



ANNUAL REPORT
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE

for the period

October 1, 2004 through September 30, 2005

FUNCTION

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The Panels engage in a number of activities to fulfill the functions the Federal Food, Drug and Cosmetic Act envisions for device advisory Panels. With the exception of the Medical Devices Dispute Resolution Panel, each Panel, according to its specialty area, advises the Commissioner of Food and Drugs regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each Panel, according to its specialty area, may also make appropriate recommendations to the Commissioner of Food and Drugs on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug Panel. The functions of the dental drug Panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory Panel proceedings or Agency decisions or actions.

MEETINGS

The Medical Devices Advisory Committee held 17 meetings during the reporting period in Gaithersburg, Maryland.

Below are the dates of all device panel meetings during FY 2005 (10/1/04 to 9/30/05) and UNDERLINED dates represent meetings that had closed sessions:

<u>10/06/04</u> Devices	Joint meeting of the Dental Products Panel and the Ear, Nose and Throat Panel
<u>11/30/04</u>	Neurology Devices Panel
01/13/05	Circulatory System Devices Panel
03/17/05	Circulatory System Devices Panel
04/11-13/05	General and Plastic Surgery Devices Panel
04/22/05	Circulatory System Devices panel
05/13/05	Anesthesiology and Respiratory Therapy Devices Panel
05/17/05	Obstetrics and Gynecology Devices Panel
06/08/05	Gastroenterology and Urology Devices Panel
06/17/05	Neurology Devices Panel
06/22-23/05	Circulatory System Devices Panel
06/23/05	Obstetrics and Gynecology Devices Panel
07/15/05	Immunology Devices Panel
08/9/05	General Hospital and Personal Use Devices Panel
08/25-26/05	General and Plastic Surgery Devices panel
<u>09/8-9/05</u>	Orthopaedic and Rehabilitation Devices Panel
09/27/05	General Hospital and Personal Use Devices Panel

DENTAL PRODUCTS PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Panel met once during the reporting period at a joint meeting with the Ear, Nose and Throat Devices Panel in Gaithersburg, Maryland.

The date of the meeting was October 6, 2004.

The joint meeting on October 6, 2004 included a closed session to permit a discussion of trade secret or confidential commercial information.

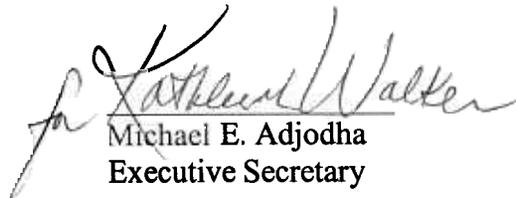
ACCOMPLISHMENTS

In the open session, during this joint meeting of the Dental Products Panel and the Ear, Nose and Throat Devices Panel, the discussion included the role of the medical/dental provider in the diagnosis, treatment and follow-up of snoring and obstructive sleep apnea (OSA); the ability of the patient to self diagnose and treat OSA; the types of clinical data that would be needed to support an over-the-counter (OTC) intended use; and the components of adequate device labeling. The Panel agreed that clinical data should be included in a marketing application to assist in evaluating the safety and effectiveness of treatment. There were differing opinions on the necessity and type of controls but concurrence on the need for safety and effectiveness data, particularly for devices indicated for OSA. Overall, the Panel did not support OTC availability for any of the device types currently marketed with the prescription use only restriction.

Closed Committee Deliberations: On October 6, 2004, the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information relevant to pending and future device submissions for ear, nose and throat devices. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

September 30, 2005

Date


Michael E. Adjodha
Executive Secretary

Dental Products Panel Roster

Chairperson

Jon B. Suzuki, D.D.S., Ph.D.

Expertise: Periodontics
Term: 3/22/04 - 10/31/05
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Expertise: Cariology; Dental Sciences,
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*Consumer Representative

**Industry Representative

Ear, Nose, and Throat Devices Panel Roster

Chairperson

Eric A. Mair, M.D., FAAP

Expertise: Otolaryngology, Pediatric
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Sigfrid D. Soli, Ph.D.

Expertise: Sensory and Communicative
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Expertise: Otolaryngology
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*** Carolyn R. Stern, M.D.**

Expertise: Family Medicine
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Expertise: Medical Devices Quality System
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Debara L. Tucci

Expertise: Sensory Aids Technology
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Page 2 – Ear, Nose and Throat Devices Panel Roster (continued)

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**** R. Michael Crompton, JD, MPH**

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* Consumer Representatives

** Industry Representatives

NEUROLOGICAL DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Panel met two times during the reporting period in Gaithersburg, Maryland.

The dates of those meetings were November 30, 2004, and June 17, 2005.

