

Food and Drug Administration
Center for Drug Evaluation and Research

ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)
Clinical Pharmacology Subcommittee (CPSC)
November 14-15, 2005
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

AGENDA
(DRAFT 9/28)

Day 1: Monday, November 14, 2005

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| 8:30 | Call to Order | Jurgen Venitz, M.D., Ph.D.
Chair, CPSC |
| | Conflict of Interest Statement | Mimi Phan, Pharm.D.
Executive Secretary, ACPS |
| 8:45 | Update on previous meeting recommendations
Background to the topics of this meeting | Lawrence Lesko, Ph.D.
Director, Office of Clinical Pharmacology and
Biopharmaceutics (OCPB), CDER, FDA |
| <i>Topic 1 Translation of Pharmacogenomics (PGx) Information Into Label Updates for Approved Products</i> | | |
| 9:30 | How new insights into PGx lead to revisions
of product labels. | Shiew-Mei Huang, Ph.D.
Deputy Director for Science, OCPB |
| 10:00 | A clinical perspective on the optimal way to translate
PGx information into drug product and clinical assay
labels | David Flockhart, M.D., Ph.D.
Indiana University |
| 10:30 | Break | |
| 10:45 | New insights on warfarin: How CYP 2C9 and
VKORC1 information may improve benefit/risk | Brian Gage, M.D.
Washington University |
| 11:05 | Commentary on current status and next steps
with integrating PGx information into safe and
effective prescribing of warfarin | Michael Caldwell, M.D., Ph.D.
Marshfield Clinic |
| 11:15 | Open Public Hearing | |

11:30 Committee Discussion and questions for the committee Jurgen Venitz, M.D., Ph.D.

1:00 Lunch

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Day 1: Monday, November 14, 2005 (continued)

Topic 2 A Critical Path Pilot Project in Pharmacometrics (Quantitative Methods)

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| 2:00 | Conflict of Interest Statement | Mimi Phan, Pharm.D.
Executive Secretary, ACPS |
| 2:05 | Lessons learned from FDA-industryEOP2A meetings | Bob Powell, PharmD
Director, PM, OCPB, FDA |
| 2:35 | Case study: Application of quantitative methods to assess a genomic enrichment design and a biomarker titration design for a Phase III clinical study | Yaning Wang, PhD
OCPB, FDA |
| 3:05 | Commentary on disease modeling and the case study | Jeffrey S. Barrett, Ph.D.
Jurgen Venitz, M.D., Ph.D.
CPSC |
| 3:35 | Open public hearing | |
| 3:50 | Break | |
| 4:05 | Committee discussion and questions for the committee | Jurgen Venitz, M.D., Ph.D.
Chair, CPSC |
| 5:05 | Wrap-up of Day 1 | Lawrence Lesko, Ph.D.
Director, OCPB, CDER, FDA |
| 5:30 | Adjourn | |

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Day 2: Tuesday, November 15, 2005

Topic 3 Biomarkers in the Critical Path and Their Use in Drug Development and Drug Product Labels

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| 8:30 | Call to Order | Jurgen Venitz, M.D., Ph.D.
Chair, CPSC |
| | Conflict of Interest Statement | Mimi Phan, Pharm.D.
Executive Secretary, ACPS |
| 8:45 | Update on the Critical Path Biomarker-Surrogate Endpoint Project | Janet Woodcock, M.D.
Deputy Commissioner for Operations and Chief Operating Officer, FDA |
| 9:30 | Use of Biomarker Information in Drug Product Labels to Individualize Pharmacotherapy | Lawrence Lesko, Ph.D.
Director, OCPB, CDER, FDA |
| 10:00 | An Industry Perspective | Douglas Mayers, M.D.
Boehringer Ingelheim Pharmaceuticals, Inc. |
| | Clarifying Questions | |
| 10:45 | Break | |
| 11:00 | CDRH Perspective on analytical and clinical considerations that go into a FDA approval of a "diagnostic test". Presentation of case studies | Steve Gutman, M.D.
Director, OIVD, CDRH |
| | Clarifying Questions | |
| 11:20 | Open Public Hearing | |

11:50	Committee discussion and questions for the committee	Jurgen Venitz, M.D., Ph.D. Chair, CPSC
1:00	Summary of recommendations	Lawrence Lesko, Ph.D. Director, OCPB, CDER, FDA
1:30	Adjourn	