

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

**Nonprescription Drugs Advisory Committee (NDAC)**

**Hilton Hotel - The Ballrooms  
620 Perry Parkway  
Gaithersburg, Maryland  
March 23, 2005**

**AGENDA**

*The committees will Discussion Topics: (1) microbiologic surrogate endpoints used to demonstrate the effectiveness of antiseptic products used in health care settings (2) related public health issues, (3) trial design issues and (4) statistical issues.*

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8:00	Call to Order and Introductions	<b>Alastair Wood, M.D., Chair (NDAC)</b>
	Conflict of Interest Statement	<b>Shalini Jain, PA-C</b> Acting Executive Secretary Nonprescription Drugs Advisory Committee
8:15	Issue Overview	<b>Susan Johnson, Pharm.D., Ph.D, Associate Director</b> Division of Over-the-Counter Drug Products Office of Drug Evaluation V, CDER

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8:25	Prevention of Surgical Site Infections	<b>Michelle Pearson, M.D.</b> Chief, Prevention & Evaluation Centers for Disease Control and Prevention
8:45	Regulatory History of Healthcare Antiseptic Drug Products	<b>Tia Frazier, R.N., M.S., Regulatory Project Manager</b> Division of Over-the-Counter Drug Products Office of Drug Evaluation V, CDER
8:55	Testing of Health Care Antiseptic Drug Products	<b>Michelle Jackson, Ph.D., Microbiologist</b> Division of Over-the-Counter Drug Products Office of Drug Evaluation V, CDER
9:15	Microbiological Surrogate Endpoints in Clinical Trials of Infectious Diseases	<b>John Powers, M.D., Lead Medical Officer</b> Antimicrobial Drug Development and Resistance Initiatives Office of Drug Evaluation IV, CDER
9:45	<b>Question and Answer Period</b>	
10:00	Break	
10:15	Antiseptics and Infection Control Practice	<b>John Boyce, M.D.</b> Clinical Professor, Department of Internal Medicine Yale School of Medicine New Haven, CT

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***AGENDA (Continued)***

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| 10:45 | The Quest for Clinical Benefit  | <b>Steven Osborne, M.D., Medical Officer</b><br>Division of Over-the-Counter Drug Products<br>Office of Drug Evaluation V, CDER  |
| 11:05 | OTC-TFM Monograph<br>Statistical Issues of Study Design<br>and Analysis   | <b>Thamban Valappil, Ph.D., Statistician</b><br>Center for Drug Evaluation and Research<br>Office of Pharmaceutical Science<br>Division of Biometrics III  |
| 11:25 | Discussion & Questions from the<br>Committee  | <b>Susan Johnson, Pharm.D., Ph.D.</b>  |
| 12:00 | <b>Lunch</b>  |  |
| 1:00  | Open Public Hearing   |  |
| 2:00  | <u>Industry Presentation:</u><br><br>The Value of Surrogate Endpoint<br>Testing for Topical Antimicrobial<br>Products | <b>George Fischler,</b><br><b>Manager Microbiology Research &amp; Development</b><br>The Dial Corporation<br>Scottsdale, AZ<br>Representing: The Cosmetics, Toiletries and Fragrance<br>Association (CTFA) and the Soap and Detergent Association<br>(SDA) |
|       | Statistical Issues in Study Design  | <b>James P. Bowman,</b><br><b>Technical Director and Biostatistician</b><br>Hill Top Research Inc.<br>Miami, OH<br>Representing: The Cosmetics, Toiletries and Fragrance<br>Association (CTFA) and the Soap and Detergent Association<br>(SDA)             |
| 2:45  | <b>Questions and Answer Period</b>  |  |
| 3:00  | Break   |  |
| 3:15  | Committee Discussion  |  |
| 5:00  | Meeting adjourns  |  |