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: CMC Guidance 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: CMC Guidance Issues

Presented for: NAPM

Date Presented: May 15, 2000

Presented by: Frank O. Holcombe
Associate Director for Chemistry
Office of Generic Drugs
CDER/FDA

Number of Pages: 9

Melissa Lamb

Attachment

90S-0308

M705

National Association of Pharmaceutical Manufacturers

Mid-Year Meeting and Educational Conference

CMC Guidance Issues

May 15, 2000
Newark, New Jersey

Frank O. Holcombe, Jr., Ph.D.
Associate Director for Chemistry
Office of Generic Drugs
CDER/FDA

General Guidances

- **Methods Validation**
  (Update, incorporation of Q2A, Q2B)

- **Changes to an Approved NDA or ANDA (11/99)**
  (Revision 1)

- **Revision of CFR 314.70 - Postapproval Changes**

General Guidances

- **BACPAC I (11/98 draft)**
- **BACPAC II**
- **Drug Substance Guidance (1987 update)**

- **Stability Testing of Drug Substances and Drug Products (11/98 draft)**
  (Q1A , Q1B, Q1C, site stability)

- **Drug Product Guidance**

Guidance Development

- **AAPS/FDA Workshop - May 30 to June 2, 2000**
  - **PacPac - Post Approval Changes in Packaging**
  - **AmPac - Post Approval Changes in Analytical Methods**

- **Drug Master Files for Bulk Antibiotic Drug Substances**
  - **Working Group - Exploratory phase; eventual workshop**

Guidance Development

Advisory Panel Subcommittee

- **Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products: CMC Documentation (11/98 draft)**

- **Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products: CMC Documentation**

General Guidances

- Post Approval Changes - Sterile Aqueous Solutions (PacSas, under revision)
- SUPAC-IR (still under revision)
- SUPAC-TDS
- Drug Master Files (1989 update)
- Chiral Information for Drug Substances (1992 update)

ANDA Specific Guidances

- ANDA - Impurities in Drug Substances (11/99)
- ANDA - Impurities in Drug Products (12/98 draft)
- ANDA - Blend Uniformity Analysis (8/99 draft)
- ANDA - Data for Electronic Submission (9/99)
- Major, Minor, FAX, and Telephone Amendments to Original ANDAs (8/99)

Miscellaneous

- **CMC: IND Phase 2/3 (2/99 draft)**
- **CMC: IND Formal Meetings**
- **Proprietary Drug Names**

ICH Topics

- **Brussells, July 2000**

  Q1A (update) (now up to proposed Q1G)

  Q3A (update)

  Q3B (update)

  M4 - Q Common Technical Document

- **Q6A - Step 4**

  conversion into CDER guidance