

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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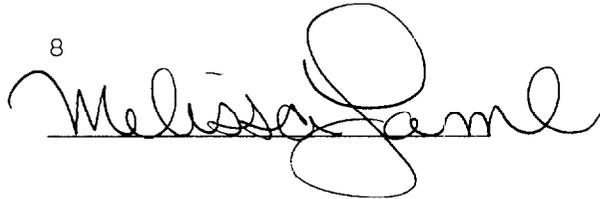
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Date: November 1, 1999  
To: Dockets Management Branch (HFA-305)  
From: Melissa Lamb  
Office of Generic Drugs

Subject: A Century of Progress: A Millenium of Challenge Ahead

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: A Century of Progress: A Millenium of Challenge Ahead  
Presented for: ISPE Annual Meeting  
Date Presented: 11/1/1999  
Presented by: Douglas L. Sporn  
Number of Pages: 8

  
Melissa Lamb

Attachment

90S-0308

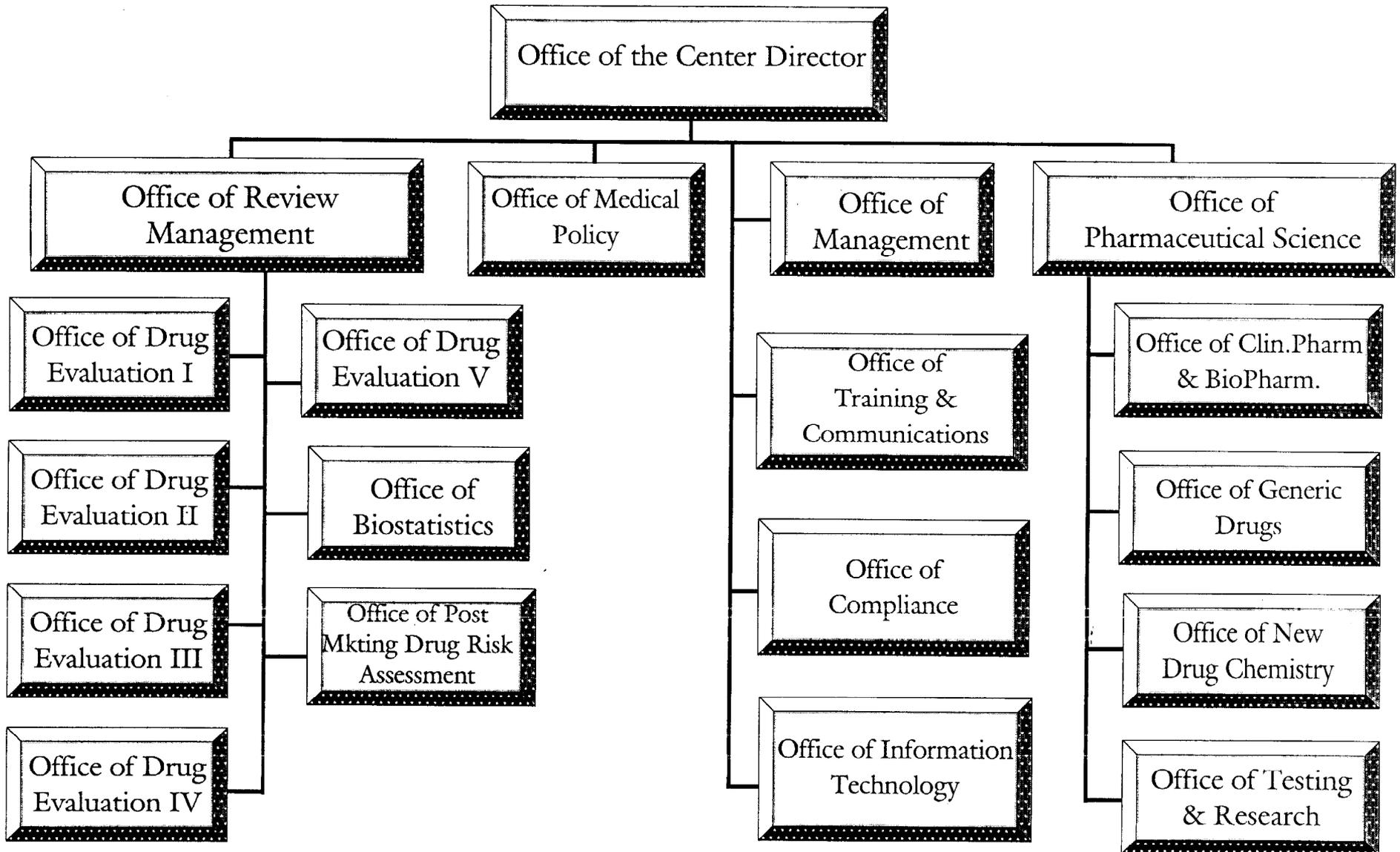
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ISPE Annual Meeting

