

FDA Science Board Advisory Committee Meeting

April 9, 2003

5630 Fishers Lane, Room 1066

- 8:00 a.m.** **Call To Order**
Michael P. Doyle, Ph.D., Chair, FDA Science Board
- Waiver Statements**
Susan Bond, Office of the Commissioner
- Introductory Remarks**
Norris E. Alderson, Ph.D., Associate Commissioner for Science, FDA
- 8:15 a.m.** **Welcome & Overview of FDA's Initiative to Improve the Development and Availability of Innovative Medical Products**
Mark B. McClellan, M.D., Ph.D., Commissioner of Food & Drugs
- 8:45 a.m.** **Quality Systems Approach to Medical Product Review**
Janet L. Woodcock, M.D., Director, Center for Drug Evaluation & Research (CDER)
- 9:00 a.m.** **Quality Teams to Improve Regulatory Processes**
David W. Feigal Jr., M.D., M.P.H., Director, Center for Devices & Radiological Health (CDRH)
- 9:15 a.m.** **Break**
- 9:30 a.m.** **Quality Systems for Clinical Pharmacology & Biopharmacology Review**
Larry Lesko, Ph.D., Office of Clinical Pharmacology and Biopharmaceutics, CDER
- Quality Systems for CMC Review**
Yuan-yuan Chiu, Ph.D., Director, Office of New Drug Chemistry, CDER
- 10:00 a.m.** **Questions & Discussion with Board/Presenters**
- 10:30 a.m.** **Update on Pharmaceutical Manufacturing Initiative**
Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Science, CDER
- 10:45 a.m.** **Update on Patient Safety Initiative**
Kelly Cronin, Senior Advisor, Office of Policy & Planning, FDA
- 11:00 a.m.** **Fostering Technology Development – Pharmacogenomics**
Janet Woodcock, M.D., CDER
- 11:30 a.m.** **Questions & Discussion with Board/Presenters**
- 12:00 p.m.** **Lunch**
- 1:00 p.m.** **Open Public Comment**
- 2:00 p.m.** **Industry Use of Pharmacogenomics and Regulatory Issues**
Brian Spear, Ph.D., Director Pharmacogenomics, Global Pharmaceutical Research and Development, Abbott Laboratories
- 2:30 p.m.** **Pharmacogenomics – Preclinical Studies**
Frank Sistare, Ph.D., Acting Director, Office of Testing & Research, CDER
- 3:00 p.m.** **Pharmacogenomics – Drug Metabolism/Dosage**
Larry Lesko, Ph.D., CDER
- 3:30 p.m.** **Ethical Issues with Regulatory Review of Pharmacogenomic Data**
Benjamin Wilfond, M.D., Medical Genetics Branch, National Human Genome Research Institute, National Institutes of Health
- 3:45 p.m.** **Questions & Discussion with the Board/Presenters**
Janet Woodcock to present questions
- 4:30 p.m.** **Closing Remarks/Future Direction**
Michael P. Doyle, Ph.D.