



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville MD 20857

Federal Advisory Committee Desk  
United States Acquisitions Section  
Anglo-American Acquisitions Division  
Library of Congress  
Washington, DC 20540-4174

Dear Sir or Madam,

Enclosed please find the Closed Meeting Report of the Food and Drug Administration (FDA) for the fiscal year 2005. A list of the Advisory Committees that held closed meetings during FY 2005 is attached.

These reports are submitted pursuant to Section 10(d) of the Federal Advisory Committee Act which requires each advisory committee which hold closed meeting "shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of title 5, United States Code."

-If you should need further information, please contact me directly 301-827-1220.

Sincerely,

A handwritten signature in black ink, appearing to read "Theresa L. Green", is written over a circular stamp. The signature is fluid and cursive.

Theresa L. Green  
Committee Management Officer  
Advisory Committee Oversight and  
Management Staff

Enclosures

List of the  
Advisory Committees of the Food and Drug Administration  
That Held Closed Meetings  
Fiscal Year 2005

*Center for Biologics Evaluation and Research:*

Blood Products Advisory Committee,

Cellular, Tissue and Gene Therapies Advisory Committee (formerly the  
Biological Response Modifiers Advisory Committee),

Vaccines and Related Biological Products Advisory Committee,

*Center for Devices and Radiological Health:*

Medical Devices Advisory Committee. (consisting of reports for Dental Products  
Panel; Ear Nose and Throat Devices Panel; Neurology Devices Panel; Orthopedic and  
Rehabilitation Devices Panel



ANNUAL REPORT  
OF THE  
BLOOD PRODUCTS ADVISORY COMMITTEE

For the period

October 1, 2004 through September 30, 2005

FUNCTION

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility, and advises the Commissioner of Food and Drugs of its findings regarding the safety, effectiveness, and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological product licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; 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.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met five times during the reporting period. Meetings were held in Gaithersburg, Maryland and Rockville, Maryland.

The dates of those meetings were October 21-22, 2004, March 17-18, 2005, July 21, 2005, July 22, 2005, and September 29, 2005.

The meetings on March 17-18, 2005, July 22, 2005, and September 29, 2005 included closed sessions to permit discussion of trade secret or confidential commercial information or matters of a personal nature.

## ACCOMPLISHMENTS

March 17-18, 2005. The Committee discussed and made recommendations on the following topics: the safety of albumin revisited, the review of standards for plasma products for transfusion, and a study design for abbreviated uniform donor history questionnaire. FDA is currently evaluating these issues. On March 18, 2005 in open session, the Committee reviewed and discussed the Laboratory of Molecular Virology. On March 18, 2005, the Committee held a closed session to permit discussion of personnel and program actions for the Laboratory of Virology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

July 22, 2005 Subcommittee meeting. The Subcommittee discussed and made recommendations on the research programs in the Office of Blood Research and Review. These discussions related to components of the Strategic Plan of 2004 and FDA's Critical Path to New Medical Products. The Subcommittee held a closed session to permit discussion of personnel and program actions for the intramural programs in the Office of Blood Research and Review. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6) and the review of trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The recommendations will be discussed at a future meeting of the Blood Products Advisory Committee.

September 29, 2005. The Committee reviewed, discussed, and made recommendations on the safety of Exjade (deferasirox – tablets for oral suspension) for the treatment of chronic iron overload due to blood transfusions manufactured by Novartis Pharmaceuticals. FDA is currently evaluating the recommendations. The Committee also reviewed and discussed the research programs in the Laboratory of Hemostasis and the Laboratory of Plasma Derivatives, Division of Hematology, Office of Blood Research and Review. The Committee held a closed session to permit discussion of personnel and program actions for the Laboratory of Hemostasis and the Laboratory of Plasma Derivatives. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

Detailed information related to these meetings is available in the annual report.

