



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 1, 2004

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 2004. A list of the Advisory Committees that held closed meetings during FY 2004 is attached.

These reports are submitted pursuant to Section 10(d) of the Federal Advisory Committee Act which requires each advisory committee which holds closed meetings "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, which appears to read "Theresa L. Green". The signature is written in a cursive style with a long horizontal flourish extending to the right.

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

Enclosures

List of FY 2004 Closed FDA Advisory Committee Meetings

Center for Devices and Radiological Health:

Medical Devices Advisory Committee –

December 11, 2003	Orthopaedic and Rehabilitation Devices Panel
July 13, 2004	Dental Products Panel
February 3, 2004	Radiological Devices Panel
February 5–6, 2004	Ophthalmic Devices Panel

Center for Biologics Evaluation and Research:

October 9–10, 2003	Biological Response Modifiers Advisory Committee
March 18–19, 2004	Blood Products Advisory Committee
May 6, 2004	Vaccines & Related Biological Products Advisory Committee
September 22–23, 2004	Vaccines & Related Biological Products Advisory Committee

Center for Drug Evaluation and Research:

October 28, 2003	Anti-Infective Drugs Advisory Committee
November 19, 2003	Anesthetic and Life Support Drugs Advisory Committee
May 7, 2004	Non-Prescription Drugs Advisory Committee
May 7, 2004	Dermatologic and Ophthalmic Drugs Advisory Committee



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ANNUAL REPORT
OF THE
MEDICAL DEVICES ADVISORY COMMITTEE

for the period

October 1, 2003 through September 30, 2004

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 21 meetings during the reporting period in Gaithersburg, Maryland.

Below are the dates of all device panel meetings during FY 2004 (10/1/03 to 9/30/04) and UNDERLINED dates represent meetings that had closed sessions:

10/02/03	Circulatory System Devices Panel
10/03/03	Ophthalmic Devices Panel
10/14-15/03	General and Plastic Surgery Devices Panel
11/20/03	Circulatory System Devices Panel
11/21/03	General and Plastic Surgery Devices Panel
<u>12/11/03</u>	Orthopaedic and Rehabilitation Devices Panel
<u>02/03/04</u>	Radiological Devices Panel
<u>02/5-6/04</u>	Ophthalmic Devices Panel
02/23/04	Neurological Devices Panel
03/05/04	Ophthalmic Devices Panel
03/17-18/04	Circulatory System Devices Panel
03/25/04	General and Plastic Surgery Devices Panel
04/21/04	Circulatory System Devices Panel
06/2-3/04	Orthopaedic and Rehabilitation Devices Panel
06/03/04	Obstetrics and Gynecology Devices Panel
06/08/04	Circulatory System Devices Panel
06/15/04	Neurological Devices Panel
<u>07/13/04</u>	Dental Product Panel
07/28-29/04	Circulatory System Devices Panel
08/31/04	Orthopaedic and Rehabilitation Devices Panel
09/21/04	Circulatory System Devices Panel

DENTAL PRODUCTS 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 13, 2004.

The meeting on July 13, 2004, included a closed session to permit a discussion of trade secret or confidential commercial information.

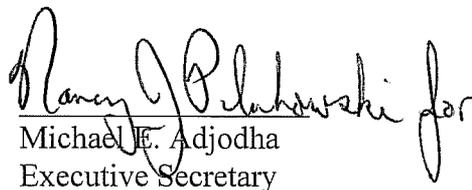
ACCOMPLISHMENTS

In the open session, the Panel recommended an approval with conditions on a PMA from BioMimetic Pharmaceutical, Inc. for the GEM21S™. The GEM 21S™ is a combination product consisting of a beta-tricalcium phosphate bone void filler combined with Becaplermin, a wound-healing drug, to treat osseous defects resulting from periodontal disease, cystectomy, apicoectomy, deficient alveolar ridges, and tooth extraction. The Panel's conditions included: (1) there should be no labeling claims of superiority over other devices considering the primary endpoint, i.e. clinical attachment level; and (2) labeling should be restricted to use only for periodontal related defects.

Closed Committee Deliberations: On July 13, 2004, the meeting was closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future agency issues (5 U.S.C.552b(c)(4)).

