

M E M O R A N D U M

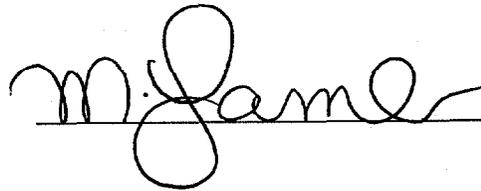
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

---

Date: February 8, 2000  
To: Dockets Management Branch (HFA-305)  
From: Melissa Lamb  
Office of Generic Drugs  
Subject: FDA/USP Link

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: Compendial Operations FDA/USP Link  
Presented for: 1999 Fall Technical Workshop  
Date Presented: 10/18/99  
Presented by: Yana Mille, Sandra Hill,  
Vinetta Howard-King, Larry Ouderkirk  
Number of Pages: 7



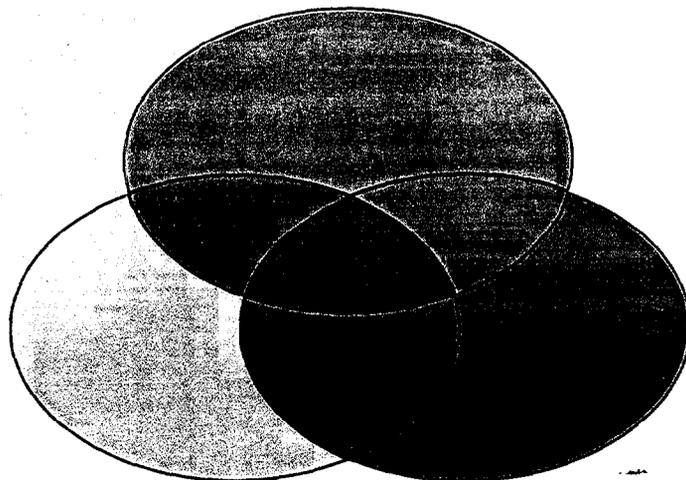
Attachment

3869 '00 FEB 11 A9:25

90S-0308

M651

# Compendial Operations



**FDA/USP  
LINK**

1999 Fall Technical Workshop

OCTOBER 18, 1999

Hyatt Regency, Bethesda, MD

---

## Deputy Center Director for Pharmaceutical Science

**Office of Pharmaceutical Science**  
Director  
Deputy Director

**Associate Director for  
Quality Implementation**

- Project Management of Coordinating Committees
- Guidance Development and Implementation Activities
- Scientific Training (OPSTC)
- Compendial Operations Staff

**Associate Director for  
Operations**

- Information Technology (OPSIT)
- Planning/Evaluation
- Administrative Management

