FDA Science Board Advisory Committee Meeting
April 15, 2005
5630 Fishers Lane, Room 1066

8:30 a.m. **Call to Order**
Kenneth I. Shine, M.D., Chair, FDA Science Board

8:40 a.m. **Welcome and opening remarks**
Lester M. Crawford, D.V.M., Ph.D., Acting Commissioner of Food and Drugs
Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, FDA

9:10 a.m. **Introduction to Drug Safety**
Steven K. Galson, M.D., Acting Director, Center for Drug Evaluation and Research, FDA

9:20 a.m. **Pre-Market Drug Safety**
Armando Oliva, M.D., Associate Director for Policy, Office of New Drugs,
Center for Drug Evaluation and Research, FDA

9:40 a.m. **Improvements in Drug Safety Information**

Labeling and Electronic Initiatives
Rachel E. Behrman, M.D., M.P.H., Deputy Director, Office of Medical Policy,
Center for Drug Evaluation and Research, FDA

Drug Safety Initiative
Steven K. Galson, M.D., Acting Director, Center for Drug Evaluation and Research, FDA

10:20 a.m. **Break**

10:40 a.m. **Post-Market Drug Safety**
Paul J. Seligman, M.D., M.P.H., Director, Office of Drug Safety,
Center for Drug Evaluation and Research, FDA

11:00 a.m. **Drug Safety Resources**
Theresa M. Mullin, Ph.D., Assistant Commissioner for Planning, FDA

11:15 a.m. **Applying New Science to Drug Safety**
Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, FDA

11:30 a.m. **Committee Questions and Discussion**

12:30 p.m. **Lunch**

1:30 p.m. **Open Public Hearing**

2:30 p.m. **Safety Systems for Vaccines, Blood and Tissues**
Jesse L. Goodman, M.D., M.P.H., Director, Center for Biologics Evaluation and Research, FDA

3:00 p.m. **Committee Questions and Discussion**

3:15 p.m. **cGMPs for Vaccines**
Mary Malarkey, B.S., Director, Office of Compliance and Biologics Quality,
Center for Biologics Evaluation and Research, FDA

3:45 p.m. **Committee Questions and Discussion**

4:30 p.m. **Adjourn**