MINUTES OF THE
SCIENCE BOARD TO THE FDA

Washington DC North/Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877

Monday, December 3, 2007

The Science Board to the FDA (Science Board) meeting was convened at approximately 8:00 a.m.

Members Present for December 3rd, 2007
Kenneth I. Shine, M.D., *Chair*
Gail Cassell, Ph.D., D.Sc.(hon)
Susan Kay Harlander, Ph.D.
Lonnie King, D.V.M., M.P.A.
John Linehan, Ph.D.
Barbara J. McNeil, M.D., Ph.D.
David R. Parkinson, M.D.
F. Xavier Pi-Sunyer, M.D., M.P.H.
Allen D. Roses, M.D.
Larry Sasich, Pharm.D., M.P.H., F.A.S.H.P.
Catherine Woteki, Ph.D., R.D.

Executive Secretary
Carlos Peña, Ph.D., M.S.

FDA Participants
Norris Alderson, Ph.D., Associate Commissioner for Science
Robert Buchanan, Ph.D., Center for Food Safety and Applied Nutrition (CFSAN)
Jesse Goodman, M.D., M.P.H., Director, Center for Biologics Evaluation and Research (CBER)
Larry Kessler, Sc.D., Center for Devices and Radiological Health (CDRH)
Carlos Peña, Ph.D., M.S., Executive Secretary, Office of Science and Health Coordination
Carl Sciacchitano, Office of Regulatory Affairs (ORA)
William Slikker, Jr., Ph.D., Director, National Center for Toxicological Research (NCTR)
Stephen Sundlof, D.V.M., Ph.D., Director, Center for Veterinary Medicine (CVM)
Andrew von Eschenbach, M.D., Commissioner of Food and Drugs
Janet Woodcock, M.D., Deputy Commissioner and Chief Medical Officer/Acting Director, Center for Drug Evaluation and Research (CDER)

Presentations
Commissioner's Report
Andrew von Eschenbach, M.D., Commissioner of Food and Drugs
Report to the Science Board: Critical Path Update
Janet Woodcock, M.D., Deputy Commissioner and Chief Medical Officer

Update from the FDA on the Science Board Subcommittee Review of the National Antimicrobial Resistance Monitoring System (NARMS) Program
Stephen Sundlof, D.V.M., Ph.D., Director, Center for Veterinary Medicine
Report to the Science Board: Drug Safety Update
Janet Woodcock, M.D., Acting Director, Center for Drug Evaluation and Research
Report to the Science Board: Update on Melamine Activities
Norris Alderson, Ph.D., Associate Commissioner for Science
Report of the Subcommittee on Science and Technology
Gail Cassell, Ph.D., D.Sc.(hon), Subcommittee Chair, Science Board
Comments from the Science Board Chair
Kenneth I. Shine, M.D., Chair, Science Board

Summary of Committee Discussions and Recommendations

Commissioner's Report

Presentation Summary

- The Commissioner of Food and Drugs presented to the Science Board an update on the state of FDA, new legislation under FDA Amendments Act of 2007, reauthorizations of the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA), postmarket surveillance efforts, food protection activities, strategic objectives, and future challenges of the agency.

Committee Discussion

- The Science Board discussed the review of science at the agency, interaction with the Science Board, and opportunities for the Science Board to be engaged with the agency in the future.

Report to the Science Board: Critical Path Update

Janet Woodcock, M.D., Deputy Commissioner and Chief Medical Officer

- Dr. Woodcock presented the Science Board an update on FDA's critical path initiative and progress to date. Dr. Woodcock presented the Conceptual framework for Critical Path, specific areas of accomplishment, areas to focus upon in 2008 and longer term targets. She identified targeted areas including biomarker development, clinical trials modernization, bioinformatics, and manufacturing. She discussed expansion of the critical path initiative to additional regulated product areas and associated metrics to measure the success of the critical path initiative.

Committee Discussion

- The Science Board discussed approval process timelines as it relates to the critical path initiative. The Science Board also discussed application of the critical path initiative to food safety and the challenges associated with regulatory oversight and progress.