20/26/05  
Date

Donald W. Jehn  
Donald W. Jehn  
Executive Secretary

# Blood Products Advisory Committee

## Committee Roster

### ***Chairman***

**James R. Allen, M.D., M.P.H.**

Expertise: Public Health, Epidemiology

Term: 02/08/02 - 09/30/06

President and CEO

American Social Health Association

P.O. Box 13827

Research Triangle Park, NC 27709

**Judith R. Baker, M.H.S.A.\***

Expertise: Consumer Representative

Term: 06/29/05-09/30/08

Regional Coordinator

Federal Hemophilia Treatment Centers/Region IX

Childrens Hospital Los Angeles

4650 Sunset Boulevard, Box 54

Los Angeles, CA 90028

**Kenneth Davis, Jr., M.D.**

Expertise: Trauma, Critical Care

Anesthesiology

Term: 02/08/02 - 09/30/05

Professor of Surgery and Clinical Anesthesia

Vice Chairman, Dept. of Surgery

231 Albert Sabin Way, ML 558

Cincinnati, OH 45267-0558

**Donna M. DiMichele, M.D.**

Expertise: Pediatric Hematology, Oncology

Term: 02/08/02 - 09/30/05

Associate Prof. of Clinical Pediatrics

Weill Med. College & Graduate School of

Medical Sciences

Cornell University

525 East 68th Street, Room P-695

New York, New York 10021

**Samuel H. Doppelt, M.D.**

Expertise: Orthopedic Surgery, Transplantation

Term: 02/08/02 - 09/30/05

Chief, Dept. of Orthopedic Surgery

The Cambridge Hospital

1493 Cambridge Street

Cambridge, MA 02139

### ***Executive Secretary***

Donald Jehn

Center for Biologics Evaluation and Research

1401 Rockville Pike (HFM-71)

Food and Drug Administration

Rockville, MD 20852-1448

TEL: (301) 827-1277

FAX: (301) 827-0294

E-mail: Donald.Jehn@fda.hhs.gov

**Judy F. Lew, M.D.**

Expertise: Infectious Disease, Molecular Epidemiology

Term: 02/08/05 - 09/30/05

Asst. Prof. of Pediatrics

Univ. of Florida

Dept. of Pediatric Immunology & Infectious Diseases

P.O. Box 100296

Gainesville, FL 32610

**Catherine S. Manno, M.D.**

Expertise: Hematology, Oncology

Term: 11/30/04 - 09/30/07

Associate Professor of Pediatrics

The Children's Hospital of Philadelphia

Physician-in-Chief Office

9th Floor, Main Hospital

34th Street and Civic Center Boulevard

Philadelphia, PA 19104

**Keith C. Quirolo, M.D.**

Transfusion Medicine, Hematology, Biology

Term: 11/30/04 - 09/30/07

Hemoglobinopathy Pediatrician

Department of Hematology

Children's Hospital and Research Center at

Oakland

747 52nd Street

Oakland, CA 94609-1809

**George B. Schreiber, Sc.D.**

Expertise: Epidemiology, Health Studies

Term: 11/30/04 - 09/30/07

Associate Director for Health Studies

Westat

1650 Research Blvd., WB272

Rockville, MD 20850

Jonathan C. Goldsmith, M.D.  
Expertise: Internal Medicine/Hematology  
Term: 02/13/03 – 02/17/05  
Vice President, Medical Affairs  
Immune Deficiency Foundation  
40 West Chesapeake Avenue, Suite 308  
Towson, MD 21204

Donna S. Whittaker, Ph.D.  
Expertise: Medical Technology, Transfusion  
Medicine, Immunology  
Term: 11/30/04 - 09/30/07  
Director  
Robertson Blood Center (MCXI-BBC)  
36000 Darnall Loop, Box #7  
Fort Hood, TX 76544

Louis M. Katz, M.D.\*\*  
Expertise: Industry Representative  
Term: 06/29/05-09/30/08  
Executive Vice President, Medical Affairs  
Mississippi Valley Regional Blood Center  
5500 Lake View Parkway  
Davenport, IA 52807

