

M E M O R A N D U M

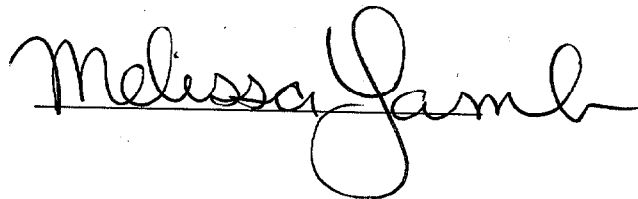
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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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



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**

- **Brussels, 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**