

Agenda July 12, 2000

Nonprescription Drugs Advisory Committee Food and Drug Administration Center for Drug Evaluation and Research Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda MD

Labeling & Remarketing Issues – The Today Sponge (NDA 18-683), Allendale Pharmaceuticals

1:00 Call to Order, Introductions

Louis Cantilena, M.D., Chair

Conflict of Interest Statement

Sandra Titus, Ph.D., Executive Secretary, NDAC

1:10 Open Public Hearing

2 :10 Welcome

Charley Ganley, M.D., Director DOTCD

2:15 Allendale Pharmaceuticals Presentations

Communicating Effectiveness Data for the Today Sponge

Forrest Greenslade, Ph.D., Intercare 21st Consulting

Today Sponge: A Contraceptive Option for Women

Elizabeth B. Connell, M.D., Professor Emeritus, OBGYN, Emory University School of Medicine

Toxic Shock Syndrome and the Today Sponge

Mary Delaney, MS, Research Associate, Brigham & Women's Hospital, Harvard

Relative Public Health Need for the Today Sponge

Robert Geidner Antoniotti, President, Planned Parenthood of Maryland

Today Sponge

R.J.Staab, Ph.D., Chief Scientific Officer, Allendale

3:00 FDA Presentation

Chronology

Ling Chin, M.D., MPH, Medical Officer, DOTCD

Safety

Claudia Karwoski, Pharm.D., Safety Evaluator, DDRE 1, OPDRA

Labeling

Gloria Chang, R.Ph., Interdisciplinary Scientist, DOTCDP

3:45 Charge to Committee

Charley Ganley, M.D., Director DOTCD

4:00 Committee Discussion

5:00 Adjourn