

**Food and Drug Administration**  
**Center for Drug Evaluation and Research (CDER)**

**Advisory Committee for Reproductive Health Drugs (ACRHD)**

**December 15, 2003**

Hilton Grand Ballroom  
620 Perry Parkway, Gaithersburg, MD

**AGENDA**

- |             |  |  |
|-------------|--|--|
| <b>8:00</b> | Call to Order and Opening Remarks<br>Introductions | Linda Giudice, M.D., Ph.D.<br>Chair, ACRHD   |
| <b>8:10</b> | Conflict of Interest Statement                     | Jayne E. Peterson, R.Ph., J.D.<br>Acting Executive Secretary, ACRHD, FDA                         |
| <b>8:20</b> | Opening Remarks                                    | Daniel Shames, M.D.<br>Director, Div. of Reproductive and<br>Urologic Drug Products (DRUDP), FDA |

*Issue: The public health issues, including the safety and potential clinical benefit, associated with combining folic acid and an oral contraceptive into a single combination product.*

- |             |   |   |
|-------------|---|---|
| <b>8:30</b> | <b><u>FDA Presentations</u></b><br>Folate Nutrition and Metabolism and Influence<br>on Neural Tube Defects (NTDs) | Barry Shane, Ph.D.<br>Professor, Dept. of Nutritional<br>Sciences and Toxicology<br>University of California, Berkeley  |
|             | Folic Acid and Safety   | Patrick J. Stover, Ph.D.<br>Associate Professor of<br>Nutritional Biochemistry<br>Cornell University  |
|             | Folic Acid Fortification in the U.S.:<br>Planning, Implementation, and Monitoring                                 | Elizabeth Yetley, Ph.D.<br>Lead Scientist for Nutrition<br>Center for Food Safety and<br>Applied Nutrition (CFSAN), FDA   |
|             | Assessing the Impact of Fortification on the<br>Epidemiology of NTDs  | Joe Mulinare, M.D., MSPH<br>National Center on Birth Defects<br>and Developmental Disabilities<br>Centers for Disease Control<br>and Prevention (CDC)                 |
|             | Folic Acid Supplementation and Fortification<br>in Nova Scotia  | Michiel Van den Hof, M.D.<br>Division Head, Maternal/Fetal Medicine<br>Dalhousie University<br>Halifax, Nova Scotia   |
|             | What is the Minimum Effective Dose of Folic Acid<br>for Preventing NTDs?  | James L. Mills, M.D., M.S.<br>Chief, Pediatric Epidemiology Section<br>Epidemiology Branch<br>Div. of Epidemiology, Statistics and<br>Prevention Research, NICHD, NIH |

# Advisory Committee for Reproductive Health Drugs (ACRHD)

December 15, 2003

Hilton Grand Ballroom  
620 Perry Parkway, Gaithersburg, MD

## AGENDA (cont.)

**10:00** Questions to Speakers

**10:15** Break

**10:30** **Invited Sponsor Presentations (Johnson and Johnson, Pharmaceutical Research & Development, L.L.C.)**

Proposal Background and Overview

Andrew J. Friedman, M.D.  
Director, Women's Health Care Research  
Ortho-McNeil Pharmaceutical, Inc.

Neural Tube Defects: Efficacy and Safety of  
Folic Acid

Godfrey P. Oakley, Jr., M.D., MSPM  
Visiting Professor, Dept. of Epidemiology  
Rollins School of Public Health  
Emory University

Need for Increased Folic Acid Intake Among  
Reproductive Age Women

Anna Maria Siega-Riz, Ph.D., R.D.  
Associate Professor of Maternal and Child  
Health and Nutrition  
University of North Carolina at Chapel Hill

Oral Contraceptive Use, Pregnancy Intendedness  
and Folic Acid Intake

Andrew M. Kaunitz, M.D.  
Professor and Assistant Chairman  
University of Florida Health Science Center

Summary and Conclusion

Andrew J. Friedman, M.D.

**12:00** Questions to Speakers

**12:15** Lunch

**1:15** Open Public Hearing

**2:15** Presentation of Questions and Committee Discussion

**3:15** Break

**3:30** Continuation of Committee Discussion

**5:00** Adjourn