September 30, 2004

Date


Nancy J. Pelukowski for
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

Leslie B. Heffez, DMD

Expertise: Oral/Maxillofacial Surgery

Term: 8/29/00 – 10/31/03

Professor and Head,

Oral/Maxillofacial Surgery

College of Dentistry, University of
Illinois at Chicago

801 South Paulina Street MC 835

Chicago, IL 60612

Executive Secretary

Michael E. Adjodha

Center for Devices and Radiological Health

Office of Device Evaluation/DAGID

9200 Corporate Blvd. HFZ-480

Rockville, MD 20850

(301) 827-5283 x 123

(301) 480-3002

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

William J. O'Brien, M.S., Ph.D.

Expertise: Material Sciences

Term: 3/22/04 - 10/31/07

Professor of Dentistry

Dept. of Biologic and Materials Science

Univ. of Michigan School of Dentistry

1011 N. University, Room 2203

Ann Arbor, MI 48103

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

The Univ. of Texas Hlth. Sci. Ctr. at San
Antonio

7703 Floyd Curl Drive, Rm. 3-55IU

San Antonio, TX 78284-7894

Elizabeth D. Rekow, D.D.S., Ph.D.

Expertise: Dental Sciences

Term: 8/29/00 - 10/31/03

Dir. Translational Research, Prof. Orthodontics

NYU College of Dentistry

345 East 24th Street

Room 1003S

New York, NY 10010-409

Raymond J. Fonseca, M.D.

Expertise: Oral Surgery

Term: 8/29/00 - 10/31/03

Dean

School of Dental Medicine

University of Pennsylvania

4001 Spruce Street

Philadelphia, PA 19104-6003

****Daniel R. Schechter, Esq.**

Expertise: Business Law

Term: 1/13/02 - 10/31/05

General Counsel

Parkell, Inc.

155 Schmitt Boulevard

Farmingdale, NY 11735

Domenick T. Zero, D.D.S., M.S.

Expertise: Cariology; Dental Sciences, Clinical

Term: 3/22/04 - 10/31/07

Professor and Chairman

Preventive and Community Dentistry

Indiana Univ. School of Dentistry

415 Lansing Street

Indianapolis, IN 46202-2876

***Elizabeth S. Howe**

Expertise: Social Sciences
Term: 12/16/01 - 10/31/05
Outreach Coordinator
National Foundation for Ectodermal
Dysplasias
P. O. Box 2069
Auburn, WA 98071

John R. Zuniga, Ph.D., D.M.D.

Expertise: Oral Surgery; Neurosciences
Term: 3/22/04 - 10/31/06
Professor and Graduate Program Director
Dept. of Oral and Maxillofacial Surgery
Univ. of North Carolina School of Dentistry
115 Brauer Hall, CB#7450
Chapel Hill, NC 27599-7450

Man Wai Ng, D.D.S., M.P.H.

Expertise: Pediatric Dentistry; Dental Health,
Clinical
Term: 3/22/04 - 10/31/06
Chief, Department of Dentistry
Department of Dentistry
Children's Hospital Boston
300 Longwood Ave.
Boston, MA 02115

**Industry Representative

*Consumer Representative

OPHTHALMIC DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

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

The dates of those meetings were October 3, 2003, February 5-6, 2004, and March 5, 2004.

The meeting on February 5-6, 2004, included a closed session to permit a discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

At the October 3, 2003 meeting:

In the open session, a PMA supplement for the STAAR Myopic Implantable Contact Lens (ICL™) was recommended for approval with conditions. The device, a phakic intraocular lens, is indicated for the correction of moderate to high myopia with placement in the posterior chamber of the phakic eye. The Panel's conditions included changes in the indications for use, additions to both patient and physician labeling and consideration of post-market studies.

At the February 5-6, 2004 meeting:

In the open session, during the first day, a PMA for the ARTISAN™ Myopia Phakic Intraocular lens was recommended for approval with conditions. The device is indicated for the reduction or elimination of myopia in adults. The conditions included:

- Agency should determine the age and minimum corneal endothelial cell count allowable for implantation of the lens.
- The sponsor should reanalyze the existing data for pigment dispersion and elevated intraocular pressure in the minority subset of the cohort.
- Perform a 2-3 year post-market study to further evaluate the incidence of retinal detachments, lens explants, and cataract formation.
- Strengthen the physician and patient labeling with various recommendations including clarification or elimination of confusing terms, and additional warnings and precautions.