Harvey G. Klein, M.D.  
Expertise: Transfusion Medicine  
Term: 02/08/02 - 09/30/05  
Chief, Dept. of Transfusion Med.  
National Institutes of Health  
Warren G. Magnuson Clinical Center  
10 Center Dr., Bldg. 10, Rm. 1C711  
Bethesda, MD 20892

Matthew J. Kuehnert, M.D.  
Expertise: Infectious Diseases, Internal  
Medicine, Biochemistry and Cell Biology  
Term: 11/30/04 - 09/30/07  
CDR, U.S. Public Health Service Assistant  
Director for Blood Safety  
Division of Viral and Rickettsial Diseases  
Centers for Disease Control and Prevention  
(CDC)  
1600 Clifton Road, Mailstop A-30  
Atlanta, GA 30333

Suman Laal, Ph.D.  
Expertise: Immunology, Microbiology  
Term: 02/08/02 - 09/30/05  
Assistant Professor  
Department of Pathology  
New York University School of Med.  
423 East 23rd Street, Rm. 18124N  
VA Medical Center  
New York, NY 10010

\*CONSUMER REPRESENTATIVE

\*\*NON-VOTING INDUSTRY REPRESENTATIVE



ANNUAL REPORT  
OF THE  
CELLULAR, TISSUE AND GENE THERAPIES ADVISORY COMMITTEE  
(formerly the Biological Response Modifiers Advisory Committee)

For the period

October 1, 2004 through September 30, 2005

FUNCTION

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Foods and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met four times during the reporting period. Meetings were held in Bethesda, Maryland and Rockville, Maryland.

The dates of those meetings were March 3-4, 2005, May 20, 2005, July 29, 2005, and September 29, 2005.

The meetings on May 20, 2005, July 29, 2005, and September 29, 2005 included a closed session to permit discussion of matters of a personal nature and trade secret and/or confidential information.

ACCOMPLISHMENTS

May 20, 2005 in Rockville, Maryland via teleconference. The Committee reviewed and discussed the following topics: the Clinical Proteomics Program and the research programs in the Division of Therapeutic Proteins. The Committee held a closed session to discuss and make recommendations on personnel and program actions for the Laboratory of Chemistry and the Laboratory of Immunology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

July 29, 2005 in Bethesda, Maryland via teleconference. The topics included an Open Public Hearing on the Division of Therapeutic Proteins. The Committee held a closed session to discuss and make recommendations on personnel and program actions for the Laboratory of Chemistry and the Laboratory of Immunology. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

September 29, 2005 Subcommittee meeting. The Subcommittee discussed and made recommendations on the research program of the Office of Cellular, Tissue and Gene Therapies. The discussions related to components of the Strategic Plan of 2004 and FDA's Critical Path to New Medical Products. The Committee held a closed session to permit discussion of personnel and program actions for intramural programs in the Office of Cellular, Tissue and Gene Therapies. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6) and the review of trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The recommendations will be discussed at a future meeting of the Cellular, Tissue and Gene Therapies Advisory Committee.

Detailed information related to these meetings is available in the annual report.

October 26, 2005  
Date

Gail Dapolito  
Gail Dapolito  
Executive Secretary

**Cellular, Tissue and Gene Therapies Advisory Committee  
(formerly the Biological Response Modifiers Advisory Committee)**

**Committee Roster**

***Chair***

**Mahendra S. Rao, M.D., Ph.D.**

Expertise: Cellular Biology  
Term: 05-22-2001 - 03-31-2006  
Chief Stem Cell Biology Section  
Laboratory of Neurosciences, 4B17  
Gerontology Research Center  
National Institute on Aging  
National Institutes of Health  
5600 Nathan Shock Drive  
Baltimore, Maryland 21224

**Jonathan S. Allan, D.V.M.**

Expertise: Veterinary Medicine  
Term: 09-30-2002 - 03-31-2006  
Scientist  
Department of Molecular and Experimental  
Medicine  
Department of Virology and Immunology  
Southwest Foundation for Biomedical  
Research  
7620 N.W. Loop 410 at Military Drive  
San Antonio, Texas 77030

