

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

October 21 - 22, 2002  
CDER Advisory Committee Conference Room  
5630 Fishers Lane  
Rockville, MD

**AGENDA**

Day 1: Monday, October 21, 2002

8:30 Call to Order Vincent H. L. Lee, Ph.D., Acting Chair

Conflict of Interest Kathleen Reedy, Exec. Sec.

8:45 Introduction to Meeting Helen Winkle, Acting Director OPS

9:00 **Subcommittee Reports**

9:00 Non-Clinical Studies Frank Sistare, Ph.D.  
Robert Osterberg, Ph.D.

9:45 Process Analytical Technologies Thomas Layloff, Ph.D.

10:30 Break

10:45 **Other Updates**

10:45 Risk Based CMC Review Yuan-yuan Chiu, Ph.D.  
Vilayat Sayeed, Ph.D.

11:15 Blend Uniformity Ajaz Hussain, Ph.D.  
Invited Guests:  
Tobias Massa, Ph.D., Eli Lilly  
Thomas Garcia, Ph.D., Pfizer

11:45 **Open Public Hearing**

12:45 **Lunch**

1:45 **Regulatory issues related to crystal habits - polymorphism**

1:45 Introduction Gary Buehler, R.Ph.

2:00 Scientific considerations of pharmaceutical  
solid polymorphism Lawrence Yu, Ph.D.

2:45 Expert comments  
Kenneth R Morris, Ph.D. Purdue  
Harry G. Brittain, Ph.D. Center for Pharmaceutical Physics  
Leslie Benet, Ph.D. UCSF

10/15/02

3:15 **Break**

3:30 **Polymorphism cont.**

Committee Discussion

4:45 **Conclusions and Summary Remarks**

Ajaz Hussain, Ph.D.

5:00 **Adjourn**

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