

**Food and Drug Administration
Center for Drug Evaluation and Research**

**MEETING OF THE ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE
(ALSDAC)**

March 11, 2008

Washington DC Hilton-Silver Spring
8727 Colesville Road
Silver Spring, MD

AGENDA

New Drug Application (NDA) 22-225, sugammadex sodium injection (proposed tradename BRIDION), Organon USA Inc., proposed indication of routine reversal of shallow and profound neuromuscular blockade (NMB) induced by rocuronium or vecuronium and immediate reversal of NMB at three minutes after administration of rocuronium.

- | | | |
|------|---|--|
| 8:30 | Call to Order and Introduction of Committees | John T. Farrar, M.D.
Acting Chair, ALSDAC |
| 8:35 | Conflict of Interest Statement | Mimi Phan, Pharm.D., R.Ph.
Designated Federal Officer, ALSDAC |
| 8:40 | Introduction to Meeting | Bob Rappaport, M.D.
Director, Division of Anesthesia, Analgesia, and
Rheumatology Products (DAARP)/CDER/FDA |

INDUSTRY PRESENTATION

- | | | |
|------|---|--|
| 9:00 | Sugammadex: A Novel Reversal Agent for NMB | TBD
Organon/Schering-Plough representative |
| | Introduction | TBD
Organon/Schering-Plough representative |
| | Unmet Medical Need | TBD
Organon/Schering-Plough representative |
| | Mechanism of Action, Pharmacology,
Pharmacokinetics and Drug-Drug Interactions | TBD
Organon/Schering-Plough representative |
| | Efficacy and Safety Clinical Overview | TBD
Organon/Schering-Plough representative |
| | Summary | TBD
Organon/Schering-Plough representative |

**Food and Drug Administration
Center for Drug Evaluation and Research**

**MEETING OF THE ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE
(ALSDAC)**

March 11, 2008

Washington DC Hilton-Silver Spring
8727 Colesville Road
Silver Spring, MD

AGENDA

New Drug Application (NDA) 22-225, sugammadex sodium injection (proposed tradename BRIDION), Organon USA Inc., proposed indication of routine reversal of shallow and profound neuromuscular blockade (NMB) induced by rocuronium or vecuronium and immediate reversal of NMB at three minutes after administration of rocuronium.

10:30 *Questions from the Committee*

10:45 **Break**

FDA PRESENTATIONS

11:00 **Sugammadex: Efficacy and Outlier Analysis**

Rob Shibuya, M.D.

Medical Officer, Division of Anesthetic, Analgesic, and Rheumatology Products (DAARP)/CDER/FDA

11:20 **Sugammadex: Safety Considerations**

Arthur Simone, M.D., Ph.D.

Medical Officer, Division of Anesthetic, Analgesic, and Rheumatology Products (DAARP)/CDER/FDA

11:40 *Questions from the Committee*

12:00 Lunch

1:00 **Open Public Hearing**

2:00 **FDA Summary of Issues**

Bob Rappaport, M.D.

Director, Division of Anesthetic, Analgesic, and Rheumatology Products (DAARP)/CDER/FDA

2:30 *Discussion*

3:30 *Questions to the Committee and Recommendations*

5:00 **Adjourn**