



December 14, 2006

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 Reports of the Food and Drug Administration (FDA) for the fiscal year 2006.

The Food and Drug Administration has 30 advisory committees. The FDA also administers an advisory committee on behalf of the Office of the Secretary, Department of Health and Human Services. The FDA held 62 advisory committee meetings in FY2006. Of the 62 advisory committee meetings, 48 were fully open to the public and 14 were partially closed. FDA closes portions of the meetings to permit discussion of matters of a personal nature (see 5 U.S.C. 552b(c)(6)) or discussion of trade secret and/or confidential information (see 5 U.S.C. 552b(c)(4)).

These reports are submitted pursuant to Section 10(d) of the Federal Advisory Committee Act, which requires that an advisory committee holding a closed meeting "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 301-827-1220.

Sincerely,

A handwritten signature in black ink, appearing to read "Theresa L. Green".

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 2006

Center for Biologics Evaluation and Research:

Allergenic Products Advisory Committee
Blood Products Advisory Committee
Cellular, Tissue and Gene Therapies Advisory Committee
Vaccines and Related Biological Products Advisory Committee

Center for Drug Evaluation and Research:

Nonprescription Drugs Advisory Committee
Anesthetic and Life Support Drugs Advisory Committee

Center for Devices and Radiological Health:

Medical Devices Advisory Committee (consisting of reports for General and Plastic Surgery Devices Panel; Obstetrics and Gynecology Devices Panel; Ophthalmic Devices Panel; Orthopaedic and Rehabilitation Devices Panel; Radiological Devices Panel)

National Center for Toxicological Research:

Science Board to the National Center for Toxicological Research



ANNUAL REPORT
OF THE
ALLERGENIC PRODUCTS ADVISORY COMMITTEE

For the period

October 1, 2005 through September 30, 2006

FUNCTION

The Committee reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease, and makes appropriate recommendations to the Commissioner of Food and Drugs of its findings regarding the affirmation or revocation of biological product licenses, on the safety, effectiveness, and labeling of the products, on clinical and laboratory studies of such products, on amendments or revisions to regulations governing the manufacture, testing and licensing of allergenic biological products. 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 once via teleconference during the reporting period. The meeting was held in Bethesda, Md.

The date of this meeting was September 13, 2006.

The meeting on September 13, 2006 included a closed session to permit discussion of matters of a personal nature and trade secret and/or confidential information.

ACCOMPLISHMENTS

September 13, 2006 in Bethesda, Maryland. The Committee reviewed and discussed the FDA's proposed strategy for the reclassification of Category IIIA allergenic products. The Committee also heard an update on of the research programs in the Laboratory of Immunobiochemistry, Division of Bacterial, Parasitic and Allergenic Products. The Committee held a closed session to discuss and make recommendations on personnel and program actions for the Laboratory of Immunobiochemistry located in the Office of Vaccines 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). 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 25, 2006
Date

Gail Dapolito
Gail Dapolito
Executive Secretary

**Allergenic Products Advisory Committee
Committee Roster**

Chair

Larry Borish, M.D.
Expertise: Allergy/Immunology/
Genetics
Term: 07-22-2004 - 08-31-2007
Professor of Medicine
Department of Medicine
Division of Allergy/Immunology
Box 801355
University of Virginia Health System
Charlottesville, VA 22908-1355

Lynelle C. Granady, M.D.
Expertise: Allergy/Immunology/
Pediatrics
Term: 12-04-2002 - 08-31-06
Associate Physician
ENT and Allergy Associates, L.L.P.
12 East 87th Sgreet
New York, NY 10128

Fred M. Atkins, M.D.
Expertise: Pediatrics
Term: 03-31-2006 – 08-31-2009
Director of Ambulatory Pediatrics
Professor of Pediatric
National Jewish Medical and Research
Center
1400 Jackson Street
Denver , CO 80206

Christy Olson, RN*
Expertise: Allergies
Term: 09-13-2004 - 08-31-2008
Nursing Educator
Allergy & Asthma Network
Mother's of Asthmatics
Rochester, MN

Steven A. Ostrove, Ph.D.**
Expertise: Biochemistry
Term: 09-27-2005 - 08-31-2007
President
Ostrove Associates, Inc
249 Keats Ave
Elizabeth, NJ 07208

Executive Secretary

Gail Dapolito
Center for Biologics Evaluation and
Research
Food and Drug Administration
1401 Rockville Pike
HFM-71
Rockville, MD 20842-1448
E-mail: gail.dapolito@fda.hhs.gov
Phone: 301-827-0314
Facsimile: 301-827-0294

Jay M. Portnoy, M.D.
Expertise: Allergy, Asthma,
Immunology
Term: 09-27-2005 - 08-31-2008
Chief, Section of Allergy, Asthma and
Immunology
The Children's Mercy Hospital
2401 Gillham Rd
Kansas City, MO 64108

Gillian M. Shepherd, M.D.
Expertise: Allergy, Immunology
Term: 03-31-2006 - 08-31-2009
Clinical Associate Professor of Medicine
Weill Medical College of Cornell
University
235 East 67th Street, Suite 203
New York , NY 10021

Michael E. Weiss, M.D.
Expertise: Allergy, Immunology
Term: 07-22-2004 - 08-31-2007
Allergist
Northwest Asthma & Allergy Center
8301 161st Avenue, NE
Redmond, WA 98052

Marsha Wills-Karp, Ph.D.
Expertise: Immunobiology
Term: 09-27-2005 - 08-31-2008
Professor of Pediatrics
Children's Hospital Medical Center
Department of Pediatrics
Division of Immunobiology
3333 Burnett Ave
Cincinnati, OH 45229-3039

*Consumer Representative

**Industry Representative



ANNUAL REPORT
OF THE
BLOOD PRODUCTS ADVISORY COMMITTEE

For the period

October 1, 2005 through September 30, 2006

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 three times during the reporting period. Meetings were held in Gaithersburg, Maryland.

The dates of those meetings were November 3-4, 2005, March 9-10, 2006, and July 13, 2006.

The meetings on March 9-10, 2006 and July 13, 2006 included closed sessions to permit discussion of trade secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

November 3-4, 2005. The Committee discussed and made recommendations on the following topics: approaches to over-the-counter (OTC) home-use HIV test kits, and Alpha-1 Protease Inhibitor products. The Committee made preliminary suggestions and heard from the public regarding whether the Agency should proceed with considering OTC HIV test kits. The Committee recommended that the Agency should consider OTC HIV test kits. This topic will be discussed further at a subsequent meeting. The Committee also discussed possible types of studies that industry should consider for Alpha-1 Protease Inhibitor products for asthmatics.

March 9-10, 2006. The Committee discussed and made recommendations on the following topics: rapid tests for detection of bacterial contamination of platelets, a "Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (Draft)", the proposed studies to support the approval of over-the-counter home-use HIV test kits, a summary of the research programs in the Office of Blood Research and Review, and the research programs in the Division of Hematology, Office of Blood Research and Review. The Committee met in closed session to permit discussion of personnel and program actions for the research programs in the Division of Hematology. 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 13, 2006. The Committee reviewed, discussed, and made recommendations on the following topics: FDA's review of NABI Biopharmaceuticals' Hepatitis B IGIV for prevention of recurrent HBV disease after orthotopic liver transplantation, and a the review of the research programs in the Laboratory of Bacterial, Parasitic and Unconventional Agents, Division of Emerging and Transfusion Transmitted Diseases. The Committee held a closed session to permit discussion of personnel and program actions for the Laboratory of Bacterial, Parasitic and Unconventional Agents. 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.

