

## **Gastrointestinal Drugs Advisory Committee**

Food and Drug Administration  
Center for Drug Evaluation and Research  
Marriott Washingtonian Center, 9751 Washington Boulevard, Gaithersburg, MD

*New drug application (NDA) 21-597, Serostim® (somatropin), Serono Inc.*

*“For the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support. Serostim therapy should be used in conjunction with optimal management of Short Bowel Syndrome.”*

### **Agenda for June 25, 2003**

- 8:30 Call to Order, Introductions:** M. Michael Wolfe, M.D., Acting Chair  
**Meeting Statement:** Thomas H. Perez, M.P.H., Executive Secretary
- 8:45 Opening Comments:** Robert Justice, M.D., M.S., Director,  
Division of Gastrointestinal and Coagulation Drug Products
- 8:50 Serono Inc. Presentation**  
Introduction & Regulatory History Pamela Williamson Joyce, RAC  
Vice President, Regulatory Affairs & Quality Assurance, Serono, Inc.
- Short Bowel Syndrome (SBS): Douglas W. Wilmore, M.D., FACS  
Unmet Medical Need Brigham & Women’s Hospital Harvard Medical School
- SBS Phase III Clinical Study Joseph Gertner, M.B., M.R.C.P., Vice President,  
IMP 20317 Efficacy and Safety Head, Metabolic & Endocrine Clinical Develop. Unit Serono, Inc.
- Risk/Benefit and Conclusions Pamela Williamson Joyce, RAC  
Vice President, Regulatory Affairs & Quality Assurance, Serono, Inc.
- 10:00 Break**
- 10:15 Questions on Presentations**
- 10:45 FDA Presentation**  
Clinical Summary Hugo Gallo-Torres, M.D., Ph.D., PNS, Medical Team Leader  
Division of Gastrointestinal and Coagulation Drug Products
- 11:30 Questions on Presentations**
- 12:00 Lunch**
- 1:00 Open Public Hearing**
- 2:00 Charge to the Committee** Robert Justice, M.D., M.S., Director,  
Division of Gastrointestinal and Coagulation Drug Products
- 2:05 Discussion of Questions**
- 3:00 Break**
- 3:15 Discussion of Questions – continued**
- 5:00 Adjourn**