



**MINUTES OF A MEETING**

December 12, 2001

**Meeting Type:** Informational

**Subject:** Discussion of information related to the safe use of OTC drug products.

**Project Manager:** Walter J. Ellenberg, Ph.D.

**FDA Participants:**

Center for Drug Evaluation and research (CDER)

Charles Ganley, M.D., Director, Division OTC Drug Products  
Linda Katz, M.D., M.P.H., Deputy Director, Division OTC Drug Products  
Jonca Bull, M.D., Acting Director ODE V  
Robert Temple, M.D., Director, Office of Medical Policy  
Debbie Lumpkins, Interdisciplinary Scientist, Team Leader  
David Hilfiker, M.S., Supervisor, Regulatory Project Manager  
Walt Ellenberg, Ph.D., Regulatory Project Manager  
Dan Keravich, R.Ph., Regulatory Project Manager  
Carol Holquist, Safety Evaluation-Medical Errors, OPDRA  
Claudia Karwoski, Safety Evaluator, Team Leader, OPDRA  
Jerry Phillips, M.D., Associate Director, OPDRA  
Anne Trontell, Deputy Director, DDRE 1&2  
Ellen Shapiro, Director. Division of Public Affairs

**Consumer Healthcare Products Association Representatives**

Michael J. Valentino (CHPA Chairman), Executive Vice President, Global Head OTC,  
Novartis Consumer Health  
Thomas C. Blinn, Vice President, Global Personal Health Care, The Procter & Gamble  
Company  
William L. McComb, President, McNeil Consumer Healthcare  
Mark P. Olesnavage, Executive Vice President, Perrigo Company  
Marc E. Robinson, President, Warner-Lambert Consumer Healthcare, North American  
Region, Pfizer Inc.  
Douglas A. Rogers, President, Whitehall-Robins Consumer Healthcare U.S.  
Manfred E. Scheske, President, North America, Consumer Healthcare, GlaxoSmithKline  
Anthony R. Temple, M.D., Vice President, Medical Affairs, McNeil Consumer  
Healthcare

98N-0337

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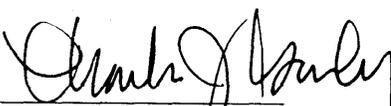
**CHPA staff: (2)**

Michael D. Maves, M.D., MBA, President  
Eve E. Bachrach, Senior Vice President, General Counsel and Secretary

**Discussion:** The goal of the meeting was to allow the representatives of CHPA to provide root cause analysis concerning the cross-dosing of OTC drug products and use according to label.

The CHPA representatives discussed some root causes for cross-dosing and use inconsistent with product labeling for OTC products. The trade group also discussed possible changes in labeling and consumer education programs with the goal of improving correct use of products.

Minutes Prepared by:   
Walter J. Ellenberg, Ph.D.  
Regulatory Project Manager

Minutes Concurrence:   
Charles Ganley, MD.  
Director, Division of OTC Drug Products

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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DATE: 1-25-02

FROM: Director  
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0337

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. \_\_\_\_\_

  
Charles J. Ganley, M.D.

Attachment