10/24/06
Date

Will F *William Freas*
FOR 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: 02-08-2002 - 09/30/2006
President and CEO
American Social Health
Administration
P.O. Box 13827
Research Triangle Park, NC 27709

Executive Secretary

Donald W. Jehn, M.S.

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

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

Expertise: Consumer Representative
Term: 06-27-2005 - 09-30-2008
Regional Coordinator
Federal Hemophilia Treatment Centers/
Region IX
University of California, Los Angeles
Division of Pediatric
Hematology/Oncology
924 Westwood Avenue, Suite 200
Los Angeles, CA 90024

Catherine S. Manno, M.D.

Expertise: Hematology, Oncology
Term: 11-30-2004 - 09-30-2007
Professor of Pediatrics
The Children's Hospital of Philadelphia
University of Pennsylvania School of Medicine
9th Floor, Main Hospital
34th Street & Civic Center Blvd.
Philadelphia, PA 19104

Mark Ballow, M.D.

Expertise: Immunology/Pediatrics
Term: 02-02-2006 - 09-30-2008
Interim Chair, Department of Pediatrics
Chief, Division of Allergy & Immunology
Women and Children's Hospital of Buffalo
219 Bryant Street
Buffalo, NY 14222

Thomas C. Quinn, M.D.

Expertise: Biology/Parasitology
Term: 02-02-2006 - 09-30-2008
Professor of Medicine & Deputy Director
Infectious Disease Division
The Johns Hopkins University
Ross Research Building, Room 1159
720 Rutland Avenue
Baltimore, MD 21205

Henry M. Cryer III, M.D., Ph.D.

Expertise: Trauma/Critical Care
Term: 02-02-2006 - 09-30-2009
Chief, Trauma & Critical Care
Division of General Surgery
University of California, Los Angeles
10833 Le Conte Ave., Rm. 72-178 CHS
Los Angeles, CA 90024-1602

Keith C. Quirolo, M.D.

Expertise: Transfusion Medicine, Hematology,
Biology
Term: 11-30-2004 - 09-30-2007
Hemoglobinopathy Pediatrician
Clinical Director, Apheresis Program
Department of Hematology
Children's Hospital & Research Center at Oakland
747 52nd Street
Oakland, CA 94609-1809

Adrian M. Di Bisceglie, M.D.

Expertise: Infectious Diseases/Hepatology
Term: 02-02-2006 - 09-30-2009
Professor of Internal Medicine
Chief of Hepatology
Saint Louis University School of Medicine
3635 Vista Ave. at Grand Blvd.
P.O. Box 15250
St. Louis, MO 63110-0250

George B. Schreiber, Sc.D.

Expertise: Epidemiology, Health Studies
Term: 11-30-2004 - 09-30-2007
Vice President, Health Studies
Westat
1650 Research Blvd., TB186
Rockville, MD 20850

Maureen A. Finnegan, M.D.

Expertise: Biochemistry/Orthopaedic Surgery

Term: 02-02-2006 - 09-30-2009

Associate Professor

Department of Orthopedic Surgery

U.T. Southwestern Medical Center

5323 Harry Hines Blvd.

Dallas, TX 75390-8883

Matthew J. Kuehnert, M.D.

Expertise: Infectious Diseases, Internal Medicine

Medicine, Biochemistry and Cell Biology

Term: 11-30-2004 - 09-30-2007

CDR, U.S. Public Health Service

Assistant Director for Blood Safety

Division of Healthcare Quality Promotion
Centers for Disease Control & Prevention (CDC)

1600 Clifton Road, Mailstop A-07

Atlanta, GA 30333

Louis M. Katz, M.D. **

Expertise: Industry Representative

Term: 06-27-2005 - 09-30-2008

Executive Vice President, Medical Affairs

Mississippi Valley Regional Blood Center

5500 Lake View Parkway

Davenport, IA 52807

Roshni Kulkarni, M.D.

Expertise: Pediatric Hematology

Term: 02-02-2006 - 09-30-2009

Director, Division of Hereditary Blood Disorders

Center for Disease Control & Prevention (CDC)

Professor, Dept. of Pediatrics & Human Development

Michigan State University

B-220 Clinical Center

East Lansing, MI 48824

Frederick P. Siegal, M.D.

Expertise: Hematology/HIV Medicine

Term: 02-02-2006 - 09-30-2009

Medical Director, Comprehensive HIV Center

Saint Vincent's Catholic Medical Centers,

Saint Vincent's Manhattan

NR 1425

153 West 11th Street

New York, NY 10011

Irma O.V. Szymanski, M.D.

Expertise: Hematology/Blood Banking

Term: 02-02-2006 - 09-30-2007

Professor of Pathology, Emerita

University of Massachusetts Medical Center

Department of Pathology

55 Lake Avenue North

Worcester, MA 01655-0212

Donna S. Whittaker, Ph.D.

Expertise: Medical Technology, Transfusion

Medicine, Immunology

Term: 11-30-2004 - 09-30-2007

LTC, MS, USA

Chief, Department of Clinical Support Services

U.S. Army Medical Dept. Center & School

3151 Scott Road, Suite 1334

Fort Sam Houston, TX 78234

* Consumer Representative

**Industry Representative



ANNUAL REPORT
OF THE
CELLULAR, TISSUE AND GENE THERAPIES ADVISORY COMMITTEE

For the period

October 1, 2005 through September 30, 2006

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 once during the reporting period. The meeting was held in Gaithersburg, Md.

The date of this meeting is February 9-10, 2006.

The meeting on February 9-10, 2006 included a closed session to permit discussion of secret and confidential information or matters of a personal nature.

ACCOMPLISHMENTS

February 9-10, 2006 in Gaithersburg, Maryland. The Committee discussed and made recommendations related to the following: 1) the development of meaningful and relevant potency assay measurements for cell and gene therapy products; 2) a collaboration between FDA and the National Toxicology Program, National Institute of Standards and Technology to assess the risk of retroviral vector-mediated insertional mutagenesis and tumorigenesis in a murine model. The Committee also received information on the scope and mission of the research program of the Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation. The Committee held a closed session to discuss and make recommendations on issues related to the management and operation of the research program of 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 were utilized by FDA as part of its independent intramural program review.

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

November 2, 2006

Date

Gail Dapolito

Gail Dapolito
Executive Secretary

Cellular, Tissue and Gene Therapies Advisory Committee Committee Roster

Chair

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, FL 33612

Jonathan S. Allan, D.V.M.
Expertise: Veterinary Medicine
Term: 09-30-2002 – 03-31-2006
Scientist
Department of Virology and
Immunology
Southwest Foundation for Biomedical
Research
7620 N.W. Loop 410 at Military Drive
San Antonio, TX 77030

David M. Harlan, M.D.
Expertise: Transplantation/
Autoimmunity
Term: 09-30-2002 – 03-31-2006
Chief, Islet and Autoimmunity Branch
National Institute of Diabetes and
Digestive and Kidney Disease, NIH
10 Center Drive, Bldg. 10, Rm 8N307
Bethesda, MD 20892

Mahendra S. Rao, M.D.
Expertise: Neurobiology/Anatomy
Cellular Biology
Term: 05-22-2001 –12-31-05
Chief, Stem Cell Biology Section
Laboratory of Neurosciences, 4B17
Gerontology Research Center
National Institute on Aging, NIH
5600 Nathan Shock Drive
Baltimore, MD 21224

Executive Secretary

Gail Dapolito
Center for Biologics Evaluation and
Research
Food and Drug Administration
1401 Rockville Pike
HFM-71
Rockville, MD 20842-1448
E-mail: gail.dapolito@fda.hhs.gov
Phone: 301-827-0314
Facsimile: 301-827-0294