**Michèle P. Calos, Ph.D.**

Expertise: Biochemistry/Molecular Biology  
Term: 09-13-2004 - 03-31-2008  
Associate Professor of Genetics  
Department of Genetics, Rm. 334  
Stanford University School of Medicine  
300 Pasteur Drive  
Stanford, California 94305-5120

**Jeffrey S. Chamberlain, Ph.D.**

Expertise: Genetics/Gene Therapy  
Term: 09-29-2005 – 03-31-2009  
Professor  
Departments Neurology, Medicine and  
Biochemistry  
Health Sciences Center  
University of Washington School of Medicine  
1959 N.E. Pacific Street  
Seattle, Washington 98195-7720

***Executive Secretary***

**Gail Dapolito**

Center for Biologics Evaluation and Research  
Food and Drug Administration  
1401 Rockville Pike (HFM-71)  
Rockville, Maryland 20852-1448  
E-mail: [dapolito@cber.fda.gov](mailto:dapolito@cber.fda.gov)  
Phone: 301-827-0314  
Facsimile: 301-827-0294

**James J. Mule, Ph.D.**

Expertise: Tumor Immunology /  
Immunotherapy  
Term: 01-05-2004 - 03-31-2007  
Associate Center Director  
Translation Science and Technology  
Development  
Michael McGillicuddy Endowed Chair  
Melanoma Research and Treatment  
H. Lee Moffitt Cancer Center and  
Research Institute  
12902 Magnolia Drive, SRB-2  
Tampa, Florida 33612

**Sharon F. Terry, MS\***

Expertise: Genetics/Consumer  
Representative  
Term: 01-23-2005 - 03-31-2008  
President and CEO  
Genetic Alliance Organization  
Suite 404  
4301 Connecticut Avenue, NW  
Washington, DC 20008-2369

**William W. Tomford, Ph.D.**

Expertise: Orthopedic Surgery  
Term: 09-13-2004 - 03-31-2008  
Professor of Orthopedic Surgery  
Massachusetts General Hospital  
55 Fruit Street  
Boston, Massachusetts 02114

Kurt C. Gunter, M.D.\*\*  
Expertise: Industry Representative  
Term: 09-29-2005 – 03-31-2009  
Vice President, Clinical and Medical  
Affairs/Government Relations  
ZymeQuest, Inc.  
100 Cummings Center  
Suite 436H  
Beverly, Massachusetts 01915-6122

David M. Harlan, M.D.  
Expertise: Transplantation, Autoimmunity  
Term: 09-30-2002 - 03-31-2006  
Captain, U.S. Public Health Service and  
Chief, Islet and Autoimmunity Branch  
National Institute of Diabetes and Digestive  
and Kidney Disease, NIH, DHHS  
10 Center Drive, Building 10, Room 8N307  
Bethesda, Maryland 20892

Anastasios A. Tsiatis, Ph.D.  
Expertise: Biostatistics  
Term: 09-30-2002 - 03-31-2006  
Professor  
Department of Statistics  
North Carolina State University, Box  
8203  
2501 Founders Drive  
Raleigh, North Carolina 27696

Walter John Urba, M.D., Ph.D.  
Expertise: Hematology/Oncology  
Term: 09-29-2005 – 03-31-2009  
Medical Director  
Robert W. Franz Cancer Research Center  
Earle A. Chiles Research Institute  
Providence Portland Medical Center  
4805 N.E. Glisan St., 5F-40  
Portland, Oregon 97213

\*Consumer Representative

\*\*Industry Representative



ANNUAL REPORT  
OF THE  
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

For the period

October 1, 2004 through September 30, 2005

**FUNCTION**

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

**MEMBERSHIP**

A roster of members is attached.

**MEETINGS**

The Committee met three times during the reporting period. Meetings were held in Bethesda, Maryland. One meeting was held by teleconference.

The dates of those meetings were February 16-17, 2005, March 15, 2005, and September 22, 2005.