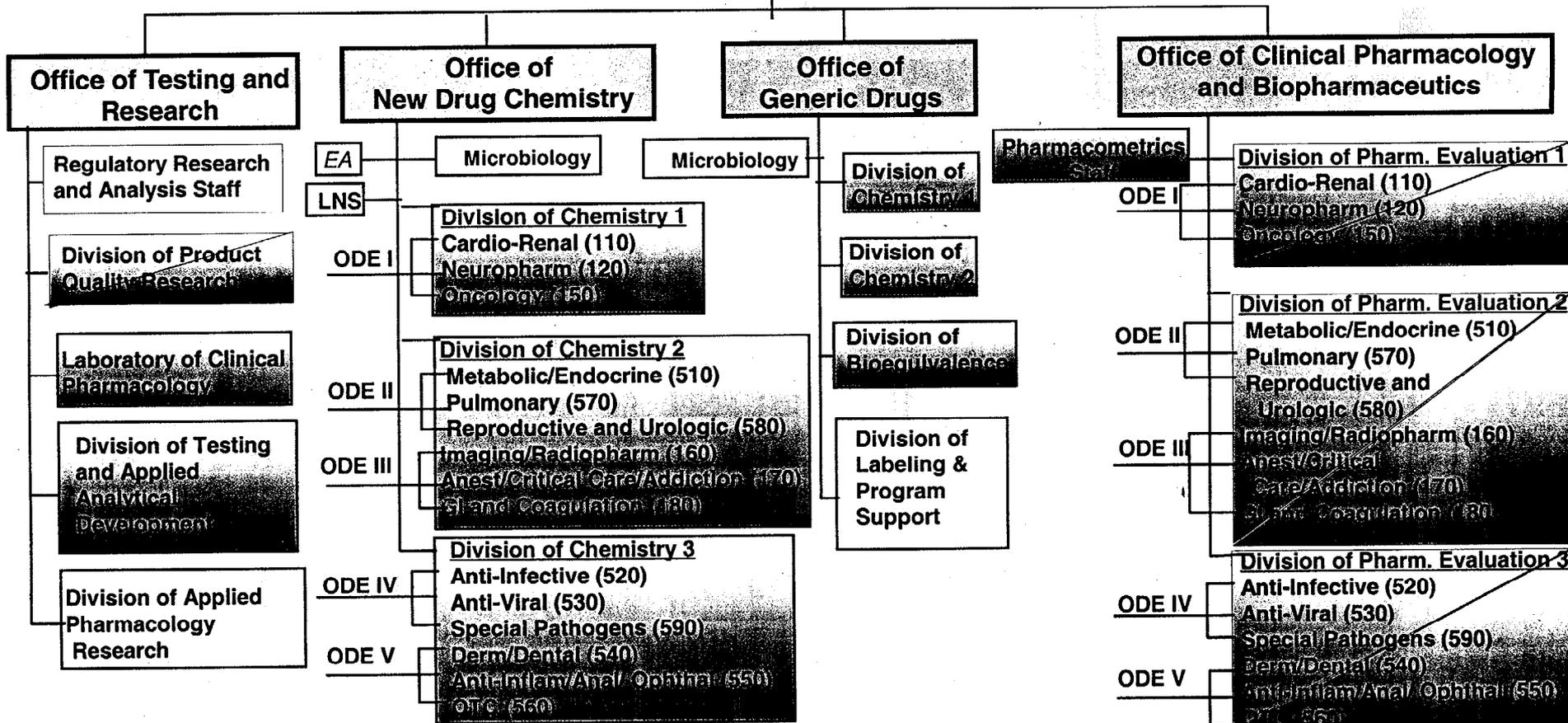
### Coordinating Committees

1. Medical Policy/Clinical Pharmacology Section
2. Pharmacology/Toxicology
3. Chemistry, Manufacturing, Controls
4. Biopharmaceutics
5. Compliance
6. Project Management
7. Information Technology
8. Research
9. Administrative Management
10. International Affairs
11. Reviewer Affairs
12. Statistical Policy
13. Complex Drug Substances

= Biopharmaceutics  
 = Clinical Pharmacology  
 = Development and Testing  
 = Pharm/Tox  
 = CMC

### International Activities Coordinating Committee

1. ICH
2. Bilateral: EU/EC and US/FDA
3. Trilateral: Canada/HPB and US/FDA
4. WHO
5. Foreign Visitors



# Compendial Operations Staff

- **Yana Mille**
- **Sandra Hill**
- **Vinetta Howard-King**
- **Larry Ouderkirk**



VOLUME

25

NUMBER 5

BIMONTHLY SEPT.—OCT. 1999

### HIGHLIGHTS

- ▶ Open-Dish Studies on Potential Labile Preparations (Headquarters; Stimuli)
- ▶ Concordance of Foreign Pharmacopeial Tests and Assays—Summary of Comments (Stimuli)
- ▶ USP and USAN Council Propose Changing Names Amiodarone and Amrinone (Headquarters; In-Process Revision; Nomenclature)
- ▶ New Information Chapter on Interpretation and Treatment of Analytical Data (In-Process Revision)
- ▶ New Information Chapter on In Vitro Absorption-Indicating Cell Culture System (Previews)
- ▶ Thirty-First Interim Revision Announcement Pertaining to USP 23 and to NF 18