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

Matthew J. Allen, D.V.M., Ph.D.
Expertise: Veterinary Medicine
Term: 05-25-2006 – 03-31-10
Associate Professor
Department of Orthopedic Surgery
SUNY Upstate Medical University
750 East Adams Street
Syracuse, NY 13210

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

Richard J. Chappell, Ph.D.
Expertise: Biostatistics and Medical Informatics
Term: 05-25-06 - 03-31-10
Professor
Department of Biostatistics and Medical Informatics
The University of Wisconsin-Madison Medical School
600 Highland Avenue, KL6/430
Madison, Wisconsin 53792

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

Stanton L. Gerson, M.D.
Expertise: Stem Cell Biology
Term: 05-25-06 - 03-31-10
Professor of Medicine, Oncology & Environmental Health Sciences
Wearn Building Room 153
Case Western Reserve University
University Hospital of Cleveland
11100 Euclid Avenue
Cleveland, Ohio 44106-5065

Farshid Guilak, Ph.D.
Expertise: Biomedical Engineering
Term: 05-25-06 - 03-31-09
Laszlo Ormandy Professor of Orthopedic Surgery
Orthopedic Research Laboratories
Duke University Medical Center
MSRB Room 375, Box 3093
Durham, North Carolina 27710

Kurt C. Gunter, M.D.**
Expertise: Industry Representative
Term: 09-29-2005 - 03-31-2009
Medical Director, Cellular Therapy
Hospira, Inc.
Department 87W, Building H1
275 North Field Drive
Lake Forest, Illinois 60045

Larry W. Kwak, M.D., Ph.D.
Expertise: Tumor Immunology/Lymphoma
Term: 05-25-06 - 03-31-10
Chairman
Department of Lymphoma/Myeloma
University of Texas
M.D. Anderson Cancer Center
1515 Holcombe Boulevard – Unit 429
Houston, Texas 77030

Doris A. Taylor, Ph.D.
Expertise: Cardiovascular Cellular Therapy
Term: 05-25-06 - 03-31-10
Medtronic Bakken Professor
Center for Cardiovascular Repair
University of Minnesota
7-105A BSBE
312 Church Street SE
Minneapolis, Minnesota 55455

Sharon F. Terry, M.D.*
Expertise: Genetics / Consumer Representative
Term: 11-29-2004 - 03-31-2008
President and CEO
Genetic Alliance Organization
Suite 404
4301 Connecticut Ave, 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, MA 02114

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 NE Glisan St, 5F-40
Portland, OR 97213

Savio Lau-Ching Woo, Ph.D.
Expertise: Gene Therapy/Molecular
Medicine
Term: 05-25-06 - 03-31-10
Professor of Gene and Cell Medicine
Mount Sinai School of Medicine
One Gustave L. Levy Place, Box 1496
New York, New York 10029

*Consumer Representative

**Industry Representative



ANNUAL REPORT
OF THE
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

For the period

October 1, 2005 through September 30, 2006

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 five times during the reporting period. Meetings were held in Bethesda, Maryland and Gaithersburg, Maryland. One meeting was held by teleconference.

The dates of those meetings were November 16-17, 2005, December 14-15, 2005, February 17, 2006, May 18, 2006, and May 19, 2006.

The meetings on November 16-17, 2005 and May 19, 2006 included closed sessions to permit discussion of secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

November 16-17, 2005 meeting. The Committee reviewed and discussed the use of Madin-Darby Canine Kidney Cells (MDCK) for manufacture of inactivated influenza virus vaccines. In addition the Committee discussed and made recommendations on developing new pneumococcal vaccines for U.S. Licensure for adults. The Committee held a closed session related to this topic to permit discussion and review of trade secret and/or confidential information in accordance with 5 U.S.C. 552b(c)(4).

December 14-15, 2005 meeting. The Committee reviewed and made recommendations on the safety and efficacy of a Rotavirus vaccine manufactured by Merck. The Committee also reviewed and made recommendations on the safety and efficacy of Zostavax, a zoster vaccine live, manufactured by Merck. Rotateq, the Rotavirus vaccine and Zostavax were both licensed by the FDA.

February 17, 2006 meeting via teleconference. The Committee reviewed, discussed and made recommendations on the strain selection for the Influenza Virus Vaccine for the 2006-2007 season including strain characterization. A Center for Disease Control and Prevention (CDC) representative also presented an update to the Committee on the Influenza A (H5N1) Viruses.

May 18, 2006 meeting. The Committee reviewed, discussed and made recommendations on the safety and efficacy of Gardasil (human papillomavirus, types 6, 11, 16, 18, recombinant vaccine) manufactured by Merck. The vaccine, Gardasil, was licensed by FDA.

May 19, 2006 Subcommittee meeting. The Subcommittee discussed and made recommendations on the research program of the Office of Vaccines Research and Review. This discussion 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 Vaccines 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 Vaccines and Related Biological Products Advisory Committee.

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

October 24, 2006
Date

Christine Walsh
Christine A. Walsh, RN
Executive Secretary

Vaccines and Related Biological Products Advisory Committee Committee Roster

Chair

Ruth A. Karron, M.D.
Expertise: Pediatrics/Infectious Diseases
Term: 02-01-2003 – 01-31-2007
Professor
Department of International Health
Johns Hopkins School of Hygiene and
Public Health
624 N. Broadway
Hampton House, Room 117
Baltimore, MD 21205

David M. Markovitz, M.D.
Expertise: Infectious Diseases
Term: 02-01-2002 – 01-31-2006
Professor
Division of Infectious Diseases
Department of Internal Medicine
University of Michigan Medical Center
1150 West Medical Center Dr., Rm 5220
Ann Arbor, MI 48109

Gary D. Overturf, M.D.
Expertise: Pediatrics
Term: 02-01-2002 – 01-31-2006
Professor of Pediatrics and Pathology
University of New Mexico Center
Ambulatory Care Center, 3rd Floor
2211 Lomas Avenue, N.E.
Albuquerque, NM 87131

Monica M. Farley, M.D.
Expertise: Bacterial Infectious Diseases
Term: 02-01-2004 – 01-31-2008
Professor of Medicine
Department of Medicine
Emory University School of Medicine
VA Medical Center
Research - Infectious Diseases (151)
1670 Clairmont Road
Atlanta, GA 30033

Executive Secretary

Christine A. Walsh, RN
Center for Biologics Evaluation and
Research
Food and Drug Administration
1401 Rockville Pike
HFM-71
Rockville, MD 20842-1448
E-mail: Christine.walsh@fda.hhs.gov
Phone: 301-827-0314
Facsimile: 301-827-0294

Seth Hetherington, M.D.**
Expertise: Industry Representative
Term: 11-15-2005 – 09-30-2008
Senior Vice President
Clinical and Regulatory Affairs
Icagen, Inc.
4222 Emperor Boulevard, Suite 350
Durham, North Carolina 27703

Lisa Jackson, M.D., M.P.H.
Expertise: Epidemiology & Infec. Dis.
Term: 05-25-06 – 01-31-10
Senior Scientific Investigator
Group Health Cooperative
1730 Minor Avenue, Suite 1600
Seattle, Washington 98101

Philip S. LaRussa, M.D.
Expertise: Pediatrics / Virology
Term: 02-01-2004 – 01-31-2008
Professor of Clinical Pediatrics
Columbia University, PH-4 West – 462
622 West 168th Street
New York, NY 10032

John Modlin, M.D.
Expertise: Pediatrics
Term: 11-15-2005 – 01-31-2009
Professor of Pediatrics
Dartmouth-Hitchcock Medical Center
Pediatric Administration
One Medical Center Drive
Lebanon, NH 03756

