

**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 Dobbelen, 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, Pharmacology/Toxicology
DAARP/CDER/FDA

12:00 Lunch

1:00 **Open Public Hearing**

2:00 *Questions from the Committee*

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2:20 **FDA Summary of Issues**

Mary Purucker, M.D., Ph.D.
Medical Team Leader,
DAARP/CDER/FDA

2:50 **Break**

3:05 *Discussion*

4:05 *Questions to the Committee and Recommendations*

5:00 **Adjourn**