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

Introduction  June Bray, M.B.A, R.Ph.
Vice President, Regulatory Affairs
Organon, a part of Schering-Plough Corp.

Unmet Medical Need  Ronald D. Miller, M.D.
Professor and Chairman, Department of Anesthesia and Perioperative Care- University of California, San Francisco, School of Medicine, San Francisco, CA

Mechanism of Action, and Pharmacology and Pharmacokinetics  Anton Bom, M.D., Ph.D.
Senior Research Fellow, Pharmacology, Organon, a part of Schering-Plough Corp.

Non-clinical Safety Overview  Diels van Den Dobbelsteen, Ph.D.
Principal Toxicologist
Organon, a part of Schering-Plough Corp.
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**Efficacy and Safety Clinical Overview**  
Patrick Boen, M.D.  
Senior Director Medical Services, Anesthesia  
Organon, a part of Schering-Plough Corp.

**Summary**  
Ronald D. Miller, M.D.  
Professor and Chairman,  
UCSF, CA

10:30  *Questions from the Committee*

10:45  *Break*

**FDA PRESENTATIONS**

11:00  *Sugammadex: Efficacy and Outlier Analysis*  
Robert B. Shibuya, M.D.  
Medical Officer,  
DAARP/CDER/FDA

11:20  *Sugammadex: Safety Considerations*  
Arthur Simone, M.D., Ph.D.  
Medical Officer,  
DAARP/CDER/FDA

11:40  *Preclinical FDA Response*  
Adam Wasserman, Ph.D.  
Supervisory, Pharmcology/Toxicology  
DAARP/CDER/FDA

12:00  *Lunch*

1:00  *Open Public Hearing*

2:00  *Questions from the Committee*
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