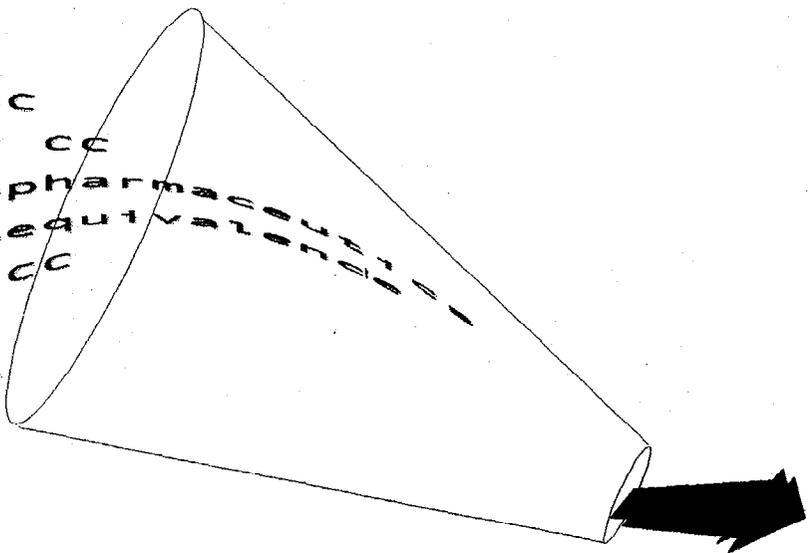
# Pharmacoepial Forum

The Journal of Standards Development and Official Compendia Revision

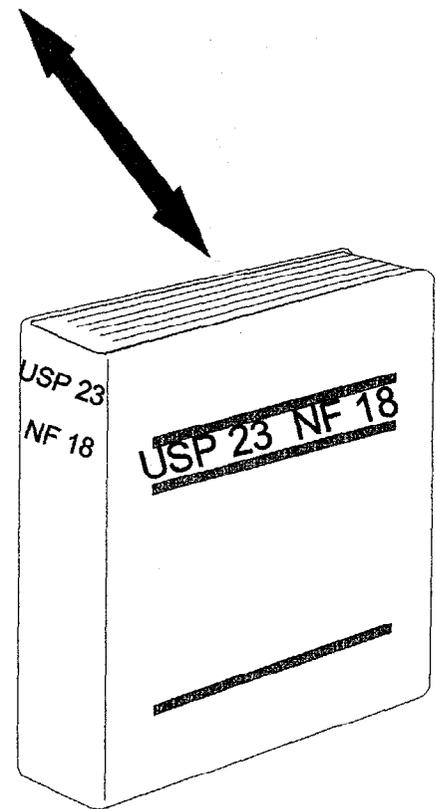
Headquarters Column	8703-8708
Pharmacoepial Previews	8709-8774
In-Process Revision	8775-8926
Stimuli to the Revision Process	8927-8991
Nomenclature	8993-9004
Thirty-First IRA	9005a
Reference Standards Catalog	9007-9031
Index	9032-9058

*PHARMACOPEIAL FORUM* is published to provide an opportunity for public review of and comment on revision activities affecting the *United States Pharmacopeia* and the *National Formulary*. It also provides a forum for the exchange of ideas and information relating to the development and revision of standards and analytical methods.

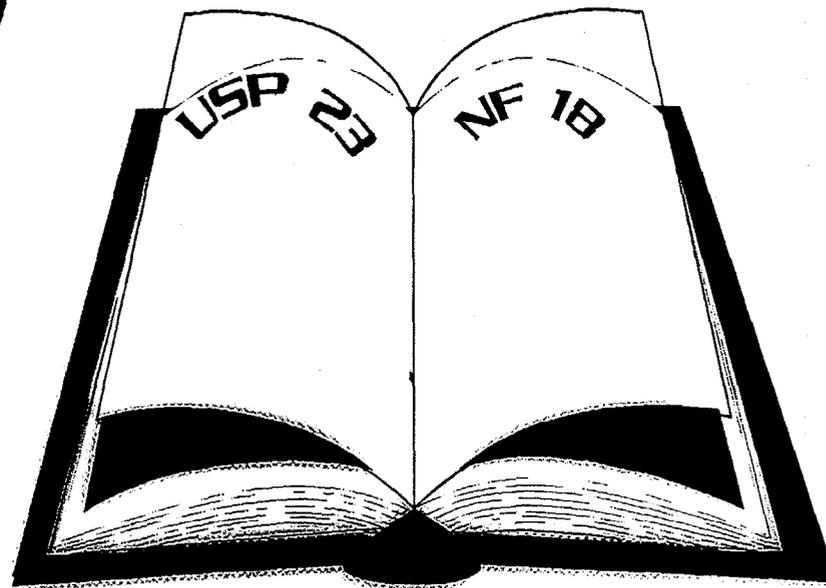
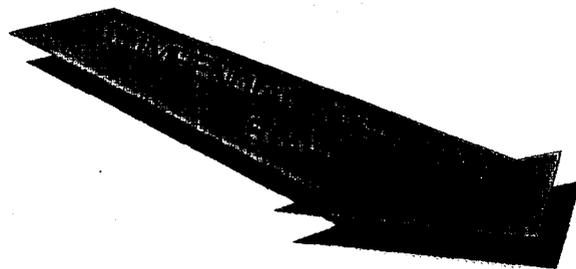
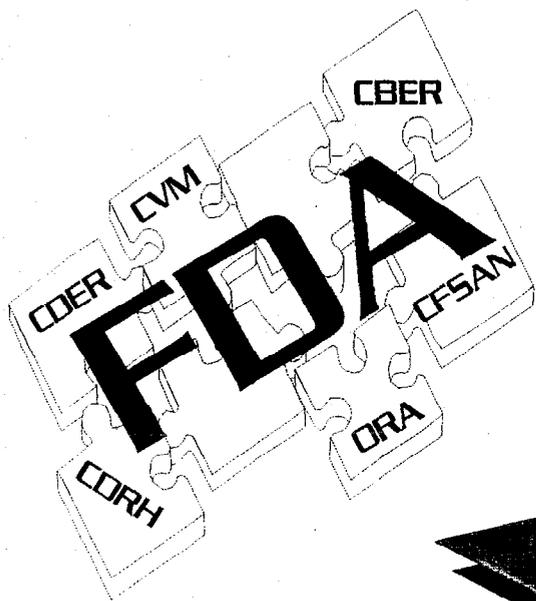
OGD  
ONDC  
CMC CC  
Biopharmaceutics  
Bioequivalency  
BP CC  
CCC  
ORA  
OC



**COMPENDIAL  
OPERATIONS  
STAFF**



# COORDINATION WITHIN THE AGENCY



# AD HOC REVIEWER PROGRAM