Agency Action: On September 10, 2004, FDA issued an approval order for the device.

On the second day, a PMA for the Viewpoint™ Conductive Keratoplasty (CK) System was recommended for approval with conditions. This radiofrequency electro-surgical corneal shaping device is indicated for the temporary spherical treatment in the non-dominant eye of presbyopic emmetropes or presbyopic hyperopes. One condition was slightly restricting the indications statement to reflect an intended range of refractive correction to 1.00 to 2.25 diopters of effect.

Ophthalmic Devices Panel (*continued*)

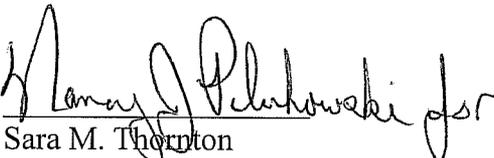
The other condition strengthened the physician and patient labeling by adding information: (a) safety and effectiveness of retreatments have not been determined; (b) nystagmus should be a contraindication; (c) a table that defines the frequency of induced astigmatism and the effect on near and distance vision; and (d) a graph of the total effect of regression over time to focus attention on the temporary nature of the procedure's vision improvement.

Closed Committee Deliberations: On February 6, 2004, 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 was closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

At the March 5, 2004 meeting:

The Panel discussed issues related to the appropriate clinical trial design for the evaluation of multifocal or accommodative intraocular lenses (IOLs) in a cohort of subjects who have undergone clear lens extraction to correct presbyopia. Clear lens extraction is an intraocular surgical procedure in which the non-cataractous crystalline lens is removed and replaced with a multifocal or accommodative lens for refractive correction. There was no vote taken nor consensus requested of the Panel. The purpose of the meeting was to assist FDA in working with industry to design clinical trial protocols that would establish the reasonable safety and effectiveness of clear lens extraction with implantation of a multifocal or accommodative IOL.

September 30, 2004
Date


Sara M. Thornton
Executive Secretary

Ophthalmic Devices Panel Roster

Chairperson

Jayne S. Weiss, M.D.

Expertise: Ophthalmological Surgery
Term: 3/25/02 - 10/31/04
Prof. Ophthalmology and Pathology
Director of Ophthalmic Pathology
Kresge Eye Institute, Wayne State Univ.
4717 St. Antoine Blvd.
Detroit, MI 48201

Arthur Bradley, Ph.D.

Expertise: Visual Physiology
Term: 11/1/00 - 10/31/04
Professor of Visual Science
Indiana Univ. School of Optometry
Dept. of Visual Sciences
800 East Atwater Ave.
Bloomington, IN 47405-

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

Expertise: Ophthalmological Surgery
Term: 3/25/02 - 10/31/05
Professor of Ophthalmology
Department of Ophthalmology
Jules Stein Eye Institute, UCLA Sch of
Medicine
100 Stein Plaza
Los Angeles, CA 90095-7004

Michael R. Grimmatt, M.D.

Expertise: Ophthalmology
Term: 11/1/00 - 10/31/04
Grimmett Eye Care, PLLC.
3385 Burns Road
Suite 209
Palm Beach Gardens, FL 33410

Allen C. Ho, M.D.

Expertise: Ophthalmology
Term: 3/25/02 - 10/31/05
Associate Surgeon
Retinovitreal Associates
910 East Willow Grove Avenue
Wyndmoor, PA 19038

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
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Alice Y. Matoba, M.D.

Expertise: Ophthalmology
Term: 2/27/00 - 10/31/03
Associate Prof. of Ophthalmology
Baylor College of Medicine, Cullen
Eye Institute
6565 Fannin, NC-205
Houston, Texas 77030

William D. Mathers, M.D.

Expertise: Ophthalmology
Term: 11/1/03 - 10/31/07
Professor of Ophthalmology
Department of Ophthalmology
Oregon Health Sciences University
3375 SW Terwilliger Blvd.
Portland, OR 97201-4197

****Ronald E. McCarley**

Term: 11/18/01 - 10/31/05
President & CEO
Ophtec, USA, Inc.
6421 Congress Avenue Suite 112
Boca Raton, FL 33487

Timothy T. McMahon, O.D., F.A.O.

