

# Pharmacy Compounding Advisory Committee

July 13-14, 2000, Meeting

## AGENDA

Advisory Committee Conference Room, 1066  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

### Objective:

*The committee will review five drug products for inclusion on a list of drug products that cannot be compounded because they have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective.*

*The committee will discuss and provide FDA with advice about drug products that present demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of those drug products.*

## DAY 1: THURSDAY, JULY 13, 2000

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**8:30 a.m. Call to Order/General Introductory Remarks** Dr. Randy Juhl  
Chair, Pharmacy Compounding Advisory Committee

Conflict of Interest Dr. Igor Cerny  
Advisors and Consultants Staff, CDER

Introductory Remarks Ms. Lana Ogram  
Director, Division of Prescription Drug Compliance and Surveillance, CDER

### **3,4-diaminopyridine and 4-aminopyridine - Updates to the Committee**

• Introduction Ms. Jane Axelrad  
Associate Director for Policy, CDER

• Acorda Therapeutics Dr. Andrew Blight  
Vice President of Research & Development

Dr. Veronica Mallon  
Vice President of Intellectual Property & Government Affairs

Committee Discussion

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### **DAY 1: THURSDAY, JULY 13, 2000 (CONT.)**

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**9:30 a.m. Withdrawn or Removed List of Drug Products**      Capt. George Scott  
Regulatory Operations Officer  
Division of Prescription Drug Compliance and Surveillance, CDER

**10:00 a.m. Break**

**10:15 a.m. Demonstrably Difficult to Compound**

- **Introduction: Factors and Approach**      Dr. Kathleen Anderson,  
Consumer Safety Officer  
Division of Prescription Drug Compliance and Surveillance, CDER

Committee Discussion

- **Metered-Dose Inhalers & Dry Powder Inhalers**      Dr. Brian Rogers  
Chemistry, Manufacturing, and Controls Reviewer  
Office of New Drug Chemistry, CDER

Committee Discussion

**11:30 p.m. Lunch**

**1:00 p.m. Open Public Hearing**

**2:00 p.m. Demonstrably Difficult to Compound**

- **Transdermal Delivery Systems**      Dr. Vinod P. Shah  
Senior Research Scientist  
Office of Pharmaceutical Science, CDER

Dr. Amit Mitra  
Review Chemist  
Office of Pharmaceutical Science, CDER

Committee Discussion

**3:30 p.m. Break**

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## *AGENDA*

### **DAY 1: THURSDAY, JULY 13, 2000 (CONT.)**

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**3:45 p.m.    Demonstrably Difficult to Compound**

Committee Discussion of Transdermal Delivery Systems (cont.)

**5:00 p.m.    Adjourn**