |   |
| 11:20 | Physicians' Global Severity Scale: What Constitutes Success and the Utility of an Inflammatory Only Scale |   |
|       | James Leyden, M.D., University of Pennsylvania  |   |
| 11:35 | Considerations on Success Criteria in Acne Trials   |   |
|       | Alan Shalita, M.D., State University of New York, Brooklyn  |   |
| 11:50 | Problems with Lesion Counts and Why They are Still Useful   |   |
|       | Albert Kligman, M.D., University of Pennsylvania  |   |
| 12:10 | Questions to the Speakers (Pochi, Leyden, Shalita and Kligman)  |   |
| 12:30 | Lunch   |   |

- 1:30 Statistical Analyses of Acne Clinical Trial Data  
Mohamed Alosh, Ph.D., Biostatistics Team Leader, Division of Biometrics III, FDA
- 2:30 Questions (Alosh)
- 2:45 Combination Topical Products for the Treatment of Acne Vulgaris  
Markham C. Luke, M.D., Ph.D., Dermatology Clinical Team Leader, Dermatology, DDDDP, FDA
- 3:00 Labeling for Efficacy: The Clinical Study Section  
Joseph Porres, M.D., Ph.D., Medical Officer, DDDDP, FDA
- 3:15 Break
- 3:30 Questions to the Speakers (Luke and Porres)
- 4:00 Acne Therapy: A Methodologic Review  
Harold Lehmann, M.D., Ph.D., Johns Hopkins Medical Center
- 4:20 Questions (Lehmann)
- 4:30 Committee Discussion
- 5:30 Tentative Adjournment for the Day

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**November 5, 2002**

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- 8:00 Call to Order and Opening Remarks  
Robert S. Stern, M.D.  
Chair, DODAC
- Introduction of Committee
- Conflict of Interest Statement  
Karen M. Templeton-Somers, Ph.D.  
Acting Executive Secretary, DODAC
- 8:15 Open Public Hearing (Industry)  
Donald A. Berry, Ph.D., Berry Consultants, LLC
- 8:45 Questions to Committee
- Discussion
- 9:30 Break
- 10:00 Questions and Discussion
- 11:00 Adjourn