

**Food and Drug Administration
Center for Drug Evaluation and Research
Summary Minutes of the Advisory Committee for Pharmaceutical Science**

July 19, 2001
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, Maryland

PARTICIPANTS

Members Present

Stephen R. Byrn, Ph.D., Chair
Judy Boehlert, Ph.D.
Joseph Bloom, Ph.D.
John Doull, M.D., Ph.D.
Nair Rodriguez-Hornedo, Ph.D.
William J. Jusko, Ph.D.
Vincent H. L. Lee, Ph.D.
Jürgen Venitz, M.D., Ph.D.

Consumer Representative

Gloria L. Anderson, Ph.D.

Invited SGE Consultant

William H. Barr, Pharm.D., Ph.D.

Invited Guests Participants

(Robert) Gary Hollenbeck, Ph.D.
Williams Kerns, D.V.M., M.S., D.A.C.V.P.
Leon Lachman, Ph.D.
Marvin C. Meyer, Ph.D.
Jeanne Moldenhauer, Ph.D.
Kenneth H. Muhvich, M.S., Ph.D.
G.K. Raju, Ph.D.

Executive Secretary

Nancy Chamberlin, Pharm.D.

FDA

Wallace P. Adams, Ph.D.
Yuan-yuan Chiu, Ph.D.
Badrul Chowdhury, M.D., Ph.D.
Eric P. Duffy, Ph.D.
Ajaz S. Hussain, Ph.D.
Capt. David Hussong, Ph.D.
Robert J. Meyer, M.D.
Bryan S. Riley, Ph.D.
Vilayat A. Sayeed, Ph.D.
Helen N. Winkle

Invited Industry Guests

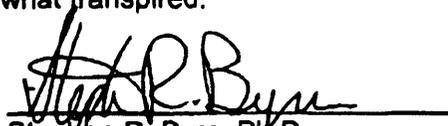
Leon Shargel, Ph.D., R.Ph.
Gordon Holt, Ph.D.

These summary minutes for the July 19, 2001 meeting of the Advisory Committee for Pharmaceutical Sciences were approved on Oct 2, 2001.

I certify that I attended the July 19, 2001 of the Advisory Committee for Pharmaceutical Sciences and that these minutes accurately reflect what transpired.



Nancy Chamberlin, Pharm.D.
Executive Secretary



Stephen R. Byrn, Ph.D.
Chair

**Food and Drug Administration
Center for Drug Evaluation and Research
Summary Minutes of the Advisory Committee for Pharmaceutical Science**

July 20, 2001
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, Maryland

PARTICIPANTS

Members Present

Stephen R. Byrn, Ph.D., Chair
Judy Boehlert, Ph.D.
Joseph Bloom, Ph.D.
John Doull, M.D., Ph.D.
Nair Rodriguez-Hornedo, Ph.D.
William J. Jusko, Ph.D.
Vincent H. L. Lee, Ph.D.
Jürgen Venitz, M.D., Ph.D.

Consumer Representative

Gloria L. Anderson, Ph.D.

Invited SGE Consultant

William H. Barr, Pharm.D., Ph.D.

Invited Academic Guests

Patrick J. McNamara, Ph.D.
Shinya Ito, M.D.
M. Peggy Neville, M.D.
Marvin C. Meyer, Ph.D.

Invited Industry Guests

Francis J. Martin, Ph.D.
Leon Shargel, Ph.D., R.Ph.

Executive Secretary

Nancy Chamberlin, Pharm.D.

FDA

Mei-Ling Chen, Ph.D.
Yuan-yuan Chiu, Ph.D.
Kofi A. Kumj, Ph.D.
Lawrence J. Lesko, Ph.D.
Arzu Selen, Ph.D.
Arthur B. Shaw, Ph.D.

NIH Participants

Klaus Gawrisch, Ph.D.
Burton J. Litman., Ph.D.

These summary minutes for the July 20, 2001 meeting of the Advisory Committee for Pharmaceutical Sciences were approved on October 2, 2001.

I certify that I attended the July 20, 2001 of the Advisory Committee for Pharmaceutical Sciences and that these minutes accurately reflect what transpired.

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Nancy Chamberlin, Pharm.D.
Executive Secretary

_____|S|_____
Stephen R. Byrn, Ph.D.
Chair

On July 20, 2001, 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 100 people in attendance.

At 8: 34 a.m., the meeting was called to order by the Chair, Stephen R. Byrn, Ph.D. This was followed by the introduction of meeting participants and the reading of the conflict of interest statement by Nancy Chamberlin, PharmD., Executive Secretary.

Clinical Pharmacology

Larry Lesko, Ph.D., introduced the topics and FDA's objectives during his presentation, *Drug Transfer into Breast Milk*. Arzu Selen, Ph.D., gave an *Overview of the Draft Lactation Studies Guidance*. Shinya Ito, M.D, presented on *Assessing Drug Transfer into Breast Milk*. Then Dr. Patrick J. McNamara, Ph.D., presented on *Drug Transfer into Milk: Clinical Methods & Issues*. The presentations were followed by the committee discussion of methods to determine drug transfer into breast milk and interpretation of data.

Complex Drug Substances-Liposome Drug Products

Mei-Ling Chen, Ph.D., noted during her *Liposome Drug Products: Introduction* that issues not addressed in the draft Liposome Drug Products Guidance such as "Equivalence Comparison" for chemistry, manufacturing and controls and Bioavailability/ Bioequivalence would be discussed in this meeting.

Francis J. Martin, Ph.D., provided an overview of a proposed Liposome Classification in his presentation of *Liposome Drug Products: Product Evolution and Influence of Formulation on Pharmaceutical Properties and Pharmacology*.

Then Arthur Shaw, Ph.D., presented *Liposome Drug Products: Chemistry Manufacturing and Control Issues*. Kofi A. Kumi, Ph.D., described *Bioavailability and Bioequivalence Issues for Liposome Drug Products*. These presentations were followed by the committee discussion of issues related to "Equivalence Comparison" for chemistry, manufacturing and controls and Bioavailability/ Bioequivalence.

Open Public Hearing Session:

Christine E. Swenson, Ph.D., Elan, presented on *Liposomal Drug Products: The Importance of Supramolecular Structure*. Then Gerard M. Jensen, Ph.D., Gilead Sciences, Inc., presented on *Liposomal Therapeutics: Process vs. Formulation*

The meeting adjourned on July 20, 2001 at 12:46 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
The Advisory Committee for Pharmaceutical Science