The meetings on February 16-17, 2005, and September 22, 2005 included closed sessions to permit discussion of secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

February 16-17, 2005 meeting in Bethesda, MD. The Committee reviewed and discussed the following topics: the strain selection for the Influenza Virus Vaccine for the 2005-2006 season including strain characterization; the FDA Critical Path Initiative; and the research programs in the Laboratory of Biophysics, and the Laboratory of Pediatrics and Respiratory Viral Diseases. In the afternoon of February 17, 2005, the Committee held a closed session to make recommendations on personnel and program actions for the Laboratory of Biophysics, and the Laboratory of Pediatrics and Respiratory Viral Diseases. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review. Also, in closed session the Committee heard an update on a Phase III trial for a vaccine manufactured by GlaxoSmithKline. Disclosure of the information reviewed involved trade secrets and/or confidential information in accordance with 5 U.S.C. 552b(c)(4). The vaccine, Fluarix, was licensed by FDA.

September 22, 2005 via teleconference on the National Institutes of Health campus in Bethesda, Maryland. The Committee discussed and reviewed the Laboratory of Retroviruses, the Laboratory of Immunoregulation, the Laboratory of Respiratory and Special Pathogens, and the Laboratory of Methods Development and Quality Control. The Committee held a closed session to make recommendations on personnel and program actions for the Laboratory of Retroviruses, the Laboratory of Immunoregulation, the Laboratory of Respiratory and Special Pathogens, and the Laboratory of Methods Development and Quality Control. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

Detailed information related to these meetings is available in the annual report.

October 26, 2005  
Date

Christine A. Walsh  
Christine A. Walsh, R.N.  
Executive Secretary

# Vaccines and Related Biological Products Advisory Committee

## Committee Roster

### ***Chair***

#### **Gary D. Overturf, M.D.**

Expertise: Pediatrics  
Term: 02/01/02 - 01/31/06  
Professor of Pediatrics and Pathology  
University of New Mexico Center  
Ambulatory Care Center, 3rd Floor  
2211 Lomas Avenue, N.E.  
Albuquerque, New Mexico 87131

#### **Monica M. Farley, M.D.**

Expertise: Bacterial Infectious Diseases  
Term: 02/01/04 - 01/31/08  
Professor of Medicine  
Department of Medicine  
Emory University School of Medicine  
VA Medical Center  
Research - Infectious Diseases (151)  
1670 Clairmont Road  
Atlanta, Georgia 30033

#### **Ruth A. Karron, M.D.**

Expertise: Pediatrics & Infectious Diseases  
Term: 02/01/03 - 01/31/07  
Associate Professor  
Division of International Health  
Johns Hopkins School of Hygiene and Public Health  
624 N. Broadway  
Hampton House, Room 117  
Baltimore, Maryland 21205

#### **Philip S. LaRussa, M.D.**

Expertise: Pediatrics / Virology  
Term: 02/01/04 - 01/31/08  
Professor of Clinical Pediatrics  
Columbia University, PH-4 West - 462  
622 West 168th Street  
New York, New York 10032

#### **David M. Markovitz, M.D.**

Expertise: Infectious Diseases  
Term: 04/01/02 - 01/31/06  
Professor  
Division of Infectious Diseases  
Department of Internal Medicine  
University of Michigan Medical Center  
1150 West Medical Center Drive, Room 5220  
Ann Arbor, Michigan 48109

### ***Executive Secretary***

#### **Christine Walsh, R.N.**

Center for Biologics Evaluation and Research  
Food and Drug Administration  
1401 Rockville Pike (HFM-71)  
Rockville, Maryland 20852  
E-mail: [walshc@cber.fda.gov](mailto:walshc@cber.fda.gov)  
Phone: 301-827-0314  
Facsimile: 301-827-0294

#### **Cindy Lyn Province, R.N., M.S.N.\***

Expertise: Consumer Representative  
Term: 04/10/03 - 01/31/07  
Associate Director  
Bioethics Center of St. Louis  
P.O. Box 6134  
Chesterfield, Missouri 63006

#### **Walter Royal, III, M.D.**

Expertise: Infectious Diseases / Neurology  
Term: 02/01/03 - 01/31/07  
Associate Professor of Medicine  
Morehouse School of Medicine  
720 Westview Drive, S.W.  
Atlanta, Georgia 30310