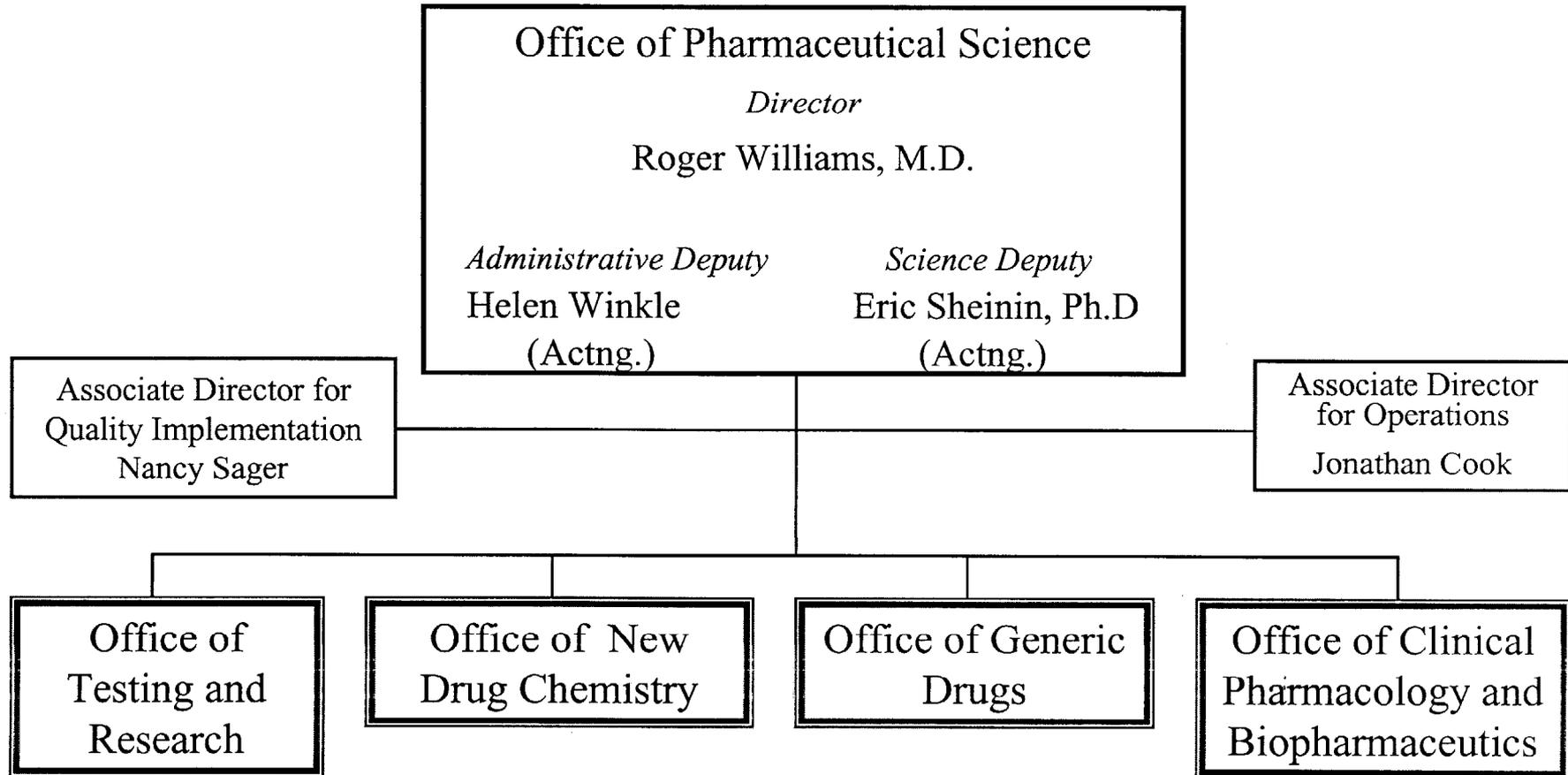
A Century of Progress:  
A Millenium of Challenge  
Ahead

Douglas L. Sporn, Director  
Office of Generic Drugs  
November 1, 1999  
New Orleans, LA