The meeting on November 30, 2004 included a closed session to permit a discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

At the November 30, 2004 meeting:

In the open session, the Panel deliberated on Confluent Surgical, Inc.'s PMA for the DuraSeal™ Dura Sealant System intended for use as an adjunct to sutured dura repair during cranial surgery to provide watertight closure. The Panel recommended conditional approval with the following conditions of the sponsor:

- conduct a postmarket surveillance study of the infection rate of patients treated with the device;
- provide data regarding MRI and CT imaging analyses to demonstrate the characteristics of the image viewed by MRI and CT and the duration of time it will be seen; and
- labeling recommendations.

At the June 17, 2005 meeting:

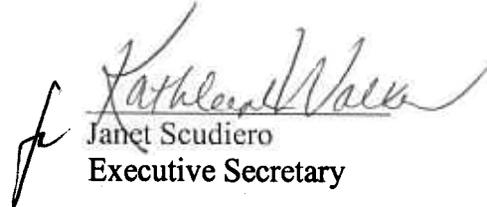
In the open session, the Panel deliberated on a PMA from Olympic Medical Corporation for the Cool-Cap®. This selective head cooling system is intended for use in infants 36 weeks of gestation or older at risk for moderate to severe hypoxic ischemic encephalopathy (HIE) to prevent or reduce the severity of HIE. The Panel recommended approval with conditions. The conditions included:

- a registry should be instituted to collect information on real world device usage to track patient outcome;
- a training and certification process should be required for all users of the device; and
- use of the device should be restricted to the protocol-defined patient population.

Neurology Devices Panel (continued)

Closed Committee Deliberations: On November 30, 2004, the meeting was closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C.552b(c)(4)) relating to pending issues and applications.

September 30, 2005
Date


Janet Scudiero
Executive Secretary

Neurological Devices Panel Roster

Chairperson

Stephen J. Haines, M.D.

Expertise: Clinical Medical Sciences
Term: 13/12/02 - 11/30/05
Professor and Head of the Dept. of
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Annapurni Jayam-Trouth, M.D.

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****Robert J. Coffey, M.D.**

Expertise: Neurosurgery
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Expertise: Interventional and Diagnostic
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and
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Page 2 – Neurological Devices Panel Roster (continued)

Chairperson

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* Consumer Representative

** Industry Representative

ORTHOPAEDIC and REHABILITATION DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Panel met one time during the reporting period in Gaithersburg, Maryland.

The date of the meeting was September 8-9, 2005.

The meeting on September 8, 2005 included a closed session to permit a discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

At the September 8-9, 2005 meeting:

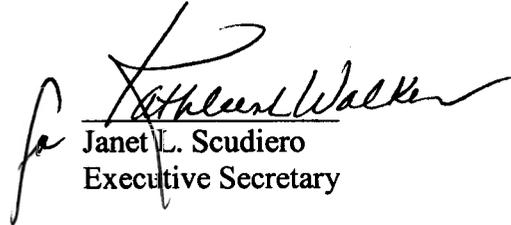
In the open session, on the first of two days, a PMA for the Smith and Nephew Birmingham Hip Resurfacing (BHR) System was discussed. This hip joint metal/metal semi-constrained resurfacing hybrid prosthesis (cemented femoral component and uncemented acetabular component) is intended to relieve hip pain and improve hip function in patients who have adequate bone stock and are at risk of requiring more than one hip joint replacement over their lifetimes. The Panel recommended conditional approval with the following conditions: the sponsor should conduct the proposed post-approval study as presented in the PMA with the addition of clinical and radiographic evaluation at the 10-year follow-up, a statistically valid sample size, and scientifically valid success criteria.

On the second day, the Panel heard presentations from orthopaedic device manufacturers and professional societies on the design of clinical studies for spinal devices to treat mild to moderate low back pain, such as prosthetic nucleus replacements, interspinous spacers, and pedicle screw based stabilizing systems. The Panel addressed FDA's questions on the design of clinical studies for these new device types. The Panel concluded that it may be too early in our understanding of these devices and the diagnostic continuum for which they are intended to create rigid guidelines for clinical studies of these device types. They recommended that each study design be considered on a case by case basis. The Panel concluded that it is most important that the patients receive clinically appropriate care and that the studies are scientifically valid.

Orthopaedic and Rehabilitation Devices Panel (continued)

Closed Committee Deliberations: On September 8, 2005, the meeting was closed to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) relating to pending issues and applications.

September 30, 2005
Date


Janet L. Scudiero
Executive Secretary

Orthopaedic and Rehabilitation Devices Panel Roster

Executive Secretary

Janet Scudiero

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****Pamela W. Adams, RAC**

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*** Connie F. Whittington, MSN, RN, ONC**

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Page 2 - Orthopaedic and Rehabilitation Devices Panel Roster (continued)

Chairperson

Michael J. Yaszemski, M.D., Ph.D.

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