Cindy Lyn Province, RN, MSN*
Expertise: Consumer Representative
Term: 04-10-2003 – 01-31-2007
Associate Director
Bioethics Center of St. Louis
P.O. Box 6134
Chesterfield, MO 63006

Walter Royal, III, M.D.
Expertise Infectious Dis/Neurology
Term: 02-01-03 – 01-31-07
Associate Professor
Department of Neurology
University of Maryland School of
Medicine
Bressler Building, Room 12-031
655 W. Baltimore Street
Baltimore, Maryland 21201

Steven Self, Ph.D.
Expertise: Biostatistics
Term: 02-01-2004 – 01-31-2008
Professor, Department of Biostatistics
University of Washington
Fred Hutchinson Cancer Research
Center
1100 Fairview Avenue, S., MS MW 500
P.O. Box 19024
Seattle, WA 98109

Jack Stapleton, M.D.
Expertise: Virology & Infec. Dis.
Term: 05-25-2006 – 01-31-2010
Professor and Director
Division Director of Infectious Diseases
Division of Internal Medicine, SW-54
University of Iowa Hospital Clinic
200 Hawkins Drive
Iowa City, Iowa 52242

Bonnie M. Word, M.D.
Expertise: Pediatric Infectious Diseases
Term: 02-01-2004 – 01-31-2008
Assistant Professor of Pediatrics
Baylor College of Medicine
Texas Children's Hospital
Clinical Care Center
6621 Fannin Street, Suite 1740.01
Houston, TX 77030

*Consumer Representative
**Industry Representative



ANNUAL REPORT
OF THE
ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE
for the period

October 1, 2005 through September 30, 2006

FUNCTION

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met one time during the reporting period in Rockville, Maryland

The date of the meeting was November 10, 2005. It was a closed session meeting to permit discussion or presentation of trade secret or confidential commercial information or disclosure would constitute a clearly unwarranted invasion of personal privacy.

ACCOMPLISHMENTS

The activities of the committee during this meeting included:

On November 10, 2005, the Committee opened to the public from 9 a.m. to 9:43 a.m. Followed by a closed session meeting, the Division of Anesthesia, Analgesia, and Rheumatology Products provided the Committee with an update on past matters and upcoming issues. No advice was sought of the Committee. The meeting was closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552(c) (4)).

Nov. 03, 2006
Date

Mimi T. Phan
Mimi T. Phan, Pharm.D.
Designated Federal Officer

Anesthetic and Life Support Drugs Advisory Committee Center for Drug Evaluation and Research

Chair

Steven L. Shafer, M.D.

Expertise: Anesthesiology
Term: 08/30/04 – 03/31/06
Professor of Anesthesia
Stanford University
VA Palo Alto health Care System
3801 Miranda Avenue
Palo Alto, California 94304

*** Mary Beth Bobek, Pharm.D.**

Term: 07/15/02 – 03/31/06
Director, Cardiovascular Pharmacotherapy
New Hanover Health Network
Department of Cardiac Services
2131 South 17th Street
P.O. Box 9000
Wilmington, North Carolina 28402-9000

Mercedes Concepcion, M.D.

Expertise: Anesthesiology
Term: 06/01/03 – 03/31/06
Associate Professor, Harvard Medical School &
Anesthesiologist
Brigham & Women's Hospital
Department of Anesthesiology
75 Francis Street
Boston, Massachusetts 02115

Robert H. Dworkin, Ph.D.

Expertise: Neuropathic Pain
Term: 01/29/04 – 03/31/07
Professor of Anesthesiology, Neurology
Oncology and Psychiatry
University of Rochester
School of Medicine and Dentistry
601 Elmwood Avenue, Box 604
Rochester, New York 14642

James C. Eisenach, M.D.

Expertise: Anesthesiology
Term: 01/29/04 - 03/31/07
Professor of Anesthesiology
Wake Forest University Medical Center
Department of Anesthesiology
Section of Obstetric and Gynecologic
Anesthesiology
Medical Center Boulevard
Winston-Salem, North Carolina 27157

John T. Farrar, M.D.

Expertise: Neurologist
Term: 07/13/04 - 03/31/08
Senior Scholar, University of Pennsylvania
Center for Clinical Epidemiology & Biostatistics
Room 816, Blockley Hall
423 Guardian Drive
Philadelphia, Pennsylvania 19104

Designated Federal Officer

Mimi T. Phan, Pharm.D.; R.Ph.

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Thomas K. Henthorn, M.D.

Expertise: Anesthesiology
Term: 07/13/04 - 03/31/07
Professor and Chair
Department of Anesthesiology
University of Colorado Health Sciences Center
4200 East 9th Avenue, Campus Box B113
Denver, Colorado 80262

****Charles McLeskey, M.D.**

Expertise: Anesthesia, Sedation
Term: 02/02/04 - 10/31/07
Vice President, Clinical Affairs
ZARS
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Salt Lake City, UT. 84119

David G. Nichols, M.D., M.B.A.

Expertise: Pediatric Anesthesiology
Term: 07/25/05 - 03/31/09
Professor, Anesthesiology/Critical Care
Medicine and Pediatrics
The Johns Hopkins School of Medicine
733 N. Broadway, Suite 115
Baltimore, Maryland 21205

Srinivasa N. Raja, M.D.

Expertise: Anesthesiology, Pain Management
Term: 07/25/05 - 03/31/08
Professor, Department of Anesthesiology and
Critical Care Medicine
The Johns Hopkins University School of
Medicine
600 N. Wolfe Street, Osler 292
Baltimore, Maryland 21287

Sulpicio de Guzman Soriano, III, M.D.

Expertise: Pediatric Anesthesiology
Term: 07/13/04 - 03/31/08
Senior Associate
Department of Anesthesia
Bader 3, Children's Hospital
300 Longwood Avenue
Boston, Massachusetts 02030

David J. Wlody, M.D.

Expertise: Anesthesiology

Term: 07/13/04 - 03/31/07

Interim Chairman

Department of Anesthesiology

Long Island College Hospital

Clinical Associate Professor and Vice Chair for
Clinical Affairs

State University of New York

Downstate Medical Center

450 Clarkson Avenue, Box 6

Brooklyn, New York 11203

* Consumers Representative

** Industry Representative



ANNUAL REPORT
OF THE
NONPRESCRIPTION DRUGS ADVISORY COMMITTEE

for the period

October 1, 2005 through September 30, 2006

FUNCTION

The Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advise the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met 4 times during the reporting period in Silver Spring and Gaithersburg, Maryland.

The dates of the meetings were: October 20, 2005, October 21, 2005, January 23, 2006 and January 24, 2006.

The meeting on October 21, 2005 included a closed session to permit discussion or presentation of trade secret or confidential commercial information or disclosure would constitute a clearly unwarranted invasion of personal privacy.

ACCOMPLISHMENTS

The activities of the committee during this meeting included:

On October 20, 2005, the committee met and discussed the benefits and risks of antiseptic products marketed for consumer use (e.g., antibacterial hand-washes and body-washes). The discussion included topics such as; the efficacy of antiseptics intended for use by consumer, and potential risks to the individual and the general population from using these products. The committee agreed that as drug products, consumer antiseptics should be expected to provide clinical benefit by reducing infection and that further studies should be conducted on populations in which there is increased risk of/or transfer of infection (e.g., immune suppressed, diarrhea, upper respiratory infection) or co-morbidity.

At the closed session of the October 21, 2006, the committee met from 8:00 am to 12 noon. The Office of Nonprescription Products provided the Committee with an update on past matters and upcoming issues. No advice was sought of the Committee. The meeting was closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552(c) (4)).

