

Food and Drug Administration
Center for Drug Evaluation and Research

Drug Safety and Risk Management Advisory Committee (DSaRM)

December 4, 2003

Holiday Inn, the Ballroom
Two Montgomery Village Ave., Gaithersburg, MD

DRAFT AGENDA

8:00 Call to Order and Opening Remarks Peter Gross, M.D.
Chair, DSaRM

Introduction of Committee

Conflict of Interest Statement Shalini Jain, PA-C, M.B.A.
DSaRM, Executive Secretary

Issue: Current screening methods to assess sound alike and look alike proprietary drug names, in order to reduce the incidence of medication error resulting from look alike and sound alike names.

8:15 **Welcome** Paul S. Seligman, M.D., M.P.H.
Director, Office of Pharmaco-epidemiology & Statistical Science
Acting Director,
Office of Drug Safety
ODS, FDA

8:20 **Proprietary Name Evaluation at FDA** Jerry Phillips, R.Ph.
Associate Director,
Medication Error Prevention,
ODS, FDA

8:40 **PhRMA: Views on Trademark Evaluation** Robert E. Lee, Jr., J.D.
Assistant General Patent Counsel
Eli Lilly and Company
Representing Pharmaceutical
and Research Manufacturer's
Association (PhRMA)

9:00 **Advancing the Science of Drug Trade Name Review** Paul Seligman, M.D., M.P.H.

9:20 **Automatic String Matching for Reduction of Drug Name Confusion** Bonnie Dorr, Ph.D.
Assistant Professor
Dept. of Computer Science
University of Maryland

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DRAFT AGENDA (cont.)

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| 9:50 | Evaluating Drug Name Confusion Using Expert Panels | R.F. Shangraw, Jr., Ph.D.
CEO
Project Performance Corporation |
| 10:20 | Focus Group Methodology | Miriam Bar-Din Kimel, Ph.D.
Senior Project Manager
MEDTAP International |
| 10:50 | Break | |
| 11:05 | Use of Laboratory and Other Simulations in Assessing Drug Name Confusion | Kraig Schell, Ph.D.
Assistant Professor
Dept. of Psychology
Angelo State University |
| 11:35 | Quantitative Evaluation of Drug Name Safety Using Mock Pharmacy Practice | Sean Hennessy, PharmD, Ph.D.
Assistant Professor
Dept. of Epidemiology & Pharmacology
Center for Clinical Epidemiology & Biostatistics
University of Pennsylvania
School of Medicine |
| 12:00 | Lunch | |
| 1:00 | Open Public Hearing | |
| 2:00 | Introduction of the Issues for Discussion | Paul Seligman, M.D., M.P.H. |
| 2:15 | Committee Discussion of Issues/Questions | |
| 3:00 | Break | |
| 3:15 | Continuation of Committee Discussion | |
| 5:00 | Adjourn | |