# FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

*Psychopharmacologic Drugs Advisory Committee Meeting (PDAC)*

HILTON WASHINGTON DC/SILVER SPRING
THE MARYLAND BALLROOMS
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND

APRIL 7, 2009

**AGENDA**

The committee will discuss safety and efficacy issues of new drug application (NDA) 20-644, Serdolect (sertindole) tablets, Lundbeck USA, proposed for the treatment of schizophrenia.

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| 8:00 a.m. | Call to Order and Opening Remarks | **Wayne Goodman, M.D.**<br>Acting Chair,<br>PDAC |
| | Introduction of Committee | |
| | Conflict of Interest Statement | **Yvette Waples, Pharm.D.**<br>Designated Federal Official |
| 8:15 a.m. | FDA Introductory Remarks | **Thomas Laughren, M.D.**<br>Director, Division of Psychiatry Products (DPP)<br>Office of New Drugs (OND)<br>CDER, FDA |

**INDUSTRY PRESENTATION**

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| 8:20 a.m. | Introduction | **Anders Gersel Pedersen, M.D.**<br>Executive VP<br>H. Lundbeck A/S |
| 8:30 a.m. | Schizophrenia, the disease with focus on suicide | **To Be Determined** |
| 8:40 a.m. | Clinical Efficacy | **Raimund Buller M.D.**<br>Director, Clinical Research, Psychosis<br>H. Lundbeck A/S |
| 9:10 a.m. | Clinical Safety | **Lasse Steen Ravn, M.D.**<br>Department Head, Safety for Psychiatry<br>H. Lundbeck A/S |
| 9:40 a.m. | Risk Management and Benefit/Risk | **Anders Gersel Pedersen, M.D.**<br>Executive VP<br>H. Lundbeck A/S |

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**AGENDA**
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| 10:10 a.m. | Clarifying Questions | |
| 10:30 a.m. | **BREAK** | |
| **FDA PRESENTATION** | | |
| 10:40 a.m. | Clinical Aspects of Safety and Efficacy of Sertindole | **Phillip Kronstein, M.D.**<br>Medical Reviewer, DPP<br>CDER, FDA |
| 11:30 a.m. | Electrophysiologic Aspects of Sertindole | **Shari Targum, M.D.**<br>Team Leader<br>Division of Cardiovascular and Renal Products<br>CDER, FDA<br><br>**Christine E. Garnett, PharmD**<br>Scientific Lead, Interdisciplinary Review Team for QT Studies<br>Associate Director, Pharmacometric Operations<br>Division of Pharmacometrics<br>Office of Clinical Pharmacology<br>CDER, FDA |
| 11:45 a.m. | Risk Management Considerations for Sertindole | **Mary Willy, Ph.D.**<br>Team Leader, Risk Management Analyst Team<br>Division of Risk Management, Office of Surveillance and Epidemiology<br>CDER, FDA |
| 12:00 p.m. | Clarifying Questions | |
| 12:15 p.m. | **LUNCH** | |
| 1:15 p.m. | Open Public Hearing | |
| 2:15 p.m. | Questions/Clarifications | |
| 3:00 p.m. | **BREAK** | |
| 3:15 p.m. | Committee Deliberations | |
| 5:00 p.m. | **ADJOURNMENT** | |