

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA

Day 1: Thursday, July 19, 2001

8:30 Call to Order Stephen R. Byrn, Ph.D., Chair
Conflict of Interest Nancy Chamberlin, Pharm.D., Exec.Sec.
8:45 Introduction to Meeting Helen Winkle

REPORTS FROM SUBCOMMITTEES

9:00 **Orally Inhaled and Nasal Drug Products Subcommittee**

9:00 Introduction to the Issues Vincent H. L. Lee, Ph.D.

9:05 Difficulties with showing a dose-response with locally acting nasal sprays and aerosols for allergic rhinitis Badrul Chowdhury, M.D., Ph.D.

9:25 Clinical study options for locally acting nasal suspension products Robert J. Meyer, M.D.
• Clinical studies
• Pharmacodynamic studies

9:45 Recommendations of the OINDP Subcommittee Committee Wallace P. Adams, Ph.D.

10:00 Discussion

Topic # 1 Does the Committee agree with the OINDP Subcommittee regarding its recommendations concerning conduct of the local delivery study based on the lowest active dose and a traditional two-week placebo-controlled rhinitis study?

Topic # 2 Does the Committee agree with the OINDP Subcommittee regarding its recommendations concerning conduct of the local study based on the lowest active dose and placebo-controlled Park study or the EEU rhinitis study designs?

10:30 Break

10:45 **NonClinical Studies Subcommittee**

Introduction to the Issues John Doull, M.D., Ph.D.

Working Group Progress William D. Kerns, DVM, MS, DACVP
Gordon Holt, Ph.D.

Future of Subcommittee Helen Winkle

Committee Discussion

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE

AGENDA Cont.

11:15 Chemistry, Manufacturing, and Controls

11:15 Introduction and Overview of Proposal Yuan-yuan Chiu, Ph.D.

11:20 Results from AAPS Workshop

Drug Substance Eric P. Duffy, Ph.D.

Drug Product Vilayat Sayeed, Ph.D.

Microbiology David Hussong, Ph.D.

GMP Pat Alcock Lefler

11:40 Proposed Next Steps Yuan-yuan Chiu, Ph.D.

11:45 Committee Discussion

Question #1 Is the approach of establishing “attributes and acceptance criteria” for drug substance, drug product and microbiology based also on the characteristics of potential candidates of “low risk” drugs appropriate?

Question #2 Is it appropriate to evaluate not only a firm’s general CGMP status but also its manufacturing history of a specific product on the “low risk” drug list? (If the answer is yes, there will be no TANDA)

12:15 Lunch

1:15 Open Public Hearing

2:15 Optimal Applications of At-line Process Controls on Pharmaceutical Production

Introduction and Overview Ajaz Hussain, Ph.D.

Case Study G. K. Raju, Ph.D.

Committee Discussion

3:30 Break

3:45 Microbiology

3:45 Introduction to the Issues David Hussong, Ph.D.

3:50 Overview of Technology Bryan S. Riley, Ph.D.

4:00 Validation Issues Kenneth H. Muhvich, Ph.D.

4:10 Industry perspective

Jeanne Moldenhauer, Ph.D.

4:20 Committee Discussion

Issue: Scientific basis for establishment of acceptance limits for microbiological tests that use newly developed technologies that do not rely on colony counts, and their application as process controls and product release criteria.

4:45 Adjourn