Meeting of the Nonprescription Drugs Advisory Committee
October 20, 2005

This is the final report of the Nonprescription Drugs Advisory Committee Meeting held on October 20, 2005. A verbatim transcript will be available in about 2 weeks, sent to the Division and posted on the FDA website at http://www.fda.gov/ohrms/dockets/ac/cder05.html#NonprescriptionDrugs

On October 21, 2005, the committee met in closed session.

All external requests should be submitted to the Freedom of Information office.

The Nonprescription Drugs Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research, met on October 20, 2005, at the Holiday Inn Washington Silver Spring, The Ballrooms, 877 Georgia Avenue, Silver Spring, Maryland. Alastair Wood, M.D. chaired the meeting. There were approximately 250 in attendance.

Nonprescription Drugs Advisory Committee (voting):
Alastair Wood, M.D. (Chair), Terrence F. Blaschke, M.D., Ernest B. Clyburn, M.D., Jack E. Fincham, Ph.D., Ruth M. Parker, M.D., Wayne R. Snodgrass, M.D., Ph.D., Robert E. Taylor, M.D., Ph.D., F.A.C.P., F.C.P., Mary E. Tinetti, M.D.

Nonpresecription Drugs Advisory Committee (absent)
Neal Benowitz, M.D.

Consultants (voting):
Rolf Halden, Ph.D., Sonia Patten, Ph.D. [CR], James Omel, M.D., [PR],
Matthew J. Arduino, M.S., Dr. P.H., Lead Biologist (CDC)

Consultants (non-voting):
Mark Hartman, Chief, Regulatory Management Branch II (EPA)

Consultants Speaker (non-voting):
Stuart Levy, MD

Guest Speaker (non-voting):
Allison E. Aiello, Ph.D., M.S.

Industry Representative (non-voting):
Read for the record: The Industry Representative for the NDAC committee recently resigned. That position being currently vacant, the center contacted and invited an Industry Representative who is a current member of a different CDER Advisory committee to participate in today's meeting. This Representative had agreed to attend however, an unexpected and last minute emergency has prevented attendence at this meeting. Thus, for today's meeting, we not have an Industry Representative.

FDA Speakers:
Susan S. Johnson, Ph.D., Collen Rogers, Ph.D., Steven Osborne, M.D.,

FDA Participants:
Charles Ganley, M.D., Susan S. Johnson, Ph.D., Collen Rogers, Ph.D., Steven Osborne, M.D., Debbie L. Lumpkins, John H. Powers, M.D., F.A.C.C.P., F.D.S.A.

Open Public Hearing Speakers (October 20, 2005):
Sally Bloomfield, M.D., Pfizer
Lawton Seal, Healthpoint, LTD
Denise Graham, Association for Professionals in Infection Control and Epidemiology, Inc
Howard Bochnek, Veriden Coorporation
Donald A. Goldmann, M.D. Self-Interest
Eugene C. Cole, DrPh, Self-Interest

On October 20, 2005, the committees discussed the benefits and risks of antiseptic products marketed for consumer use (e.g., antibacterial hand-washes and body-washes). The discussion included topics such as; the efficacy of antiseptics intended for use by consumer, and potential risks to the individual and the general population from using these products.

Alastair Wood, M.D. (Committee Chair), called the meeting to order at 8:00 a.m. The Committee members, consultants, and FDA participants introduced themselves. The conflict of interest statement was read into the record by Darrell Lyons B.S.N. The agenda proceeded as follows:

Welcome and Introductory Comments	Susan S. Johnson, Ph.D., Acting Director Division of Nonprescription Regulation Development Office of Nonprescription Products, CDER
FDA Presentations:	
Regulatory History and Attributes of Consumer Antiseptic Drug Products	Colleen Rogers, Ph.D., Microbiologist Division of Nonprescription Regulation Development, ONP, CDER
Clinical Benefit of Consumer Antiseptics	Steven Osborne, M.D., Medical Officer Division of Nonprescription Clinical Evaluation ONP, CDER
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
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
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
EPA Regulatory Process for Antimicrobials	Mark Hartman, Branch Chief Regulatory Management Branch Antimicrobials Division Environmental Protection Agency

Sponsor Presentations:

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
Importance of Fomites in the Transmission of Infectious Diseases	Charles P. Gerba Department of Soil, Water and Environmental Science and Epidemiology and Biostatics University of Arizona, Tucson, AZ

Open Public Hearing Presentations

<u>Questions to the Committee</u>:

1. **As drug products, should consumer antiseptics be expected to provide clinical benefit by reducing infection (vote)**

   Yes: 12
   No: 0
   Abstain: 0

2. **Based on the information in the background materials and today's presentations, are there any populations, outside of the healthcare setting, in which consumer antiseptic use has been demonstrated to be more effective than use of plain soap in reducing infection rates? (vote)**

   If yes, please describe the population and the category of consumer antiseptic that provided benefit (e.g., antiseptic hand-wash, antiseptic body-wash, hand sanitizer).

If no, what criteria should be used to define a consumer population for which washing with plain soap and water, or other hygiene measures that do not involve antiseptic drug products, are inadequate to reduce infection risk?

Yes: 1
No: 11
Abstain: 0

Discussion:
The committee agreed that studies should be conducted on populations in which there was increased risk of/or transfer of infection (e.g., immune suppressed, diarrhea, upper respiratory infection) or co-morbidity. See transcript for further discussion.

3. Earlier this year, NDAC met to discuss the efficacy criteria for healthcare antiseptic drug products and accepted clinical simulation testing as a surrogate for bacterial infection rate to measure efficacy of healthcare antiseptics. What type of studies/endpoints should be used to establish efficacy in populations that require consumer antiseptics?

Discussion:
See transcript for complete discussion.

4. As with many drugs, the use of consumer antiseptics may be associated with a number of adverse consequences. The extent, to which these consequences are attributable to consumer antiseptics, and the importance of the consequences to public health, are varied. How should each of the following be factored into FDA's decisions about product regulation?

a. Application site consequences for the individual user (e.g., local Irritation, dryness).

Discussion:
The committee agreed consequences for the individual user (e.g., local irritation, dryness, etc,) is important but not life-threatening. The committee recommended using labeling to address these issues.

b. Systemic consequences for the individual user (e.g., incomplete immune system development, development of antibacterial resistance in the individual).

Discussion:
The committee agreed that to find evidence of harm would require long-term surveillance that would be very difficult to study and there would probably be funding issues.

c. Societal consequences associated with chronic exposure of the environment to consumer antiseptics (e.g., widespread development of antibacterial resistance, antiseptic impact on ecosystems, secondary exposure to humans).

Discussion:
The committee suggested that the FDA require studies of benefit of these products over and above alcohol base products and soap and water.

The meeting was adjourned at approximately 4:20 p.m. October 20, 2005.

These summary minutes for the October 20th and 21st, 2005 Meeting of the Nonprescription Drugs Advisory Committee the Food and Drug Administration were approved on November 1, 2005.

I certify that I attended the October 20th and 21st, 2005, Meeting of the Nonprescription Drugs Advisory Committee of the Food and Drug Administration meeting and that these minutes accurately reflect what transpired.

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Darrell Lyons, B.S.N.
Executive Secretary

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Alastair Wood, M.D.
Chair