

M E M O R A N D U M

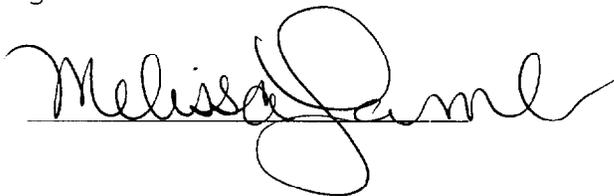
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

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Date: February 2, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: CMC Guidance Update

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: Annual Meeting and Educational Conference
Presented for: NAPM 2000 Annual Meeting and Educational Conference
Date Presented: 2/2/00
Presented by: Frank O. Holocombe
Number of Pages: 5



Attachment

90S-0308

M667

NAPM 2000

Annual Meeting and Educational Conference

CMC Guidance Update

**February 2, 2000
Rio Grande, Puerto Rico**

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

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)**

General Guidances

- **BACPAC I (11/98 draft)**
- **Drug Substance Guidance (1987 update)**
- **Stability Testing of Drug Substances and Drug Products (11/98 draft)**
- **Methods Validation (update)**
- **Drug Master Files for Bulk Antibiotic Drug Substances (11/99)**

General Guidances

- **Post Approval Changes - Sterile Aqueous Solutions (PacSas, under revision)**
- **Post Approval Changes - Packaging (PacPac workshop)**
- **Post Approval Changes - Analytical Methods (AmPac workshop) (also USP/FDA System Suitability Forum)**
- **Drug Master Files for Bulk Antibiotic Drug Substances**
- **SUPAC-IR (still under revision)**

General Guidances

- **Changes to an Approved NDA or ANDA (11/99)**
- **Revision of CFR 314.70 - Postapproval Changes**
- **ICH Documents**
 - Q1A (update)**
 - Q3A (update)**
 - Q3B (update)**
 - Q6A**
 - Common Technical Document**