On January 23, 2006, the Nonprescription Drugs and the Endocrinologic & Metabolic Drugs Advisory Committees met in joint session, to consider the safety and efficacy of new drug application (NDA) 21-887, proposing over-the-counter (OTC) use of Orlistat (tetrahydrolipstatin) 60 milligram (mg) capsules, GlaxoSmithKline Consumer Healthcare, L.P., to promote weight loss in overweight adults when used along with a reduced calorie and low fat diet. The committee agreed that Orlistat should be approved for nonprescription use. Further, the committee recommended labels should clearly state product is not for use in individuals under the age of 18 and individuals with normal weight or eating disorders. Finally, the committee recommended implementing a plan that would require the sponsor to provide usage data in these populations and revisit the issue recommending alternative strategies if necessary.

On January 24, 2006, the Nonprescription Drugs and the Pulmonary-Allergy Drugs Advisory Committees met in joint session to discuss the continued need for the designation of OTC epinephrine-metered dose inhalers for the treatment of asthma as an essential use of ozone-depleting substances (ODSs) under 21 CFR 2.125. ODSs are substances that deplete stratospheric ozone, which include chlorofluorocarbons (CFCs). Given the current practice of medicine and overall treatment goals and therapeutic strategies for asthma, the committee did not believe the use of CFCs in epinephrine MDIs available without a prescription, remained an essential use at the current time.

Detailed information related to the open sessions is available in the annual report.

10/30/06
Date

Darrell Lyons
Darrell Lyons, BSN, RN
Designated Federal Officer

NONPRESCRIPTION DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH

Chair

Alastair Wood, M.D.

Expertise: Internal Medicine, Clinical Pharmacology
Term: 08/20/01 - 05/31/06
Assistant Vice Chancellor
Professor of Medicine and Pharmacology
Vanderbilt University School of Medicine
550 Robinson Research Building
Nashville, Tennessee 37232

Neal L. Benowitz, M.D.

Expertise: Clinical Pharmacology, Poison Control
Term: 09/25/03 - 05/31/06
Chief, Division of Clinical Pharmacology
Departments of Medicine, Biopharmaceutical
Sciences and Psychiatry
University of California, San Francisco
Building 30, Room 3316, San Francisco General
Hospital
1001 Potrero Avenue
San Francisco, California 94110

Terrence F. Blaschke, M.D.

Expertise: Clinical Pharmacology/Drug Modeling
Term: 09/25/03 - 05/31/07
Associate Director, Stanford General Clinical
Research Center,
Division of Clinical Pharmacology, Room S-009
Stanford University Medical Center
Stanford, California 94305-5130

Ernest B. Clyburn, M.D.

Expertise: Internal Medicine, Special Population
Term: 01/05/01 - 05/31/08
Assistant Professor
Internal Medicine
Medical University of South Carolina
96 Jonathan Lucas Street
Suite 916 CSB
Charleston, South Carolina 29412

Designated Federal Officer

LT Darrell Lyons BSN, RN

Advisors and Consultants Staff
Center for Drug Evaluation and Research
Food and Drug Administration, HFD-021
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Rockville, Maryland 20857
Phone: (301) 827-6760
Fax: (301) 827-6776
E-mail: lyonsd@cder.fda.gov

Jack E. Fincham, Ph.D.

Expertise: Pharmacy Practice
Term: 09/25/03 - 05/31/07
Albert W. Jowdy Professor of Pharmacy Care
Department of Clinical and Administrative
Pharmacy
College of Pharmacy
The University of Georgia
Athens, Georgia 30602-2354

****George S. Goldstein, M.D.**

Expertise: Pharmaceutical Development:
Pediatrics; Clinical & Regulatory
Term: 1/16/06 - 10/31/07
Corp. VP Worldwide Medical and Regulatory
Affairs
Sterling Drug Inc. (Retired)
Pharmaceutical Consultant to CPHA
6 Pebble Beach Lane
White Plain, New York 10605

Ruth M. Parker, M.D.

Expertise: Label Comprehension
Term: 01/05/05 - 05/31/08
Associate Professor of Medicine
Department of Medicine
Emory University School of Medicine
Glenn Memorial Building
69 Jesse Hill Drive
Atlanta, Georgia 30307

* Consumer Representative

** Industry Representative (non voting)

NONPRESCRIPTION DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH

Wayne R. Snodgrass, M.D., Ph.D.

Expertise: Pediatrics, Pharmacology, Toxicology

Term: 09/25/03 - 05/31/06

Professor, Pediatrics and Pharmacology-Toxicology

Head, Clinical Pharmacology-Toxicology Unit

Medical Director, Texas Poison Center

University of Texas Medical Branch

301 University Boulevard

Galveston, Texas 77555

Robert E. Taylor, M.D., Ph.D., F.A.C.P., F.C.P.

Expertise: Pharmacology, Toxicology

Term: 01/05/05 - 05/31/08

Chairman, Department of Pharmacology

Professor of Pharmacology and Medicine

Director, Howard University Collaborative Alcohol

Ctr., Howard University College of Medicine

520 W. street, NW, Suite 3408

Washington, District of Columbia 20059

Mary E. Tinetti, M.D.

Expertise: Geriatrics, Public Health

Term: 09/25/03 - 05/31/07

Gladys Phillips Crofoot Professor of Medicine,

Epidemiology and Public Health

Director, Program on Aging

Yale University School of Medicine

333 Cedar Street

P.O. Box 208025

New Haven, Connecticut 06520-8025



ANNUAL REPORT
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE

for the period

October 1, 2005 through September 30, 2006

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 9 meetings during the reporting period in Gaithersburg, Maryland.

Below are the dates of all device panel meetings during FY 2006 (10/1/05 to 9/30/06) and UNDERLINED dates represent meetings that had closed sessions:

10/11-12/05 Dental Products Panel

*11/16-17-05 Gastroenterology and Urology Devices Panel

03/27-28/06 Obstetrics and Gynecology Devices Panel

05/23/06 Radiological Devices Panel

06/02/06 Orthopaedic and Rehabilitation Devices Panel

07/14/06 Ophthalmic Devices Panel

08/2-25/06 General and Plastic Surgery Devices Panel

08/29/06 Obstetrics and Gynecology Devices Panel

09/6-7/06 Dental Products Panel

09/19/06 Orthopaedic and Rehabilitation Devices Panel

* During this reporting period, no Gastroenterology and Urology Panel meeting was held; however, certain Panelists and pediatric SGE consultants participated in the Pediatric Advisory Committee (PAC) Meeting on November 16-17, 2005. The PAC discussed pediatric obesity and clinical trial designs for the evaluation of devices intended to treat pediatric obesity for future development of a guidance document.

GENERAL AND PLASTIC SURGERY DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

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

The date of the meeting was August 24-25, 2006.

The meeting on August 25, 2006 included a closed session to permit discussion or presentation of trade secret or confidential commercial information.

ACCOMPLISHMENTS

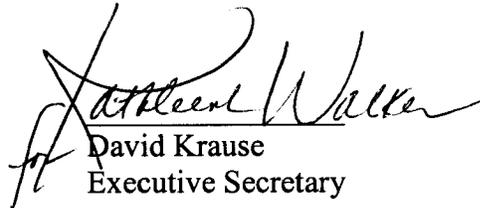
At the August 24-25, 2006 meeting:

In the open session, during the first day, the Panel recommended conditional approval on two premarket approval applications (PMAs) for BioForm Medical Inc.'s Radiesse injectable implant. The first PMA was for use of Radiesse to treat HIV associated lipoatrophy of the face. The second PMA was for use of Radiesse to treat nasolabial folds. The conditions for both PMAs included training and some post-market assessments.

