Food and Drug Administration Center for Drug Evaluation and Research

Nonprescription Drugs Advisory Committee

Holiday Inn – Versailles Ballroom 8120 Wisconsin Avenue Bethesda, Maryland

Agenda

June 12, 2003

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| 8:00 | Call to Order and Opening Remarks | Louis R. Cantilena, Jr., M.D., Ph.D. Chair |
| | Introduction of Committee | |
| | Conflict of Interest Statement | Karen M. Templeton-Somers, Ph.D. Executive Secretary |
| | Continued Over-the-Counter (OT | C) Status of Ipecac Syrup |
| 8:15 | Introduction to the Issues | Curtis Rosebraugh, M.D., M.P.H. Deputy Director, Division of Over-the- Counter Drug Products, FDA |
| | Ipecac Syrup: Regulatory History | Arlene H. Solbeck, M.S. Interdisciplinary Scientist, DOTCDP, FDA |
| 8:30 | Syrup of Ipecac: OTC or not OTC? | Milton Tenenbein, M.D. University of Manitoba, Children's Hospital |
| 9:15 | A Review of Ipecac Syrup | Anthony S. Manoguerra, Pharm.D. California Poison Control System University of California, San Diego |
| 10:00 | Break | |
| 10:15 | Syrup of Ipecac - One Advocate's Perspective | William O. Robertson, M.D. Washington Poison Center |
| 11:00 | Ipecac Abuse | Tomas Jose Silber, M.D. Children's National Medical Center |
| 11:45 | Questions from the Committee | |
| 12:00 | Lunch | |
| 1:00 | Open Public Hearing | |
| 2:00 | Committee Discussion | |
| | Questions to the Committee | |
| 3:00 | Break | |
| 4:30 | Adjourn | |