

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

***Nonprescription Drugs Advisory Committee Meeting
October 20, 2005***

***Benefits and hazards of antiseptic products marketed for consumer use
(e.g., antibacterial hand-washes and body-washes)***

AGENDA

- | | | |
|------|---|---|
| 8:00 | Call to Order | Alastair Wood, M.D., Ph.D.
Chair, Nonprescription Drugs Advisory Committee,
NDAC |
| | Conflict of Interest Statement | LT Darrell Lyons, B.S.N
Executive Secretary, NDAC |
| | Welcome and Introductory Comments | Susan S. Johnson, Ph.D., Acting Director
Division of Nonprescription Regulation
Development, Office of Nonprescription Products,
CDER |
| 8:15 | Regulatory History and Attributes
of Consumer Antiseptic Drug Products | Colleen Rogers, Ph.D., Microbiologist
Division of Nonprescription Regulation
Development, ONP, CDER |
| 8:30 | Clinical Benefit of Consumer
Antiseptics | Steven Osborne, M.D., Medical Officer
Division of Nonprescription Clinical Evaluation
ONP, CDER |
| 8:50 | Community-based Studies of
Consumer Antiseptics | Allison E. Aiello, Ph.D., M.S., Assistant Professor
Center for Social Epidemiology & Population Health
Department of Epidemiology
University of Michigan School of Public Health
Ann Arbor, MI |
| 9:10 | The Potential for Antibiotic/
Biocide Cross-resistance | Stuart B. Levy, M.D., Professor
Department of Molecular Biology & Microbiology
Tufts University School of Medicine
Boston, MA |

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AGENDA (continued)

9:30 Break

9:45 Secondary Routes of Exposure
to Biocides

Rolf U. Halden, Ph.D., P.E., Assistant Professor
Center for Water and Health
Department of Environmental Health Sciences
Johns Hopkins Bloomberg School of Public Health
Baltimore, MD

10:05 EPA Regulatory Process for
Antimicrobials

Mark Hartman, Branch Chief
Regulatory Management Branch
Antimicrobials Division
Environmental Protection Agency

10:20 **Question and Answer Period**

10:45 Introduction

Elizabeth H. Anderson
Associate General Counsel
the Cosmetic, Toiletry, and Fragrance Association
Washington, D.C.

Laboratory Studies: Resistance/
Cross-resistance Development in
Microcosm Communities

Peter Gilbert, B.Sc., Ph.D.
Professor of Microbial Physiology
School of Pharmacy and Pharmaceutical Sciences
University of Manchester, UK

Environmental Safety of Active
Pharmaceutical Ingredients

Dr. Richard Reiss
Sciences International, Inc.

The Case for Infection Control
Practices in Home and Community
Setting

Elizabeth Scott, Ph.D.
Co-director Simmons College Center for Hygiene
and Health in Home and Community Settings
Scientific board member of the International
Forum on Home Hygiene

Role of Hand Hygiene in Preventing
Transmission of Infectious Diseases

David Jay Weber, M.D., M.P.H.
Medical Director, Hospital Epidemiology
Professor of Medicine, Pediatrics & Epidemiology
University of North Carolina at Chapel Hill

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AGENDA (continued)

Importance of Fomites in the
Transmission of Infectious Diseases

Charles P. Gerba
Department of Soil, Water and Environmental
Science and Epidemiology and Biostatistics
University of Arizona
Tucson, AZ

11:45 Committee Discussion

12:00 **Lunch**

1:00 Open Public Hearing

2:00 **Question and Answer Period**

3:00 Break

3:15 Committee Discussion

5:00 Adjourn