

**FDA Science Board Advisory Committee Meeting**

April 22, 2004

5630 Fishers Lane, Room 1066

- 8:00 a.m. Call to Order**  
Kenneth I. Shine, M.D., Chair, FDA Science Board
- 8:15 a.m. Welcome and opening remarks**  
Lester M. Crawford, D.V.M., Ph.D., Acting Commissioner of Food and Drugs
- 8:30 a.m. Overview of the FDA Initiative on Obesity**  
Robert E. Brackett, Ph.D., Director, Center for Food Safety & Applied Nutrition, FDA
- 8:40 a.m. Obesity - Therapeutics**  
David G. Orloff, M.D., Director, Division of Metabolic and Endocrine Drugs, ODE II, Office of New Drugs, Center for Drug Evaluation & Research, FDA
- 9:00 a.m. Obesity - Research**  
David W.K. Acheson, M.D., Director, Food Safety and Security Staff, Center for Food Safety & Applied Nutrition, FDA
- 9:20 a.m. Break**
- 9:45 a.m. Highlights of the Obesity Working Group Report**  
Alan M. Rulis, Ph.D., Senior Advisor for Special Projects, Center for Food Safety & Applied Nutrition, FDA
- 10:15 a.m. Questions and Discussion with the Board/Presenters**
- 10:45 a.m. Update on ORA Peer Review**  
John R. Marzilli, Deputy Associate Commissioner for Regulatory Affairs, FDA
- 11:00 a.m. Open Public Hearing**
- 12:15 p.m. Lunch**
- 1:15 p.m. Introduction to Critical Path**  
Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, FDA
- 2:00 p.m. Perspective on Anti-infectives and Vaccines**  
Gail H. Cassell, Ph.D., Vice President, Scientific Affairs and Distinguished Lilly Research Scholar for Infectious Diseases, Eli Lilly and Company
- 2:20 p.m. Perspective on Chronic Disease Therapies**  
Robert M. Califf, M.D., Associate Vice Chancellor for Clinical Research and Director, Duke Clinical Research Institute, Duke University Medical Center
- 2:40 p.m. Drug Formulation and Development, and Tissue Engineering Issues**  
Robert S. Langer, Sc.D., Kenneth J. Germeshausen Professor of Chemical and Biomedical Engineering, MIT
- 3:00 p.m. Break**
- 3:20 p.m. Overview of Opportunities- Drugs**  
Robert Temple, M.D., Director, Office of Medical Policy, Center for Drug Evaluation & Research, FDA
- 3:40 p.m. Overview of Opportunities- Devices**  
Larry G. Kessler, Sc.D., Director, Office of Science and Engineering Laboratories, Center for Devices & Radiological Health, FDA
- 4:10 p.m. Overview of Opportunities- Biologics**  
Jesse Goodman, M.D., M.P.H., Director, Center for Biologics Evaluation & Research, FDA
- 4:30 p.m. Questions and Discussion with Board - Recommendations**
- 5:00 p.m. Adjourn**

4/20/2004