FDA Science Board Advisory Committee Meeting
November 5, 2004
5630 Fishers Lane, Room 1066

8:00 a.m. **Call to Order**
Kenneth I. Shine, M.D., Chair, FDA Science Board

Meeting Statement
Jan N. Johannessen, Ph.D., Executive Secretary

8:10 a.m. **Welcome and opening remarks**
Lester M. Crawford, D.V.M., Ph.D., Acting Commissioner of Food and Drugs

8:25 a.m. **Update on the Critical Path Initiative**

CDER Critical Path Activities
Douglas Throckmorton, M.D., Center for Drug Evaluation and Research, FDA

CBER Critical Path Activities
Jesse Goodman, M.D., M.P.H., Director, Center for Biologics Evaluation and Research, FDA

CDRH Critical Path Activities
Daniel Schultz, M.D., Director, Center for Devices and Radiological Health, FDA

Overview of Critical Path Docket Submissions
Lisa Rovin, J.D., Director, Critical Path Initiative, Office of the Commissioner, FDA

9:30 a.m. **Break**

9:45 a.m. **Critical Path - Current Activities and The Path Forward**
Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, FDA

10:15 a.m. **Medical Technology Innovation Task Force**
Larry G. Kessler, Sc.D., Director, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA

10:45 a.m. **Foods Critical Path White Paper**
Alan M. Rulis, Ph.D., Senior Advisor for Special Projects, Center for Food Safety and Applied Nutrition, FDA

11:00 a.m. **Questions and Discussion with the Board/Presenters**

12:00 p.m. **Lunch**

1:00 p.m. **Open Public Hearing**

2:00 p.m. **Pharmaceutical cGMP Initiative**
Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, FDA

Final Report on Process Analytical Technology and Manufacturing Science
Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Sciences, CDER, FDA

3:30 p.m. **Break**

3:45 p.m. **ORA Peer Review - Overview of Report and Plan for External Peer Review**
John R. Marzilli, Deputy Associate Commissioner for Regulatory Affairs, FDA

4:30 p.m. **Questions and Discussion with Board - Recommendations**

5:00 p.m. **Adjourn**

11/1/2004