

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 11, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Update on Chemistry, Manufacturing and Controls
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: The Generic Pharmaceutical Industry
Regulatory & Scientific Challenges
Presented for: 1999 Fall Technical Workshop
NAPM/GPIA/NPA/FDA
Date Presented: 10/19/99
Presented by: Frank O. Holcombe, Jr., Ph.D.
Number of Pages: 10



Attachment

90S-0308

M679

1999 Fall Technical Workshop
NAPM / GPIA / NPA / FDA

**The Generic Pharmaceutical Industry
Regulatory & Scientific Challenges**

**Update on
Chemistry, Manufacturing and Controls
Coordinating Committee**

October 19, 1999

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

Pre-Approval

Drug Substance

General
 Impurities: Q3A, D-ANDA/NDA
 Residual Solvents: Q3C
 Tests and Specifications: Q6A
Chiral Information (May 1992 Update)

Drug Product

General
 Tests and Specifications (Q6A)
 Degradants: Q3B, D-ANDA/NDA
 Residual Solvents: Q3C
 Container Closure Systems
 Sterilization Process Validation
 Oral Inhalation/Nasal (MDI/DPI, Other)
 Ophthalmic/Otic
 Topical/SS

General

Methods Validation: Q2A, Q2B, D
 DMFs
 Environmental Assessments
 Stability Q1A, Q1B, Q1C, D
 CMC IND Phase 2/3
 CMC IND Formal Meetings
 Proprietary Drug Names

CMC CC

314.70

Post-Approval

General
 Guidance

BACPAC I and II

SUPAC: IR/MEA, MR/MEA

PAC-SAS

PAC-OI/N

PAC-OO

PAC-SS/MEA

PAC-Analytical Testing Labs

CDS CC

314.70
 (g)

Changes
 Guidances

1) Biologicals
 2) Specified
 Biotech/Other

PAC by CDS*

Comparability Protocol
 (April 96)

Complex Drug Substance

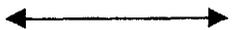
rDNA Derived Cell Metabolites
 Synthetic Peptides
 rDNA Proteins (g/ng)
 Natural Proteins (g/ng)
 Conjugated Estrogens
 Botanicals
 rDNA Reagents
 Complex Excipients

*May be part of the guidance on individual topics or drugs.

**Chemistry Manufacturing Controls
Coordinating Committee**

Co-Chair: Eric Sheinin
Co-Chair (Acting): Frank Holcombe, Jr.
Members: Chen, Cooney, Fang, Gibbs, Hoiberg, Patel
Executive Secretary: Peggy Cunningham
Project Manager: Nancy Sager

