

## Association News and Announcements

### STABILITY GUIDELINES FOR TESTING PHARMACEUTICAL PRODUCTS: ISSUES AND ALTERNATIVES

This joint conference, cosponsored by the American Association of Pharmaceutical Scientists and the Food and Drug Administration, will be held December 11-12, 1989 at the Hyatt Regency Crystal City, Arlington, Virginia.

#### Conference Goal

The goal of the Conference is to provide the opportunity for FDA and Industrial scientists to present their experiences with the use of the current guidelines for stability testing of pharmaceutical products. As with any program, there can be opportunities to improve both the science and efficiency of this aspect of our profession if issues and alternatives can be openly raised and discussed.

The Conference will consist of four Sessions which will cover various aspects of stability testing including:

1. Stability Protocol Design: New Product Development
2. Stability Protocol Design: Product/Manufacturing Modifications
3. Stability Conditions & Testing Intervals and Their Utilization for Expiration Dating
4. Statistical Approaches to Stability Testing

#### Preliminary Program Sunday, December 10

6:00-9:00 p.m. Registration

#### Monday, December 11

7:00 a.m. Registration  
*Coffee and danish available*  
8:30 a.m. *Welcoming*  
Eugene J. McGonigle, Ph.D.  
Schering-Plough Corporation  
Session I: **Stability Protocol Design:  
New Product Development**  
8:40 a.m. *Opening Remarks*  
Moderator: Barbara B. Hubert  
U.S. Pharmacopeial Convention, Inc.

#### Panel Speakers

8:45 a.m. Glenn A. Brewer, Ph.D.  
Squibb Medical Research Institute  
9:10 a.m. Guiragos Poochikian, Ph.D.  
Food and Drug Administration  
9:35 a.m. George Forcier, Ph.D.  
Pfizer Central Research

10:00 a.m. Carl J. Berninger, Ph.D.  
Food and Drug Administration  
Break  
10:25 a.m.  
10:45 a.m.-11:55 a.m. Open discussion Session I  
12:00 noon-1:15 p.m. Lunch  
Session II: **Stability Protocol Design:  
Product/Manufacturing Modifications**  
*Opening Remarks*  
Moderator: Judy P. Boehlert, Ph.D.  
Hoffmann-La Roche Inc.

#### Panel Speakers

1:30 p.m. Dennis L. Casey, Ph.D.  
Glaxo Inc.  
1:55 p.m. Francis A. Zinsitz  
Food and Drug Administration  
2:20 p.m. Charles H. Bibart, Ph.D.  
The Upjohn Company  
2:45 p.m. Henry L. Avallone  
Food and Drug Administration  
Break  
3:10 p.m.-3:30 p.m.  
3:30 p.m.-4:45 p.m. Open Discussion Session II

#### Tuesday, December 12

Session III: **Stability Conditions & Testing Intervals and  
Their Utilization for Expiration Dating**  
*Opening Remarks*  
Moderator: Robert C. Shultz  
Food and Drug Administration

#### Panel Speakers

8:35 a.m. Kenneth J. Furnkrantz  
Food and Drug Administration  
9:00 a.m. Gordon L. Hostetler, Ph.D.  
Miles Consumer Health Care  
9:25 a.m. Peter D. Smith  
Food and Drug Administration  
9:50 a.m. A. Waseem Malick, Ph.D.  
Hoffmann-La Roche Inc.  
10:15 a.m.-10:40 a.m. Break  
10:40 a.m.-11:55 a.m. Open Discussion Session III  
12:00 noon-1:10 p.m. Lunch  
Session IV: **Statistical Approaches to Stability Testing**  
*Opening Remarks*

- Moderator: Geoffrey F. Thompson, Ph.D.  
Syntax Research
- 1:20 p.m. *Current Statistical Approaches in the Center for Drug Evaluation and Research, FDA*  
Donald Schuirrmann  
Food and Drug Administration
- 1:50 p.m. Discussion
- 2:00 p.m. *Matrix Stability Testing*  
James L. Wright, Ph.D.  
Boehringer Ingelheim Pharmaceuticals Inc.
- 2:30 p.m. Discussion
- 2:40 p.m. Break
- 3:00 p.m. *Novel Statistical Approaches to Stability Protocol Design*  
Jens T. Carstensen, Ph.D.  
University of Wisconsin
- 3:30 p.m. Discussion
- 3:40 p.m.–  
3:45 p.m. *Closing Remarks*  
Eugene J. McGonigle, Ph.D.  
Schering-Plough Corporation

#### Registration Fees

The following registration fees have been established for this meeting: Meeting Registration Fees *prior to November 27*: \$375.00. Meeting Registration Fees *after November 27 and on-site*: \$425.00. Registration materials available through AAPS office: 703-548-3000.

#### CALENDAR OF EVENTS

*February 26–28, 1990.* Temporal Control of Drug Delivery, sponsored by the New York Academy of Sciences and to be held at the Sheraton Center, New York City. This conference will define the biological imperative for the construction of time-based, non-zero-order drug delivery systems. Interfacial discussions of pharmaceutical, engineering, and biological approaches to optimal temporal/spatial delivery of both simple and complex molecules will be a key aspect of the conference. Conference chairpersons: William

Hrushesky, M.D., Division of Medical Oncology, Albany Medical College, Albany, NY; Felix Theeuwes, D.Sc., ALZA Corporation, Palo Alto, CA; and Robert Langer, Sc.D., Department of Chemical Engineering, Massachusetts Institute of Technology, Cambridge, MA. For further information, contact: Conference Department, The New York Academy of Sciences, 2 East 63rd Street, New York, NY 10021. Telephone (212) 838-0230.

*April 2–4, 1990.* Symposium on Self-Medication, to be held in Stockholm. Sessions include: defining the concept of self-medication; underlying factors of significance in self-medication; methods of self-medication research; factors influencing consumer self-medication strategies and behavior; future trends and implications for pharmaceutical education and pharmacy services; plus a panel discussion on demands and expectations on self-medication research. For further information, contact: Swedish Academy of Pharmaceutical Sciences, P.O. Box 1136, S-111 81 Stockholm, Sweden. Fax: 46 8 20 55 11.

*April 4–6, 1990.* The 9th Pharmaceutical Technology Conference, to be held at the Koningshof Congress Centre, Veldhoven, the Netherlands. This conference is expected to attract participants from over 30 countries and will review contemporary scientific developments in pharmaceutical technology, including contemporary trends in dosage form design and solid dosage technology. Powder technology, bioavailability, drug release, pharmacokinetics, good manufacturing practice, aspects of pharmaceutical microbiology, and drug stability will also be included. Manuscripts for oral or poster presentation should be in the broad area of pharmaceutical technology and may deal with original research work or be of a general industrial pharmaceutical nature. Summaries of papers or posters should first be submitted by November 1, 1989. Upon acceptance, final drafts of papers or posters should be received by January 31, 1990. For more information, contact: Prof. M. H. Rubinstein, 9th Pharmaceutical Technology Conference, 24 Menlove Gardens North, Liverpool L18 2EJ, United Kingdom. Telephone 061 737 1993; telefax 061 737 1070; telex: 934999 TXLINK G (quote "MBX 517229862" in first line).