

Minutes

**BIOPHARMACEUTICS TECHNICAL COMMITTEE**

10:30 am – 1:00 pm  
June 27, 2002  
FDA – Woodmont  
1451 Rockville Pike  
Rockville, MD

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AAPS/Industry Representatives

Leon Shargel (Chair)	GPhA
Andrew Dahlem	PhRMA
Paul Fackler	GPhA
Ron Manning	USP
James Polli (by phone)	AAPS
Joel Sequeira	PhRMA

FDA Representatives

Dale Conner  
Vinod Shah  
Wallace Adams

Guests

S.W. Johnny Lau	FDA
Lawrence Yu	FDA

PQRI

Sylvia Gantt

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Welcome/Introductions

L. Shargel welcomed everyone and discussed the mission of PQRI which is “to conduct research to generate scientific information to support regulatory policy.” The BTC was asked to consider USP as well as FDA when generating research projects. The BTC concurred that all research projects should have a sound scientific basis.

BA/BE of Nasal and Inhalation Products Working Group

Wallace Adams presented a proposal entitled, “Exploratory Dose-Response Corticosteroids Using a Novel Clinical Model.” The objective of this proposal is to explore BA/BE studies of orally inhaled corticosteroids (ICS) using a pharmacodynamic (PD) or clinical response endpoint. The committee discussed the proposal and the use of plasma drug concentrations to find if there is any PK/PD relationship. The BTC agreed that the proposal should be developed further as a work plan by the BA/BE of Nasal and Inhalation Products Working Group. BTC agreed to establish a WG on inhalation and

nasal drug products. W. Adams suggested that this WG should also be in contact with FDA's working group on inhalation products.

#### IR Solid Dosage Forms In Vitro Working Group

James Polli (chair) briefly summarized the three proposals prepared by this WG:

- Criteria for dissolution profile similarity for Class 1 and Class 3 Drugs
- Influence of Common Excipients on Drug Intestinal Permeability
- Influence of Common Excipients on Intestinal Transit and Absorption of Class 3 Drugs

These proposals were considered last year by the BTC. However, the BTC did not formally approve the proposals to move forward. The BTC requested that these proposals be re-considered and prioritized. Some funding may be available from the OPS/FDA. The proposals should contain all the information that is in the new working plan format that was recently approved by the PQRI Steering Committee.

PQRI Survey of Ionizable Drugs -- This survey was made available on the PQRI website and generated very little response. The WG was directed to revise the survey to be more user friendly. The survey should be advertised more widely either through a mailing of PQRI member groups and/or at the PQRI workshop tentatively scheduled for February 2003.

#### BA/BE of Topical Products Working Group

This WG has been inactive. The BTC agreed that this WG should be reactivated.

#### Recruitment of volunteers for WG

The BTC will begin to look for volunteers who have specific technical expertise to join the various WGs.

#### Future Meeting

The next BTC meeting will be at 10:30 am on August 13, 2002 in Rockville, MD.