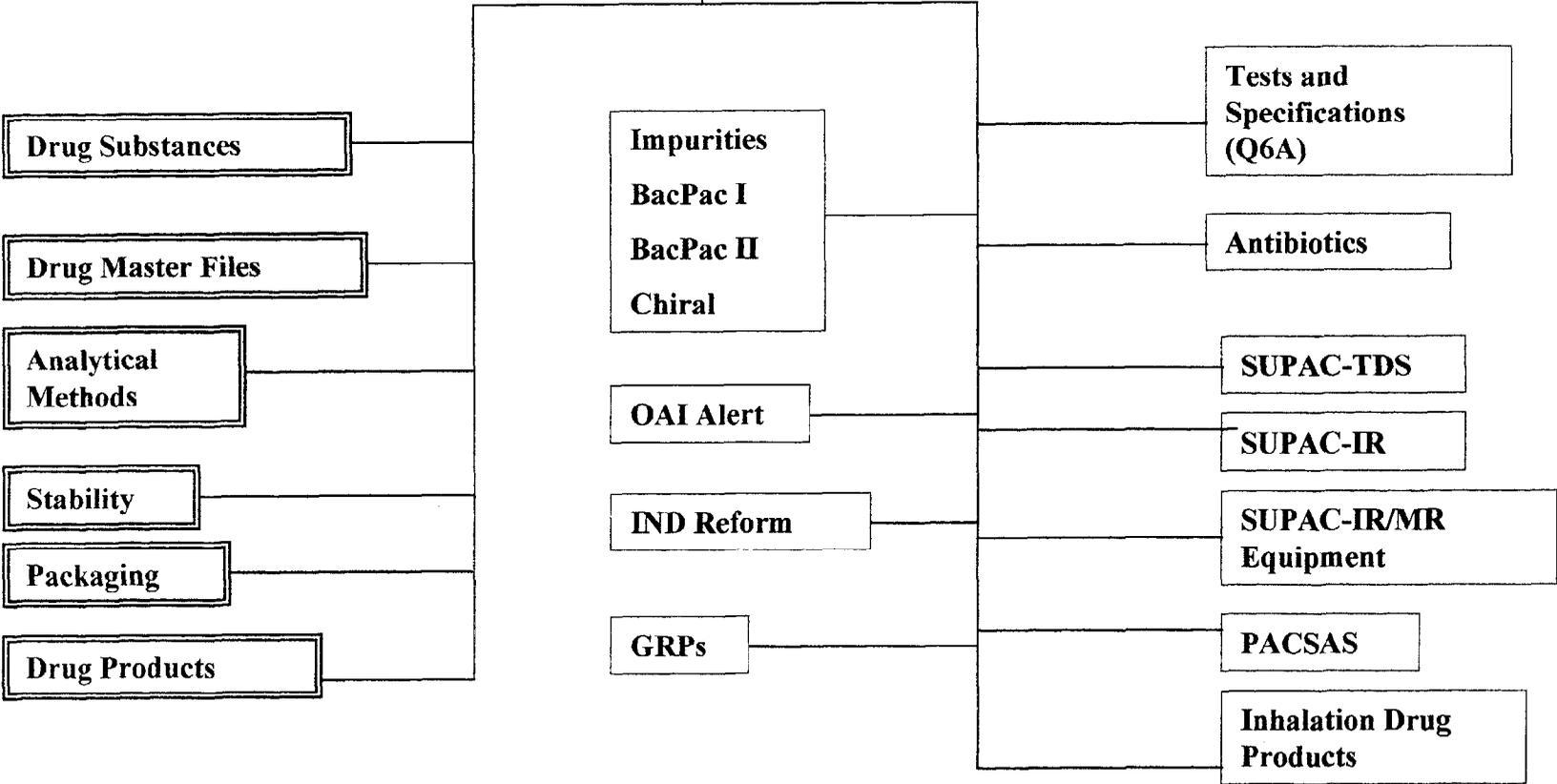
CMC CC Observers
OC
ORA
OTR
COS



**Chemistry
Team Leaders**



**Chemistry
Reviewers**



Drug Substance

- **Drug Substance Guidance (1987 update)**
- **BACPAC I - (11/98 draft)**
- **BACPAC II**
- **NDA - Impurities in Drug Substances (12/98 draft)**
- **ANDA - Impurities in Drug Substances (7/98 draft)**
- **Chiral Information on DS (1992 update)**

Drug Product

- **Drug Product Guidance (1987 update)**
- **ANDA Drug Product Impurities (12/98 draft)**
- **ANDA Blend Uniformity Analysis**
- **Post-Approval Changes - Sterile Aqueous Solutions**

Drug Product

- **Submission of Documentation in Drug Applications for Container Closure Systems Used in Packaging of Human Drugs and Biologics (Published)**
- **Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products: CMC Documentation**
- **Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products: CMC Documentation**

Drug Product

- **SUPAC IR - undergoing revision**
- **SUPAC IR/MR Manufacturing Equipment Addendum
(final 1/99)**
- **SUPAC SS Manufacturing Equipment Addendum
(draft 12/98)**
- **SUPAC Transdermal Systems**
- ***PACPAC***
- ***AMPAC***

General

- **Drug Master Files (1989 update)**
- **DMFs for Bulk Antibiotic Drugs (Administrative)**
- **Methods Validation (Q2A , Q2B)**
- **CMC: IND Phase 2/3 (2/99 draft)**
- **CMC: IND Formal Meetings**
- **Proprietary Drug Names**

General

- **Stability Testing of Drug Substances and Drug Products (Q1A , Q1B, Q1C) (6/98 draft)**
(undergoing revision)
- **Changes to an Approved NDA or ANDA**
(revised for publication)
- **Revision of 21 CFR 314.70 - Post-Approval Changes**
(public comments)

General

- **ICH Documents**

Q1A - Update, Revision, Extensions

Q3A - Update

Q3B - Update

Q6A

M4 - Common Technical Document

Q7