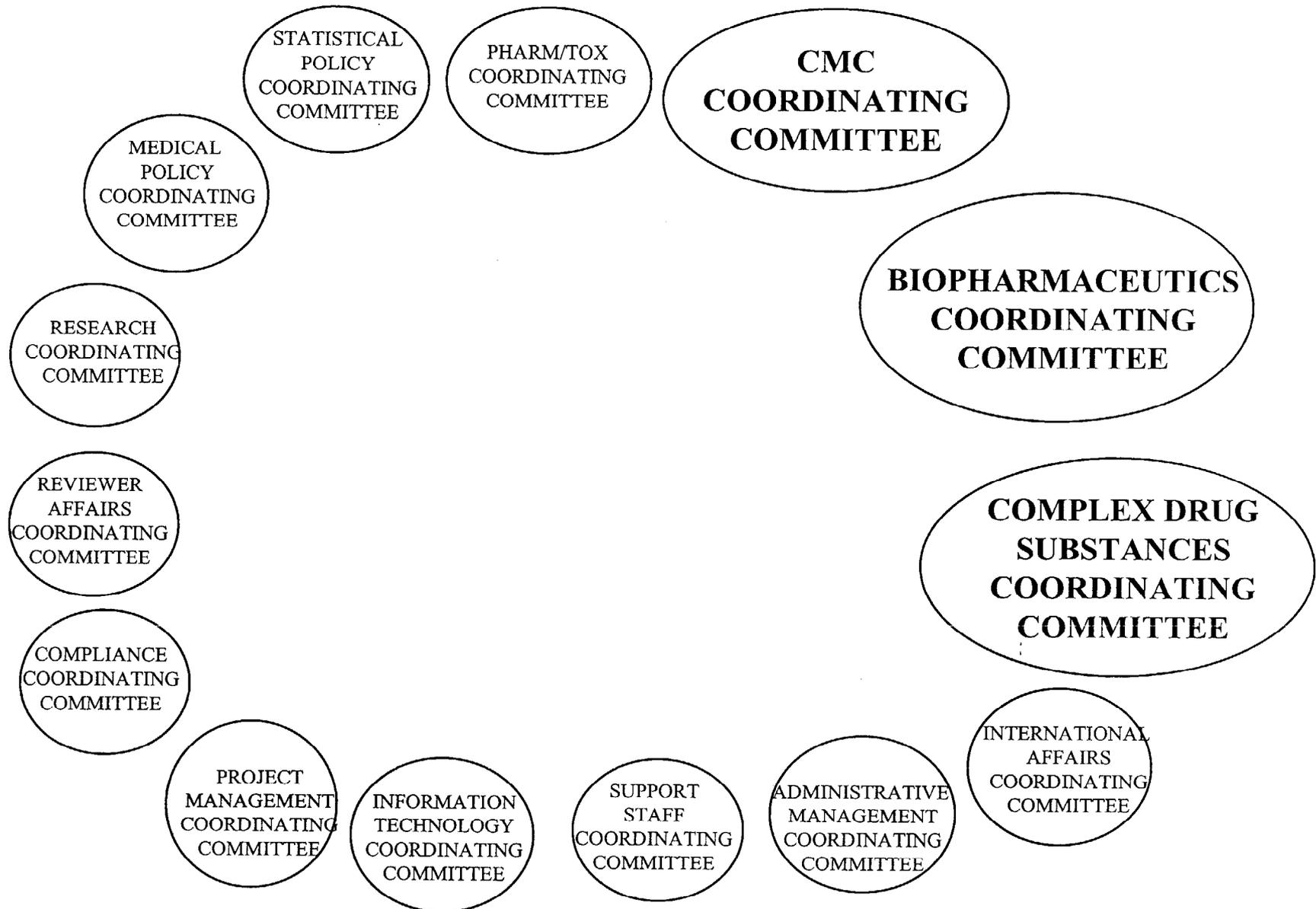
# Center for Drug Evaluation and Research



**Deputy Center Director for  
Pharmaceutical Science**



# SCIENCE/TECHNICAL REGULATORY POLICY CDER COORDINATING COMMITTEES



# Center for Drug Evaluation and Research Guidances

- ◆ Packaging Guidance (Final)
- ◆ Electronic Submission of ANDA Data (Final)
- ◆ 314.70 Guidance & Regulation
- ◆ Blend Uniformity

# Center for Drug Evaluation and Research Guidances

- ◆ Impurities in Drug Substances/  
Drug Products for ANDAs
- ◆ DMF's for Bulk Antibiotic Drug  
Substances
- ◆ Stability Guidance

# Center for Drug Evaluation and Research Guidances

- ◆ BAC PAC I
- ◆ BAC PAC II
- ◆ PAC SAS
- ◆ SUPAC-SS Equipment Addendum

# Center for Drug Evaluation and Research Guidances

- ◆ Revision Process for Equipment Addenda
- ◆ SUPAC-IR Rewrite
- ◆ Section 119 MAPP - Field Recommendations