

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)  
Cardiovascular and Renal Drugs Advisory Committee  
The National Labor College, Silver Spring, Maryland  
AGENDA  
October 16, 2007**

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*The committee will discuss regulatory considerations for extending the use of phosphate binders from the dialysis population (where they are approved) to the pre-dialysis population (where no products are approved). The committee will hear presentations from Shire Development, Genzyme Corporation, and Fresenius Medical Care.*

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| 8:00                                   | Call to Order and Introductions   | <b>Robert Harrington, M.D., F.A.C.C.</b><br>Acting Committee Chair<br>Cardiovascular and Renal Drugs Advisory Committee                          |
|  | Conflict of Interest Statement  | <b>LCDR Cathy A. Miller, M.P.H., R.N.</b><br>Designated Federal Official<br>Cardiovascular and Renal Drugs Advisory Committee                    |
| 8:05                                   | Introduction and Background   | <b>Norman Stockbridge, M.D., Ph.D.</b><br>Director, Division of Cardiovascular and Renal Products<br>FDA Center for Drug Evaluation and Research |
| 8:30                                   |   | <b>Open Public Hearing</b>   |
| <b>Sponsor Presentations:</b>          |   |  |
| 9:30                                   | Introduction of Invited Speakers  | <b>Raymond Pratt, M.D.</b><br>Research and Development Scientific Lead<br>Renal Business Unit<br>Shire Incorporated                              |
| 9:50                                   | Overview<br>Fresenius/Genzyme/Shire   | <b>Pamela M. Williamson, R.A.C.</b><br>Senior Vice President, Regulatory Affairs and<br>Collaboration Corporate Quality<br>Genzyme Corporation   |
| <b>FDA Guest Speaker Presentation:</b> |   |  |
| 10:00                                  | Chronic Kidney Disease-<br>Related Mineral and Bone<br>Disorders: Public Health Problem | <b>Kerry Willis, Ph.D.</b><br>Senior Vice President, Scientific Activities<br>National Kidney Foundation   |
| 10:15                                  |   | <b>Break</b>   |

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**Sponsor Presentations Continued:**

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| 10:30 | Pathophysiology of<br>Hyperphosphatemia  | <b>Keith Hruska, M.D.</b><br>Professor of Pediatrics, Medicine and Cell Biology<br>Unit Leader Pathobiology<br>Director Division of Pediatric Nephrology<br>Washington University School of Medicine    |
| 10:50 | Clinical Consequences of<br>Chronic Kidney Disease<br>Bone and Mineral Disease | <b>Peter McCullough, M.D., M.P.H.</b><br>Chief, Division of Nutrition and Preventive Medicine<br>William Beaumont Hospital  |
| 11:20 | Benefits and Risks of<br>Phosphate Binder Therapy<br>In Pre-Dialysis Patients  | <b>David Bushinsky, M.D.</b><br>Professor of Medicine, Nephrology Unit and of<br>Pharmacology and Physiology<br>Associate Chair of Medicine<br>University of Rochester School of Medicine and Dentistry |
| 11:50 | Fresenius/Genzyme/Shire<br>Conclusion  | <b>Jose Diaz-Buxo, M.D.</b><br>Medical Director, Products and Hospital Group<br>Senior Vice President, Home Therapies Development<br>Fresenius Medical Care   |
| 12:00 |  | Lunch   |
| 1:00  |  | <b>Questions to Presenters for Fresenius Medical Care,<br/>Genzyme Corporation and Shire Incorporated</b>   |
| 2:00  |  | <b>Break</b>  |
| 2:15  |  | <b>Committee Discussion</b>   |
| 3:00  |  | <b>Question to the Committee</b>  |
| 5:00  |  | <b>Adjournment</b>  |