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: Bioequivalence Issues

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: Bioequivalence Issues

Presented for: Trades Meeting

Date Presented: May, 2000

Presented by: Dale P. Conner, Pharm.D.

Number of Pages: 6

Melissa Lamb

Attachment

90S-0308

M 701

Bioequivalence Issues

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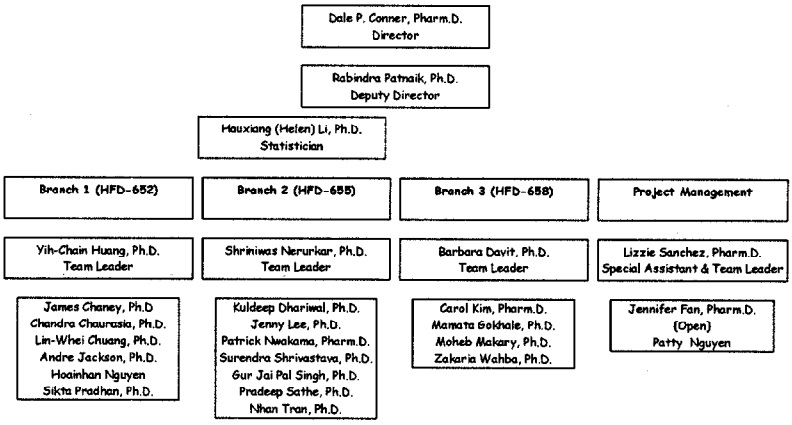
Division of Bioequivalence
Office of Generic Drugs, FDA

Introduction

- Disclaimer
  - Presentation of "current thinking"
  - Not a presentation of new policy
- Organization of Division
- Workflow

Division of Bioequivalence



Current Issues

- Application Quality
- Overages
- E-mail Correspondence
- Parenteral Q & Q Issues
- Combination Topicals
- Flavors & Colors

Application Quality

- Good Study Summary
  - Manufacturing dates
  - Lot #s lot sizes
  - T and R expiration dates
  - Content uniformity/potency with RSD
  - Clinical study dates
  - Analytical dates
  - Long-term storage stability
  - Plasma level tables

Application Quality (continued)

- Complete Dissolution Information
- List of Components & Composition
- Glossary of Terms and Numbering Systems
- Proper Tabbing
- Electronic Submissions
  - Information should be consistent with paper copy
  - DBE now has "automatic" review template generation

Overages

- Sponsors sometimes put overages in biobatch
- OGD Chemists often urge sponsors to remove overage in marketed product
- In theory some marketed products might not be BE to RLD
- Advise sponsors to avoid overages

E-mail Correspondence

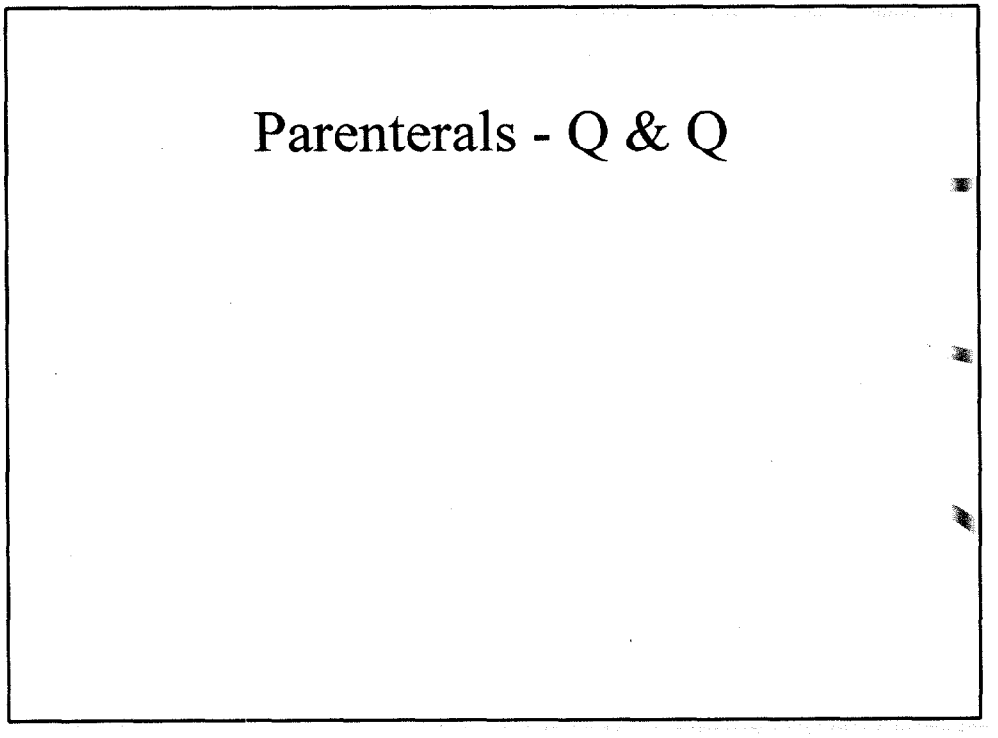
- Currently not encouraged
- Follow-up with written correspondence
- Include regular mailing address in e-mail

Flavors & Colors

- Identify flavors used in products
- If flavor or color formula has been used before in another product
  - Greater than or equal to proposed product
  - Less than proposed product
- If new flavor or color or used in amount greater than approved product
  - Submit formula and amounts of all components
  - Submit any tox information on components

Topical Combination Products

- Each component must show BE
- Example: combination antifungal and corticosteroid
  - BE study with clinical end-points for antifungal
  - Multi-point blanching BE study for the steroid component


Parenterals - Q & Q