On the second day, the Panel recommended that cyanoacrylate tissue adhesives for approximation of skin be reclassified from a Class III to a non-exempt Class II with a guidance document as the special control.

Closed Committee Deliberations: On August 25, 2006, 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, 2006
Date


David Krause
Executive Secretary

General and Plastic Surgery Devices Panel Roster

Chairperson

Joseph LoCicero, III, M.D.

Expertise: Thoracic Surgery; Laser Use
Surgery

Term: 10/2/03 - 8/31/07

Chief of Surgical Oncology
Maimonides Medical Center
4802 Tenth Ave. 4th Floor
Brooklyn, NY 11219

**** Grace T. Bartoo, Ph.D., R.A.C.**

Expertise: Biomedical Engineering,
Software

Term: 10/20/03 - 8/31/07

General Manager
Decus Biomedical, LLC
409 Walnut Street
San Carlos, CA 94070

Brent A. Blumenstein, Ph.D.

Expertise: Biostatistics; Clinical Trials Data
Management

Term: 10/2/03 - 8/31/07

Statistician
TriArc Consulting
323 N. 74 Street
Seattle, WA 98103

Cheryl A. Ewing, M.D.

Expertise: General Surgery/Oncology;
Breast Cancer

Term: 11/16/04 - 8/31/08

Assistant Clinical Professor of Surgery
Univ. California, San Francisco
1600 Divisadero Street, Room B611
Campus Box 1710
San Francisco, CA 94115

Amy E. Newburger, M.D.

Expertise: Dermatology;
Scar Management

Term: 10/2/03 – 8/31/06

Dermatology Consultants of Westchester
2 Overhill Road
Scarsdale, NY 10583

Executive Secretary

David Krause, Ph.D.

Center for Devices and Radiological Health
Office of Device Evaluation/DGRND

9200 Corporate Blvd. HFZ-410

Rockville, MD 20850

(301) 594-3090 x141

(301) 827-4350

Frank R. Lewis, Jr., M.D.

Expertise: General Surgery; Trauma
Surgery

Term: 3/31/06 - 8/31/09

Executive Director
American Board of Surgery
1617 JFK Blvd., Suite 860
Philadelphia, PA 19103

Michael J. Olding, M.D.

Expertise: General Surgery

Term: 3/31/06 - 8/31/09

Chief, Division of Plastic Surgery
Department of Surgery
George Washington University
2150 Pennsylvania Ave NW
Suite 9-400
Washington, DC 20037

A. Marilyn Leitch, M.D.

Expertise: Surgical Oncology;
Breast Cancer

Term: 10/2/03 – 8/31/06

Professor of Surgery
Univ. of Texas Southwestern Medical Sch
Univ. of Texas Southwestern Med Ctr.
5323 Harry Hines Blvd., Rm E6222
Dallas, TX 75390-9155

**Industry Representative

OBSTETRICS and GYNECOLOGY 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 the meetings were March 27-28, 2006 and August 29, 2006.

The meeting on March 28, 2006 included a closed session to permit discussion or presentation of trade secret or confidential commercial information.

ACCOMPLISHMENTS

At the March 27-28, 2006 meeting:

In the open session, on the first of two days, a premarket approval application (PMA) from Innovata plc for the Adept® Adhesion Reduction Solution (4% Icodextrin) was discussed. The proposed indication for use for the device is as an adjunct to good surgical technique for the reduction of post-surgical adhesions in patients undergoing gynecological laparoscopic surgery, which may include adhesiolysis. The Panel recommended that the PMA be found approvable with conditions. The conditions focused on modifications to the indication for use and device labeling.

On the second day, the Panel discussed general issues regarding clinical trial designs for devices intended to treat symptomatic fibroids. The Panel provided comments on clinical trial design, addressing elements of study population, outcome measures, controls, and length of follow-up.

FDA will use this input to help guide manufacturers who are developing new devices to treat fibroids.

Closed Committee Deliberations: On March 28, 2006, the meeting was closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C.552b(c)(4)) regarding pending and future device issues.

Obstetrics and Gynecology Devices Panel (continued)

At the August 29, 2006 meeting:

In the open session, the Panel discussed Mirable Medical Systems Inc.'s PMA for the T-Scan™ 2000 ED, a non-invasive device indicated for use as a complement to clinical breast examination in asymptomatic women between the ages of 30-39. The Panel recommended that the device be found not approvable. While acknowledging the need for additional tools to help physicians screen for breast cancer in women aged 30-39, the Panel noted issues of concern regarding device sensitivity, the size and population of the study, number of cancers detected in study patients, and risks associated with additional screening events.

September 30, 2006
Date



Michael Bailey
Executive Secretary

Obstetrics and Gynecology Devices Panel Roster

Chairperson

Kenneth L. Noller, M.D.

Expertise: Gynecological Cancer
Term: 5/16/03 - 1/31/07
Professor and Chair
Dept. of Obstetrics and Gynecology
Tufts University Medical School/New
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Marcelle I. Cedars, M.D.

Expertise: Reproductive Endocrinology
Term: 6/30/05 - 1/31/09
Dir., Division of Reproductive
Endocrinology
Women's Health Clinical Research Center
Univ. of California, San Francisco
1635 Divisadero St
Suite 601
San Francisco, CA 94115

**** Elisabeth M. George**

Expertise: Quality and Regulatory,
Biomedical Devices
Term: 4/1/05 - 1/31/09
Vice President of Quality, Regulatory
Sustainability and Product Security
Philips Medical Systems
3000 Minuteman Rd.
MS-240
Andover, MA 01810-1099

Paula J. Adams Hillard, M.D.

Expertise: Pediatric and Adolescent
Gynecology
Term: 3/14/04 - 1/31/08
Professor, Dept. of Ob/Gyn
Professor, Dept. of Pediatrics
Univ. of Cincinnati College of Medicine
3333 Burnet Ave. ML 4000
Cincinnati, OH 45229-3039

Hugh S. Miller, M.D.

Expertise: Perinatology
Term: 6/5/03 - 1/31/07
Private Practice
Obstetrix Medical Group
Tucson Medical Center
5301 E Grant Ave
Tucson, AZ 85712

Executive Secretary

Michael T. Bailey, Ph.D.

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Office of Device Evaluation/DRARD
9200 Corporate Blvd. HFZ-470
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(301) 594-1180 x130
(301) 594-2339

*** Diana R. Romero, Ph.D.**

Expertise: Public Health Education
Term: 2/16/06 - 1/31/10
Assistant Professor
Helibrunn Dept. of Population and Family
Health
Mailman School of Public Health,
Columbia Univ.
60 Haven Ave., B-2 Room 211
New York, NY 10032

Joseph S. Sanfilippo, M.D., MBA

Expertise: Reproductive Endocrinology;
Adolescent Gynecology
Term: 6/30/05 - 1/31/09
Dir., Clinical Operations, Reproductive
Sciences
Magee-Womens Hospital
The Univ. of Pittsburgh School of Medicine
300 Halket Street
Pittsburgh, PA 15213-3180

Howard T. Sharp, M.D.

Expertise: Laparoscopic & Hysteroscopic
Surgery
Term: 2/16/06 - 1/31/10
Associate Professor and Chief
General Division of OB/GYN
University of Utah School of Medicine
30 North 1900 East
Room 2B200
Salt Lake City, UT 84132

Jonathan W. Weeks, M.D.

