M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: March 6, 2001

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Update on Biopharmaceutics Coordinating Committee

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation:	Update on Biopharmaceutics Coordinating Committee
Presented for:	Trade Association Meeting with Industry
Date Presented:	September 20, 2000
Presented by:	Dale P. Conner, Pharm.D.
Number of Pages:	7

Melissa Lamb

Attachment

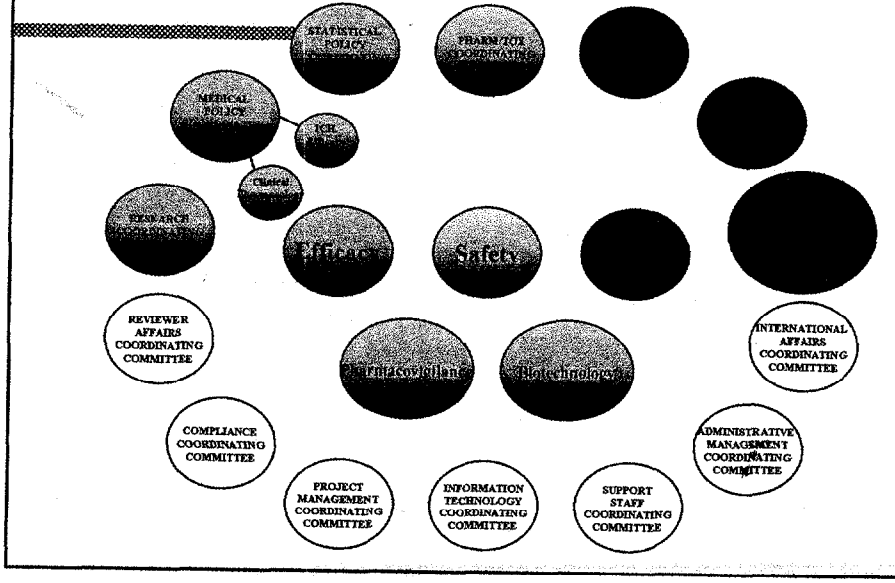
90S-0308

M708

Update on Biopharmaceutics Coordinating Committee

Dale P. Conner, Pharm.D.
Division of Bioequivalence
Office of Generic Drugs, FDA

CDER Coordinating Committees



Membership of BCC

- Chair: Roger Williams
- Biopharmaceutics Division Directors (4)
- Division of Bioequivalence Team Leaders (3)
- Selected OCPB Review Staff (3)
- OPS representatives
- Others

Guidances

- General BA/BE Guidance
- Statistical Guidance
- Topical Guidance
- Nasal BA/BE Guidance
- Bioanalytical Methods Guidance
- Food-Study Guidance
- Dissolution Testing

BA and BE Studies for Orally Administered Drug Products - General Considerations

- Features
  - Parent drug vs. metabolites
  - Enantiomers vs. racemates
  - Complex mixtures
  - Long half-life drugs
  - First-point Cmax
  - Orally administered locally acting drugs
  - No rounding of CI values

BA and BE Studies for Orally Administered Drug Products - General Considerations

- Features (continued)
  - Predose plasma concentrations
  - Washout period
  - Sampling times
  - BE waivers for MR products
  - Multiple-dose studies decreased
  - IBE/PBE proposal
- Status: Draft out for public comment

Average, Population, and Individual Approaches to Establishing Bioequivalence

- Features
  - Statistical methods for IBE
  - Statistical methods for PBE
  - Carryover
  - Outliers
  - Multiple groups
- Status: Draft out for public comment

Topical Dermatological Drug Product NDAs and ANDAs - In Vivo Bioavailability, Bioequivalence, In Vitro Release, and Associated Studies

- Features
  - Dermatopharmacokinetics
  - Comparative clinical trials
  - In vitro release
  - Systemic exposure studies
- Status: Draft out for public comment

Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action

- Features
  - In vitro methods for documentation of BA/BE for solutions
  - In vitro and in vivo methods for documentation of BA/BE of suspensions
- Status: Draft out for public comment

Bioanalytical Methods Validation for Human Studies

- Features
  - Based on conference report reported in Shah, VP et al. Pharmaceut Res 1992
- Status: Draft out for public comment

Food-Effect Bioavailability and Bioequivalence Studies

- Features
  - CI criteria for food studies
  - Change to a two-way crossover study
  - New criteria for when food study is to be performed
  - Criteria for stating food effects in NDA labeling
- Status: Draft out for public comment

Dissolution Testing of Immediate Release Solid Oral Dosage Forms

- Features
- Status: Final

BCS

- Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Containing Certain Active Moieties/Active Ingredients Based on a Biopharmaceutics Classification System
- Status: Draft out for public comment

Montreal

Stratifying BCS

General Population

On other drugs but stable