# FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

*Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP)*

ATLANTA MARRIOTT MARQUIS, 265 PEACHTREE CENTER AVENUE
ATLANTA, GEORGIA
MARCH 17, 2010

AGENDA

On March 17, 2010, the Committee will discuss and provide comments on the following topics: (1) General scientific issues related to the application of pharmacogenomics in the early stages of drug development. Pharmacogenomics examines the genetic differences that influence a person's responses, both beneficial and harmful, to certain drugs; (2) a new patient-centric clinical pharmacology approach to drug safety; (3) the design and analysis of clinical pharmacology studies focusing on how the renal function changes in the way the body absorbs, distributes, metabolizes and excretes a drug in patients with kidney impairment; (4) scientific considerations and recent developments in transporter-mediated drug interactions. These interactions are between two or more drugs that either inhibit or enhance the roles of specialized proteins known as "transporters" and, in turn, the interactions can affect a drug's safety and/or efficacy.

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| 7:30 a.m. | Call to Order | Jürgen Venitz, M.D., Ph.D.<br>Acting Chair, ACPS-CP |
| | Conflict of Interest Statement | Yvette Waples, Pharm.D.<br>Acting Designated Federal Official<br>ACPS-CP |
| 7:45 a.m. | Introduction to the Topics of the Meeting | Lawrence Lesko, Ph.D.<br>Director, Office of Clinical Pharmacology (OCP), Office of Translational Science (OTS), CDER, FDA |
| 8:15 a.m. | *Clinical Pharmacogenomics in Early Drug Development | Issam Zineh, Pharm.D., M.P.H.<br>Associate Director for Genomics Group<br>OCP, OTS, CDER, FDA |
| 8:45 a.m. | *Mechanistic ("Systems") Approach to Drug Safety | Darrell Abernethy, M.D., Ph.D.<br>Associate Director for Drug Safety<br>OCP, OTS, CDER, FDA |
| 9:10 a.m. | Break | |
| 9:25 a.m. | Open Public Hearing | |
| 9:55 a.m. | Committee Questions and Discussions | Jürgen Venitz, M.D., Ph.D.<br>Acting Chair, ACPS-CP |
| 10:55 a.m. | New Study Design and Dosing Adjustment Issues in Renal Impairment | Shiew Mei Huang, Ph.D.<br>Deputy Director, OCP, OTS, CDER<br>FDA |
| 11: 20 a.m. | Perspectives on Pharmacokinetic Studies in Patients with Renal Impairment | Richard L. Lalonde, Pharm.D.<br>Vice President and Global Head of Clinical Pharmacology<br>Pfizer, Inc. |
| 11:35 a.m. | Lunch | |
| 12:35 p.m. | Transporter-Mediated Drug Interactions | Lei Zhang, Ph.D.<br>Special Assistant to Office Director<br>OCP, OTS, CDER, FDA |

*Due to timing, Topic 2 "Mechanistic (Systems) Approach to Drug Safety" presentation was given before Topic 1 "Clinical Pharmacogenomics in Early Drug Development"

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| 1:00 p.m. | Perspectives of Transporter-Mediated Transporters In Drug Development | Joseph W. Polli, Ph.D.<br>Director<br>Preclinical Drug Metabolism and Pharmacokinetics<br>GlaxoSmithKline, Inc |
| 1:15 p.m. | Open Public Hearing | |
| 1:45 p.m. | Committee Questions and Discussion | Jürgen Venitz, M.D., Ph.D.<br>Acting Chair, ACPS-CP |
| 3:00 p.m. | Closing Remarks/Adjournment | Lawrence Lesko, Ph.D.<br>Director, OCP, OTS, CDER, FDA |