**FOOD AND DRUG ADMINISTRATION (FDA)**
**CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**
*Antiviral Drugs Advisory Committee*
**Hilton Washington, DC/Silver Spring**
**December 2, 2008**
**Agenda**
**OPEN SESSION**

The committee will discuss the safety and efficacy of new drug application (NDA) 20-725, Creon (Pancrelipase Delayed-Release Capsules), Solvay Pharmaceuticals, Inc., for the treatment of exocrine pancreatic insufficiency.

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| 10:30 a.m. – 10:35 a.m. | Call to Order<br>Introduction of Committee | **Ian McGowan, M.D., Ph.D., FRCP**<br>Chair<br>Antiviral Drugs Advisory Committee (AVDAC) |
| 10:35 a.m. – 10:40 a.m. | Conflict of Interest Statement | **Paul Tran, RPh**<br>Designated Federal Official, AVDAC |
| 10:40 a.m. – 10:45 a.m. | Opening Remarks | **Anne Pariser, M.D.**<br>Medical Team Leader<br>Division of Gastroenterology Products<br>Office of New Drugs, CDER, FDA |
| 10:45 a.m. – 11:45 a.m. | **Presentations from Sponsor**<br>Introduction | **Victor Raczkowski, M.D.**<br>Vice President, US Regulatory Affairs<br>Solvay Pharmaceuticals, Inc. |
| | Medical Need for Pancreatic Enzyme Replacement Therapy | **Virginia Stallings, M.D.**<br>Director, Nutrition Center<br>Professor of Pediatrics<br>Children's Hospital of Philadelphia |
| | Clinical Efficacy & Safety | **Earl Sands, M.D.**<br>Vice President, Research & Development<br>Solvay Pharmaceuticals, Inc. |
| | Assessment of Porcine Viruses | **X.J. Meng, M.D., Ph.D.**<br>Professor of Molecular Virology<br>College of Veterinary Medicine<br>Virginia Polytechnic Institute and State University |
| | Risk Mitigation Strategies | **Earl Sands, M.D.**<br>Vice President, Research & Development<br>Solvay Pharmaceuticals, Inc. |
| | Conclusions | **Solvay Pharmaceuticals, Inc.** |
| 11:45 a.m. – 12:45 p.m. | **Presentations from FDA** | |
| | NDA 20-725 Pancrelipase Delayed-Release Capsules (Creon®) | **Ethan Hausman, M.D.**<br>Medical Officer<br>Division of Gastroenterology Products<br>CDER, FDA |
| | Viral Safety Issues for Pancreatic Enzyme Products Creon® | **Barry Cherney, Ph.D.**<br>Deputy Director<br>Division of Therapeutic Proteins<br>CDER, FDA |
| 12:45 p.m. – 1:45 p.m. | Lunch Break | |

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| 1:45 p.m. – 2: 45 p.m. | Open Public Hearing (OPH) Session | |
| 2:45 p.m. – 2:50 p.m. | Charge to the Committee | **Anne Pariser, M.D.**<br>Medical Team Leader<br>Division of Gastroenterology Products<br>Office of New Drugs, CDER, FDA |
| 2:50 p.m. – 5:00 p.m. | Advisory Committee Discussion | |
| 5:00 p.m. | **Adjourn** | |