Expertise: Perinatology
Term: 6/5/03 - 1/31/07
Dir. Maternal-Fetal Medicine Center
Norton Suburban Hospital
4001 Dutchman's Lane
Louisville, KY 40207

Page 2 – Obstetrics and Gynecology Devices Panel Roster (continued)

Evelyn R. Hayes, Ph.D., RN, CS-FNP
Expertise: Obstetrical, Maternity Nursing
Term: 6/5/03 – 1/31/06
Professor
College of Health and Nursing Sciences
University of Delaware
319 McDowell Hall
Newark, DE 19716

*Consumer Representative

**Industry Representative

OPHTHALMIC DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

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

The date of the meeting was July 14, 2006.

The meeting on July 14, 2006 included a closed session to permit discussion or presentation of trade secret or confidential commercial information.

ACCOMPLISHMENTS

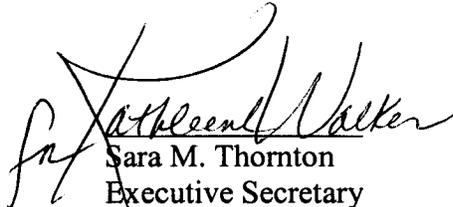
At the July 14, 2006 meeting:

In the open session, the Panel discussed, made recommendations, and voted on a PMA for VisionCare Technologies' Implantable Miniature Telescope (IMT) indicated for use in adult subjects with bilateral, stable untreatable moderate to profound central vision impairment due to macular degeneration. Following presentations by the sponsor and the FDA, the Panel recommended that the PMA be found not approvable. The Panel's recommendation was based on unresolved safety concerns in addition to uncertainty regarding the efficacy of the device.

Closed Committee Deliberations: On July 14, 2006, the meeting was 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 vitreoretinal, surgical and diagnostic devices, intraocular and corneal implants, and contact lenses. This portion of the meeting will be closed to permit discussion of the information (5 U.S.C. 552b(c)(4)).

September 30, 2006

Date


Sara M. Thornton
Executive Secretary

Ophthalmic Devices Panel Roster

Chairperson

William D. Mathers, M.D.

Expertise: Ophthalmology
Term: 11/1/04 - 10/31/07
Professor of Ophthalmology
Department of Ophthalmology
Oregon Health Sciences University
3375 SW Terwilliger Blvd.
Portland, OR 97201-4197

Neil M. Bressler, M.D.

Expertise: Clinical Trials; Choroidal
Neovascularization
Term: 12/12/05 - 10/31/09
Professor of Ophthalmology
Johns Hopkins Univ. School of Medicine
550 North Broadway, Suite 115
Baltimore, MD 21205-2002

*** Richard T. Bunner, M.A.**

Expertise: Special Education Visually
Impaired
Term: 2/16/06 - 10/31/09
Public Health Consultant
.....
Zanesville, OH 43701

Stephen A. Burns, Ph.D.

Expertise: Visual Psychophysics
Term: 11/1/04 - 10/31/08
Professor of Optometry
Indiana University
800 W. Atwater
Bloomington, IN 47405

Timothy B. Edrington, O.D., M.S.

Expertise: Cornea & Contact Lenses;
Clinical Trials
Term: 12/12/05 - 10/31/09
Professor
Southern California College of Optometry
2575 Yorba Linda Blvd.
Fullerton, CA 92653

Executive Secretary

Sara Thornton

Center for Devices and Radiological Health
Office of Device Evaluation/DOED
9200 Corporate Blvd. HFZ-460
Rockville, MD 20850
(301) 594-2053 x127
(301) 827-4601

Dale K. Heuer, M.D.

Expertise: Glaucoma; Clinical Trials
Term: 12/12/05 - 10/31/09
Professor & Chair of Ophthalmology
Medical College of Wisconsin
The Eye Institute
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Andrew J.W. Huang, M.D., M.P.H.

Expertise: Ophthalmology; Epidemiology
Term: 11/1/04 - 10/31/08
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Corneal/External
Disease and Refractive Surgery, Dept. of
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**** Barbara A. Niksch, M.B.A.**

Expertise: Regulatory and Clinical
Research
Term: 2/16/06 - 10/31/09
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Page 2 – Ophthalmic Devices Panel Roster (continued)

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President & CEO
Term: 11/18/01 – 10/31/05
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Expertise: Educational Psychology
Term: 11/18/01 – 10/31/05
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Expertise: Ophthalmology
Term: 3/25/02 – 10/31/05
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Timothy T. McMahon, O.D., .A.O.

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Anne L. Coleman, M.D., Ph.D.

Expertise: Ophthalmological Surgery
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Los Angeles, CA 90095-7004

*Consumer Representative

**Industry Representative

ORTHOPAEDIC and REHABILITATION 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 June 2, 2006 and September 19, 2006.

The meeting on September 19, 2006 included a closed session to permit discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

At the June 2, 2006 meeting:

In the open session, the Panel met to discuss and provide recommendations to FDA on a reclassification petition, submitted by RS Medical, to reclassify the non-invasive bone growth stimulator from Class III to Class II. Bone growth stimulators are intended for the treatment of an established nonunion acquired secondary to trauma and as an adjunct to lumbar spinal fusion surgery at 1 or 2 levels. The Panel recommended that non-invasive bone growth stimulators remain in Class III status.

At the September 19, 2006 meeting:

In the open session, the Panel deliberated on a PMA, submitted by Medtronic Sofamor Danek, on the Prestige Cervical Disc System, intended to treat skeletally mature patients with degenerative disc disease at one level from C3-C7. The Panel recommended that the PMA be found approvable with conditions.

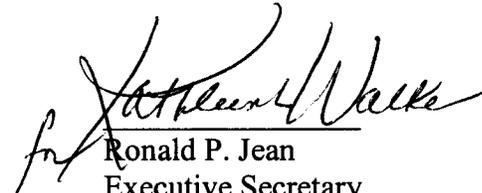
The recommended conditions included: (1) the indicated patient population should be limited to the population studied; (2) the effectiveness claims should be limited to non-inferiority; (3) there should be a post approval animal study to look at long-term bone/implant interface performance and the fate of the particulates that are generated; (4) there should be a post approval clinical study that, in addition to the sponsor's proposed post approval study, includes radiographic evaluations to detect radiolucencies, evaluation of device removals and analysis of retrievals (including the individual

Orthopaedic and Rehabilitation Devices Panel (continued)

components as well as histological specimens), and data on adjacent level surgeries and adjacent segment disease; and (5) the educational materials (e.g., patient information) should be revised to remove the language that motion implies less adjacent segment degeneration and/or effectiveness.

Closed Committee Deliberations: On September 19, 2006, 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, 2006
Date


Ronald P. Jean
Executive Secretary

Orthopaedic and Rehabilitation Devices Panel Roster

Chairperson

John S. Kirkpatrick, M.D.

Expertise: Orthopedic Implants

Term: 11/13/02 - 8/31/06

Associate Professor

Dept. of Surgery, Div. of Orthopaedic Surgery

Univ. of Alabama School of Medicine Faculty

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Executive Secretary

Ronald P. Jean, Ph.D.

Center for Devices and Radiological Health

Office of Device Evaluation/DGRND

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

Expertise: Medical Devices: Bone Graft Substitute

Term: 2/3/05 - 8/31/08

Sr. Vice President and Chief Operating Officer

Etex Corporation

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Jay D. Mabrey, M.D.

Expertise: Total Joint Replacement;

Analysis of Wear Debris

Term: 10/31/05 - 8/31/09

Chief, Department of Orthopaedics

Baylor University Medical Center

500 Gaston Avenue

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Dallas, TX 75246

Stuart B. Goodman, M.D., Ph.D.