Update from the FDA on the Science Board Subcommittee Review of the National Antimicrobial Resistance Monitoring System (NARMS) Program

Stephen Sundlof, D.V.M., Ph.D., Director, Center for Veterinary Medicine

- Dr. Sundlof presented the Science Board an update on FDA's response to the NARMS review. Dr. Sundlof presented an overview of the NAMRS program, including history, goals, and outcome of the recent review performed by the Science Board subcommittee. He presented strategic planning opportunities, including sampling strategies, surveillance strategies, and research studies. He also presented international activities, data harmonization, and the availability of NARMS related data online.

Committee Discussion

- The Science Board discussed enhancing data sharing and leveraging data resources within the agency as well as with other government organizations. Science Board members noted the importance of timely publication of information related to the NARMS program data.

Report to the Science Board: Drug Safety Update

Janet Woodcock, M.D., Acting Director, Center for Drug Evaluation and Research

- Dr. Woodcock presented the drug safety update to the Science Board. She identified current planning efforts to combine recent reviews on drug safety into a comprehensive plan in 2008. She also presented new legislation under the Food and Drug Administration Amendments Act of 2007 (FDAAA) on Postmarketing studies and surveillance, new steps in labeling procedures, and risk evaluation mitigation strategies for premarket drugs.

Committee Discussion

- The Science Board discussed new statutes as it relates to risk benefit analyses for new drugs, the marketing of drugs to specific subpopulations, and the availability of large safety studies and the use of registries. The Science Board recommended the use of clinical trials as appropriate in addressing postmarket safety signals and discussed data safety monitoring boards to ensure ethical considerations.

Report to the Science Board: Update on Melamine Activities

Norris Alderson, Ph.D., Associate Commissioner for Science

- Dr. Alderson reviewed the melamine activities since the June 2007 Science Board meeting, focusing in three areas including methods improvement and validation, safety risk assessment and prevention, and next steps for the agency. Dr. Alderson discussed the agency's food protection plan applicability and principles and next steps for the agency including continue methods refinement and validation, dose thresholds for crystal formation, dosing sequences as pre-condition for eliciting renal toxicity, effects of ammeline and ammelide, biomarkers as precursor of renal crystal formation, elimination of residues and crystals upon termination of exposure studies, and additional safety/risk assessments, as appropriate.

Committee Discussion

- The Science Board discussed regulatory oversight of products that contain contaminants, current import alerts released by the agency, and food important plans. The Science Board noted the importance of the agency's continuing involvement in emergency preparedness exercises.

Report of the Subcommittee on Science and Technology

Gail Cassell, Ph.D., D.Sc.(hon), Subcommittee Chair, Science Board

- Dr. Gail Cassell and additional presenters Drs. Eve Slater, Catherine Woteki, Thomas Caskey, Garrett Fitzgerald, Dale Nordenberg, and Mr. Peter Hutt each presented a portion of the Report's conclusions. Each focused on the imbalance between FDA resources and responsibilities. Dr. Fitzgerald outlined eight areas of emerging science in which the FDA needs new capacity. All presenters emphasized the importance of science to FDA activities and dedication of FDA staff.

Committee Discussion

- The Board unanimously accepted the Subcommittee report, and called for further review of high priority scientific programs needed by the agency, of the role of the NCTR, and of the scientific capacity and processes of the FDA's ORA. The Science Board requested Center Leaders to provide comment upon the report and Dr. Cassell to work with the agency to create a 4 page Executive

Summary. Dr. Shine also dissolved the subcommittee. The Science Board decided to solicit public comment on the Report, and asked the agency to open a public docket on its behalf to accomplish this request.

Comments from the Science Board Chair
Kenneth I. Shine, M.D., Chair, Science Board

- Dr. Kenneth Shine presented closing remarks, including the following statements:
  - The Science Board accepted the Subcommittee report and decided on steps to provide further review of the agency, including an in depth analysis of the role of NCTR, and of the scientific capacity and processes of the FDA's ORA;
  - The Science Board requested Center Leaders to provide comment upon the subcommittee report;
  - Dr. Cassell to work with the agency to create a 4 page Executive Summary;
  - The Science Board requested the agency open a docket to solicit public comment on the subcommittee report; and
  - The Science Board carry forward the Subcommittee report to the public and policymakers.

The meeting adjourned at approximately 3:30 p.m.

Please see transcript for details

I certify that I attended the December 3, 2007 meeting of the Science Board and that these minutes accurately reflect what transpired.

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Carlos Peña, Ph.D., M.S.	Kenneth I. Shine, M.D.
Executive Secretary	Chair