#### **Steven Self, Ph.D.**

Expertise: Biostatistics  
Term: 02/01/04 - 01/31/08  
Professor, Department of Biostatistics  
University of Washington  
Fred Hutchinson Cancer Research Center  
1100 Fairview Avenue, S., MS MW 500  
P.O. Box 19024  
Seattle, Washington 98109

#### **Bonnie M. Word, M.D.**

Expertise: Pediatric Infectious Diseases  
Term: 02/01/04 - 01/31/08  
Assistant Professor of Pediatrics  
Baylor College of Medicine  
Texas Children's Hospital  
Clinical Care Center  
6621 Fannin Street, Suite 1740.01  
Houston, Texas 77030

\*Consumer Representative

\*\*Industry Representative



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.

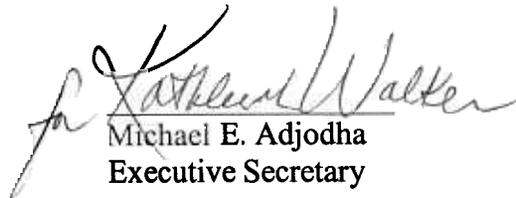
### ACCOMPLISHMENTS

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  
Associate Dean for Graduate Education,  
Research and Intl. Affairs  
Dir. of Graduate Periodontics and  
Professor of Periodontics  
Temple University School of Dentistry  
Office of the Dean  
3223 N. Broad Street  
Philadelphia, PA 19140

### **Salomon Amar, D.D.S., Ph.D.**

Expertise: Periodontics; Dental Sciences,  
Clinical  
Term: 3/22/04 - 10/31/07  
Professor  
Dept. of Periodontology and Oral Biology  
Boston University  
700 Albany Street, W201E  
Boston, MA 02118

### **David L. Cochran, D.D.S., Ph.D.**

Expertise: Periodontics  
Term: 2/19/02 - 10/31/05  
Professor and Chairman  
Dept. of Periodontics MSC 7894  
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\*Consumer Representative

\*\*Industry Representative

## Ear, Nose, and Throat Devices Panel Roster

### ***Chairperson***

#### **Eric A. Mair, M.D., FAAP**

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Page 2 – Ear, Nose and Throat Devices Panel Roster (continued)

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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:**

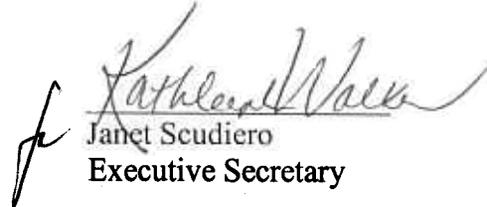
In the open session, the Panel deliberated on a PMA from Olympic Medical Corporation for the Cool-Cap®. This selective head cooling system is intended for use in infants 36 weeks of gestation or older at risk for moderate to severe hypoxic ischemic encephalopathy (HIE) to prevent or reduce the severity 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  
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#### **Mary E. Jensen, M.D.**

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#### **Jonas H. Ellenberg, Ph.D.**

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#### **Christopher M. Loftus, M.D.**

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Page 2 – Neurological Devices Panel Roster (continued)

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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:**

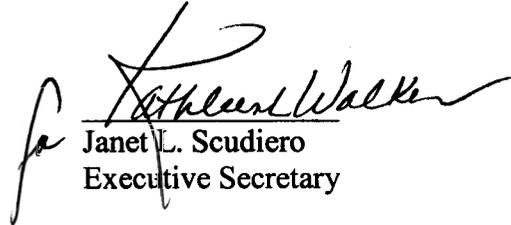
In the open session, on the first of two days, a PMA for the Smith and Nephew Birmingham Hip Resurfacing (BHR) System was discussed. This hip joint metal/metal semi-constrained resurfacing hybrid prosthesis (cemented femoral component and uncemented acetabular component) is intended to relieve hip pain 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  
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## Orthopaedic and Rehabilitation Devices Panel Roster

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

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