Expertise: Orthopaedic Surgery, Total Joint Replacement

Term: 10/31/05 - 8/31/09

Professor

Dept. of Orthopaedic Surgery

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Sally A. Rudicel, M.D.

Expertise: Orthopedics Surgery

Term: 9/1/04 - 8/31/08

Associate Professor

Dept. of Orthopaedics

Tufts Univ., New England Medical Center

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Choll W. Kim, M.D., Ph.D.

Expertise: Spinal Surgery; Biomaterials

Term: 9/1/04 - 8/31/08

Assistant Professor--Spine Surgery

Dept. of Orthopaedic Surgery

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

Expertise: Orthopaedic Surgery and

Orthopaedic Patient Care

Term: 2/3/05 - 8/31/08

Director of Nursing Systems

Piedmont Hospital

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Richard J. Friedman, M.D.

Expertise: Orthopedic Surgery

Term: 11/13/02 - 8/31/06

Clinical Professor of Orthopaedic Surgery

Medical University of South Carolina

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Sanjiv H. Naidu, M.D., Ph.D.

Expertise: Orthopedic Surgery

Term: 11/13/02 - 8/31/06

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Dept. of Orthopaedics and Rehabilitation

Pennsylvania State Univ. Hershey Med Ctr

500 University Dr.

Hershey, PA 17033

*Consumer Representative

**Industry Representative

RADIOLOGICAL DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

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

The date of the meeting was May 23, 2006.

The meeting on May 23, 2006 included a closed session to permit discussion or presentation of trade secret or confidential commercial information.

ACCOMPLISHMENTS

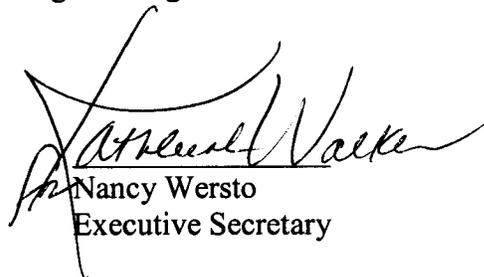
At the May 23, 2006 meeting:

In the open session, the Panel met to discuss and make recommendations on an FDA-initiated proposal to reclassify full-field digital mammography systems (FFDMs). Digital mammography systems are used for the screening of breast cancer and have been Class III devices. The Panel recommended that FFDMs be reclassified into Class II with a guidance document as special control.

Closed Committee Deliberations: On May 23, 2006, the meeting was closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) on current and pending issues regarding radiological devices.

September 30, 2006

Date



Nancy Wersto
Executive Secretary

Radiological Devices Panel Roster

Chairperson

Emily F. Conant, M.D.

Expertise: Breast Cancer
Term: 10/8/03 - 1/31/07
Associate Professor and Chief of Breast Imaging
Department of Radiology
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John D. Bourland, Ph.D.

Expertise: Medical Physics
Term: 5/5/06 - 1/31/09
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*** Charles B. Burns, MSPH, RT(R)**

Expertise: Diagnostic Radiologic Physics
Term: 03/14/04 - 1/31/08
Professor, Div. of Radiologic Science
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Univ. of North Carolina School of Medicine
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Carl J. D'Orsi, M.D.

Expertise: Radiologist
Term: 3/31/06 - 1/31/10
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Breast Imaging Ctr. Winship Cancer Institute
Emory University Hospital
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Executive Secretary

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Bharat B. Mittal, M.D.

Expertise: Radiation Oncologist
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**** Deborah J. Moore**

Expertise: Brain and Breast Cancer
Radiotherapy
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Xiao-Hua A. Zhou, Ph.D.

Expertise: Clinical Trial Design;
Biostatistics
Term: 7/13/04 - 1/31/08
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Seattle, WA 98108-1532

Page 2 – Radiological Devices Panel Roster (continued)

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Expertise: Breast Cancer

Term: 2/22/02 – 1/31/06

Medical Director

Susan G. Komen Breast Cancer Ctr.

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Prabhakar Tripuraneni, M.D.

Expertise: Cancer Radiotherapy

Term: 2/22/02 – 1/31/06

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*Consumer Representative

**Industry Representative



ANNUAL REPORT
OF THE
SCIENCE ADVISORY BOARD TO THE
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH
for the period
October 1, 2005 through September 30, 2006

FUNCTION

The Board advises the Director, NCTR, in establishing, implementing and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling their regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met one time during the reporting period in Jefferson, Arkansas.

The dates of the meeting were August 29-30, 2006, which included both open and closed sessions.

The meeting on August 30, 2006 included the closed session to permit discussion of matters of a personal nature, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

ACCOMPLISHMENTS

In open session, the Board received a report from the Site Visit Team (SVT) review of the Division of Neurotoxicology, which took place January 13 - 14, 2004. The site visit was undertaken by the SVT to evaluate the existing programs and future planned activities of the NCTR Division of Neurotoxicology. As a result of that site visit, the SVT determined that the division makes available a unique interdisciplinary approach to regulatory issues and provides a valuable resource to the FDA, serving

the latter's scientific mission as it pertains to human safety. The Board accepted the SVT report and addressed issues raised and recommendations included in the review. The Division Director provided a response to the SVT report and the Board had an opportunity to discuss the division's actions taken in response to the SVT recommendations.

The Board received Center-wide updates from the Acting Director of the National Center for Toxicological Research (NCTR) on the scientific efforts ongoing within NCTR and on the NCTR strategic focus and realignment. The Board was also informed about the scientific activities ongoing in each of the NCTR divisions by each of the NCTR Division Directors. In addition, the Board heard presentations by representatives from the other FDA Centers/Offices which provided insight into their extensive ongoing collaborations with NCTR and the scientific support available to the Agency at NCTR.

The closed portion of the meeting on August 30, 2006, was devoted to permit discussion of the qualifications and performance of individuals associated with the research programs at the Center that had undergone review. This closed committee session was held to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c) (6)).

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Date: September 27, 2006

Leonard M. Schechtman, Ph.D.
Executive Secretary

**National Center for Toxicological Research
Science Advisory Board**

Chair

Dr. Daniel Acosta, Jr., Ph.D.

Term: 03/06/00-06/30/07

Expertise: Pharmacology and Toxicology

Dean, College of Pharmacy

University of Cincinnati

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Email: daniel.acosta@uc.edu

Designated Federal Officer

Leonard M. Schechtman, Ph.D.

National Center for Toxicological Research

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Dr. Nancy Ann Gillett, DVM, Ph.D.

Term: 04/10/00-06/30/07

Expertise: Veterinary Medicine and Pathology

Sr. Vice President

Sierra Biomedical

Charles River Laboratories

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Email: Nancy.Gillett@us.crl.com

Dr. James A. Popp, DVM, Ph.D.

Term: 07/31/06-06/30/10

Expertise: Toxicology

Co-founder and Co-owner

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Dr. Michael Aschner, Ph.D., ATS

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Dr. Stephen M. Roberts, Ph.D.

Term: 07/31/06-06/30/08

Expertise: Nanotoxicology

Professor & Director

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Dr. James S. Bus, Ph.D., DABT

Term: 07/31/06-06/30/09

Expertise: Toxicology

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Dr. Anthony L. Pometto, Ph.D.

Term: 07/31/06-06/30/10

Expertise: Nutrition/food defense

Professor, Dept. of Food Science & Human Nutrition

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Dr. Pat Levitt, Ph.D.

Term: 07/01/02-06/30/06

Expertise: Neuroscience

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Dr. Paul J. Catalano, Sc.D.

Term: 04/08/03-06/30/06

Expertise: Biostatistics

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