

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

March 12, 2003
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Day 1: Wednesday, March 12, 2003

- 8:30 Call to Order Art Kibbe, Ph.D., Chair
Conflict of Interest Kathleen Reedy, Exec. Sec.
- 8:35 Introduction to Meeting Helen Winkle, Acting Director OPS
- 8:55 **Subcommittee Updates**
PAT Tom Layloff, Ph.D.
Manufacturing Ajaz Hussain, Ph.D.
Clinical Pharmacology Joseph Famulare
Jurgen Venitz, M.D.
- 9:40 **Future Subcommittees**
Biopharmaceutics Ajaz Hussain, Ph.D.
Microbiology Peter Cooney, Ph.D.
Pharmacology/Toxicology Robert Osterberg, Ph.D.
- 10:25 Break
- 10:40 **Topical Dermatological
Drug Product Nomenclature** Yuan-yuan Chiu, Ph.D.
Guest Presenters:
Keith Marshall
Herb Carlin, D.Sc.
- 12:30 Lunch
- 1:30 **Open Public Hearing**
- 2:00 **Topical Dermatological Bioequivalence -
Methods Development** Ajaz Hussain, Ph.D.
Presenters:
Ajaz Hussain, Ph.D.
Jonathan Wilkin M.D.
Dena Hixon, M.D.
Dale Conner, PharmD
- 3:15 Break
- 3:30 **Comparability Protocols** Yuan-yuan Chiu, Ph.D.
03/04/03

Presenters:
Stephen Moore, Ph.D.
Nancy Sager

5:00 Adjourn

03/04/03

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