

**Food and Drug Administration  
Center for Drug Evaluation and Research  
Summary Minutes of the Orally Inhaled and Nasal Drug Products Subcommittee  
of the Advisory Committee for Pharmaceutical Science**

July 17, 2001  
CDER Advisory Committee Conference Room  
5630 Fishers Lane  
Rockville, Maryland

**PARTICIPANTS**

**Members Present**

Vincent H. L. Lee, Ph.D., Acting Chair

**Consumer Representative**

Gloria L. Anderson, Ph.D.

**Invited SGE Consultant**

Richard C. Ahrens, M.D.  
Mark S. Dykewicz, M.D.  
Leslie S. Hendeles, PharmD., F.C.C.P.  
Dennis R. Ownby, M.D.

**Invited Guests Participants**

Walter W. Hauck, Ph.D.

**Executive Secretary**

Nancy Chamberlin, PharmD.

**FDA**

Wallace P. Adams, Ph.D.  
Badrul Chowdhury, M.D., Ph.D.  
Dale P. Conner, PharmD.  
Robert J. Meyer, M.D.  
Guirag Poochikin, Ph.D.  
Gur Jai Pal Singh, Ph.D.  
Helen N. Winkle

**Invited Industry Guests**

Izabela J. Roman, M.D., Ph.D.  
Leon Shargel, Ph.D., R.Ph.

These summary minutes for the July 17, 2001 meeting of the Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Sciences were approved on 9/25/01.

I certify that I attended the July 17, 2001 of the Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Sciences and that these minutes accurately reflect what transpired.

  
Nancy Chamberlin, Pharm.D.  
Executive Secretary

  
Vincent H. L. Lee, Ph.D.  
Acting Chair

On July 17, 2001, the Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Science met in an open public session at the CDER Advisory Committee Conference Room, 5630 Fishers Lane, Rockville, Maryland. Prior to the meeting, the members, consultants and invited guests had reviewed background material from the FDA. There were approximately 120 people in attendance.

At 8: 34 a.m., the meeting was called to order by, Vincent H. L. Lee, Ph.D., Acting Chair. This was followed by the conflict of interest statement, read by Nancy Chamberlin, PharmD., Executive Secretary, and the introduction of meeting participants.

Helen Winkle introduced the topics and presented FDA's objectives for the meeting.

Dale P. Conner, PharmD., provided an overview in his presentation of *Bioequivalence Considerations for Locally Acting Nasal Drug Products*. Then Wallace P. Adams, Ph.D., presented on *The June 1999 BA/BE Guidance for Nasal Aerosols and Nasal Sprays: History, Recommendations and Local Delivery Issues*. This was followed by Badrul Chowdhury, M.D., Ph.D.'s presentation of *Difficulties in Showing a Dose-Response with Locally-Acting Nasal Sprays and Aerosols for Allergic Rhinitis*. Then Robert J. Meyer, M.D., presented on *Clinical Study Options for Locally Acting Nasal Suspension Products*.

Following the presentations was the subcommittee discussion regarding clinical BE studies for comparison of local delivery of suspension nasal products for allergic rhinitis.

**Open Public Hearing Session:**

The AAPS Inhalation Technology Focus Group (ITFG)/ International Pharmaceutical Aerosol Consortium (IPAC) Collaboration Technical Teams representatives presented information on *Bioequivalence Studies and Other Recommendations for Orally Inhaled and Nasal Drug Products*. Cynthia L. Flynn, Ph.D., RWJ-PRI, presented *Review of CMC OINDP Issues Addressed by ITFG/IPAC-RS Collaboration*. Then Joel Sequeira, Ph.D., Schering Plough Research Institute, presented the *Review of BA/BE Team's Work; Team's Comments on Issue of Dose Response*.

Finally Piyush Patel, M.D., F.R.C.P. (C), Allied Clinical Research, Inc. presented on the *Environmental Exposure Chamber, and the Design of a Pilot Study to Determine Dose Response and Response Variability with Topical Nasal Steroids*.

The meeting adjourned on July 17, 2001 at 3:20 p.m.

For more detailed information see the verbatim transcript of this meeting on the FDA's Docket Management Branch Website address:  
[HTTP://www.fda.gov/ohrms/dockets/ac/acmenu.htm](http://www.fda.gov/ohrms/dockets/ac/acmenu.htm)

Prepared by:

Nancy Chamberlin, PharmD., Executive Secretary  
Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Science