Association News and Announcements

AAPS, FDA, USP JOINTLY SPONSORED WORKSHOP

In Vitro and _In Vivo_ Testing and Correlation for Oral Controlled/Modified Release Dosage Forms (December 14–16, 1988, Loews L'Enfant Plaza Hotel, Washington, D.C.)

For a controlled/modified release orally administered drug, this workshop will address:

1. Optimum information to characterize the drug entity.
1. Optimum information to characterize the dosage form.
3. Appropriate *in vivo–in vitro* correlation procedures.

This workshop will follow the format for previously FDA cosponsored workshops on Controlled Release Products and Clinical Evaluation of Drugs in the Elderly. That is, panels composed of academic, FDA, and industry scientists will meet prior to the workshop to suggest preliminary guidelines. These will be presented by workshop chairmen, and members of the panel will make brief, 15-minute, presentations related to specific scientific topics followed by comments, questions, and discussions of the workshop participants. Considering this input, each panel will revise their recommendations for presentation and further discussion on the last morning of the workshop. Following this, it is hoped that a consensus of views can be reached concerning the appropriate guidelines to be followed for *in vitro* and *in vivo* testing and correlation for oral controlled/modified release dosage forms. The program is listed below.

Wednesday, December 14, 1988

A. Background/General. *8:00 a.m.:* Introduction (J. P. Skelly). Objectives of the Workshop, and summary report of Workshop on Controlled Release Products, Sept.–Oct. 1985. *8:45 a.m.:* Relevant and emerging issues in GI processing of modified release dosage forms (W. H. Barr).

B. Optimum Information to Characterize the Drug Entity. *9:15 a.m.:* Preliminary Panel Recommendations (L. Z. Benet). *9:30–10:00 a.m.:* Coffee break. *10:00 a.m.:* Physical and chemical consideration of drug candidates. *10:15 a.m.:* Biological characterization: Animal models. *10:30 a.m.:* Biological characterization: Human studies. *10:45 a.m.:* Clinical response—Blood level considerations: Cardiovascular. *11:00 a.m.:* Clinical response—Blood level considerations: Antiinflammatory. *11:15–12:30 p.m.* General discussion. *12:30–1:30 p.m.:* Lunch. C. Optimum Information to Characterize the Dosage Form—Part I. *1:30 p.m.:* Preliminary Panel Recommendations (J. R. Robinson). *1:45 p.m.:* G.I. variables that effect dosage form performance. *2:00 p.m.:* The utility of animal models in development of oral dosage forms, Pro and Con. *2:15 p.m.:* Measuring oral dosage form performance in humans. *2:30 p.m.:* Food effects: Physiological considerations. *2:45–3:15 p.m.:* Coffee break. *3:15 p.m.:* Design of studies to evaluate the effect of food on oral dosage form performance. *3:30 p.m.:* Clinical variables that effect dosage form performance and study design. *3:45–5:00 p.m.:* General discussion.

Thursday, December 15, 1988

D. Optimum Information to Characterize the Dosage Form—Part II.*8:30 a.m.:* Preliminary Panel Recommendations (G. L. Amidon). *8:45 a.m.: In vivo* evaluation of drug input. *9:00 a.m.:* Quantitative assessment of plasma level variability. *9:15 a.m.:* Evaluation of the performance of special dosage forms. *9:30 a.m.:* Evaluation of oral dosage form performance: Statistical considerations. *9:45–10:15 a.m.:* Coffee break. *10:15 a.m.:* Bioequivalence considerations: Fluid content and timing of meals. *10:30 a.m.* Bioequivalence considerations: Controlled release dosage form proportionally and bioavailability. *10:45 a.m.:* Bioequivalence considerations: Generic equivalence of approved controlled release products. *11:00–12:30 p.m.* General discussion. *12:30–1:30 p.m.* Lunch.E. Appropriate *In Vivo–In Vitro* Correlation Procedures. *1:30 p.m.:* Preliminary Panel Recommendations (W. H. Barr). *1:50 p.m.:* USP criteria for controlled/modified release preparations; Acceptance Limits. *2:00 p.m.:* Flow through as an alternative dissolution method—comparison with USP methods. *2:15 p.m.: In vitro* system characterizations: Fluid motion. *2:30 p.m.:* Dissolution media considerations. *2:45–3:15 p.m.:* Coffee break. *3:15 p.m.: In vivo–in vitro* correlation: Release characteristics independent of environment. *3:30 p.m.: in vivo–in vitro* correlation: Release characteristics dependent on the environment. *3:45–5:00 p.m.:* General discussion.

Friday, December 16, 1988

F. Recommendations of the Workshop. *8:30 a.m.:* General Chairman—J. P. Skelly. Panel Recommendations. Consensus Reports of Previous Sessions by Panel Chairmen. *10:00–10:30 a.m.:* Coffee Break. Open Discussion on Issues and Workshop Consensus Development. *12:30 p.m.:* End of Workshop.

Registration information can be obtained from AAPS, 601 King Street, Alexandria, VA 22314-3105, (703) 548-3000.

CALENDAR OF EVENTS

March 14–15, 1989. A two-day intensive course on radiation sterilization and decontamination in the pharmaceutical, medical device, and cosmetic industries, to be held at the Hyatt Regency, New Brunswick, New Jersey (USA). De-

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tails from Dr. Geoffrey P. Jacobs Associates, Pharmaceutical Consultants, P.O. Box 16352, Jerusalem 91162, Israel (Telephone: 972-2-422-227; Telex: 26522 JRNET IL, Att. DEV).

March 29–31, 1989. Eighth Pharmaceutical Technology Conference, Beach Plaza Hotel, Monte Carlo, Monaco. A large number of original research and general industrial pharmaceutical papers will be presented at the conference. The aim will be to review all modern aspects of pharmaceutical technology, including contemporary trends in dosage form design and solid dosage technology. Powder technology, bioavailability, drug release, pharmacokinetics, food manufacturing practice, aspects of pharmaceutical microbiology and drug stability will also be included. Offers of papers or posters are invited for presentation. The closing date for summaries is November 1, 1988; final drafts January 31, 1989. All inquiries about the conference, including submission should be addressed to: Prof. M. H. Rubinstein, 8th Pharmaceutical Technology Conference, 24 Menlove Gardens North, Liverpool L18 2EJ, United Kingdom [Telephone: 051 722 9862; Telex: 934999 TXLINK G (for MBX 517229862); Electronic Mall: Prestel 517229862].