

**Food and Drug Administration  
Center for Drug Evaluation and Research**

**Dermatologic and Ophthalmic Drugs Advisory Committee  
Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg**

**Advisory Committee Agenda**

**September 18, 2000**

<b>8:30</b>	Call to Order, Introductions Meeting Statement Opening Comments	Committee Chair Exec Sec – Kimberly Topper Jonca Bull
<b>8:45</b>	Risk Management Options for Marketed Drugs  Post Marketing Perspective	Victor Raczkowski  Peter Honig
<b>Accutane – Pregnancy Prevention Program</b>		
<b>9:15</b>	Accutane Clinical Background/Regulatory History  PPP – OPDRA  Pregnancy exposures and teratogenicity  Questions from the Committee	Jonathan Wilkin  Amarilys Vega  Edward Lammer
<b>10:40</b>	<b>BREAK</b>	
<b>10:55</b>	Roche Introduction Accutane Benefits and Use Epidemiology Slone Data Roche PPP Risk Management  Questions from the Committee	Russell Ellison Guy Webster John LaFlore Allen Mitchell Eileen Leach Russell Ellison
<b>12:45</b>	<b>LUNCH</b>	
<b>1:45</b>	Open Public Hearing	
<b>2:45</b>	Potential Design Elements	Amarilys Vega
<b>3:05</b>	Committee Discussion  Questions to the Committee  Committee Discussion and Vote	  Jonca Bull
<b>5:30</b>	Adjourn	

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**Advisory Committee Agenda**  
**September 19, 2000**

<b>8:30</b>	Welcome Meeting Statement	Committee Chair Exec Sec – Kimberly Topper
<b>8:35</b>	Reprisal of Risk Management Overview	Jonca Bull
<b>8:40</b>	Medication Guides	Nancy Ostrove

**Accutane Associated Psychiatric Events**

<b>8:50</b>	Roche Introduction Clinical Definition Pharmacoepidemiologic Analysis Clinical Case Review Additional Data & Conclusions Risk Management	Russell Ellison Douglas Jacobs Robert Nelson Douglas Jacobs John McLane Russell Ellison
<b>10:10</b>	<b>BREAK</b>	
<b>10:25</b>	FDA Presentation Isotretinoin and Depression Drug-induced Depression Case Review Post Marketing Experience Suicide & Depression Biological Plausibility and Risk Management Options	Alan Byrne Erick Turner Marilyn Pitts Diane Wysowski Kathryn O'Connell
<b>11:40</b>	Questions to the Committee	Jonca Bull
<b>11:45</b>	Open Public Hearing (Part 1)	
<b>12:15</b>	<b>LUNCH</b>	
<b>12:55</b>	Committee Discussion and Vote	

**Accutane New Formulation**

<b>1:55</b>	Roche Presentation Safety and Efficacy Pharmacokinetics Risk Management	John McLane David Young John McLane
<b>2:35</b>	<b>BREAK</b>	
<b>2:50</b>	FDA Perspective  Questions from the Committee Questions to the Committee	Jonathan Wilkin Dennis Bashaw Kathryn O'Connell  Jonca Bull
<b>4:00</b>	Open Public Hearing (Part 2)	
<b>4:30</b>	Committee Discussion and Vote	Committee
<b>5:30</b>	Adjourn	