Expertise: Optometry
Term: 3/25/02 - 10/31/05
Professor of Ophthalmology
Dept. of Ophthalmology & Visual Sciences
University of Illinois at Chicago
1855 W. Taylor Street, Suite 3.164
Chicago, IL 60612

*** Glenda V. Such, M.Ed.**

Expertise: Educational Psychology
Term: 11/18/01 - 10/31/05
Director of Computer Training Programs
Career Services Dept.
Lighthouse International
111 E. 59th Street
New York, NY 10022

*Consumer Representative

**Industry Representative

ORTHOPAEDIC and REHABILITATION DEVICES PANEL

MEMBERSHIP

A roster of members is attached.

MEETINGS

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

The dates of the meetings were December 11, 2003, June 2-3, 2004, and August 31, 2004

The meeting on December 11, 2003, included a closed session to permit a discussion of trade secret or confidential commercial information.

ACCOMPLISHMENTS

At the December 11, 2003 meeting:

The Panel considered an FDA-initiated reclassification of the intervertebral body fusion cage device from class III to class II. The device is intended for spinal fusion procedures in skeletally mature adults with degenerative disc disease (DDD) at one or two levels from C2-C7 and L2-S1 using autogenous bone graft. The device does not include combination products, such as the intervertebral body fusion device using morphogenic proteins and scaffolds. The Panel recommended that FDA reclassify the device into class II using three special controls to reasonably assure the safety and effectiveness of the device: (1) a guidance document that may include clinical data for designs and materials beyond those currently approved; (2) device tracking for all implants not just cages for a limited period of time; and (3) testing guidelines, which include fracture toughness, potential response to wear particulates, and device retrieval analysis for a limited number of explanted devices.

Agency Action: FDA is drafting a reclassification rulemaking for this device.

Closed Committee Deliberations: On December 11, 2003, the meeting was closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

At the June 2-3, 2004 meeting:

On June 2, 2004, the open session, the Panel recommended conditional approval for Depuy Spine, Inc.'s PMA for Charité Artificial Disc. The device is intended for spinal arthroplasty in skeletally mature patients with degenerative disc disease at one level from L4-S1. The conditions were:

- A post-market study of all patients enrolled in the investigational device exemption (IDE) (including continued access patients) should be followed until the last-enrolled continued access subject reaches the 2 year time point, and the data will be provided the FDA.

Orthopaedic and Rehabilitation Devices Panel (continued)

- All patients treated with the device should be provided with documentation describing the specific components of their implant, including associated lot numbers, as well as a telephone number to be used for the reporting of any adverse events.
- A post-market *in-vitro* study to further assess wear debris.
- FDA should consider required surgeon training.
- FDA and the sponsor should discuss certain additional conditions and reach a mutually agreeable course of action. This discussion will consider whether these conditions should be addressed pre- or post-market.

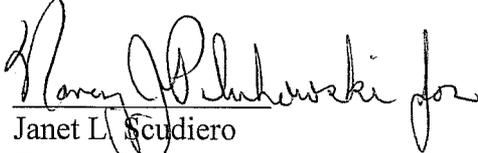
On June 3, 2004, the Panel made recommendations to FDA regarding the Orthopedic Surgical Manufacturers Association's petition to reclassify the total mobile bearing knee (MBK) and unicompartamental MBK intended to replace the total knee or part of the knee joint, respectively, from class III into class II. The Panel recommended that FDA reclassify the total MBKs into class II. They suggested five special controls to reasonably assure the safety and effectiveness of the devices: (1) a special controls guidance document; (2) testing guidelines; (3) potential use of clinical data; (4) device specific training and labeling (to be negotiated with sponsors); and (5) patient identification cards (to include patient, surgeon, hospital, and implant information). They also recommended that FDA reclassify the unicompartamental MBK into class II. The Panel recommended the same special controls as identified for the total MBK, with a stronger emphasis placed on the use of clinical data. In addition, the Panel also urged post-market surveillance to track such adverse events as osteolysis, bearing dislocations, polyethylene failures, and revisions.

Additionally, the Panel made recommendations to the FDA regarding Orthopedic Surgeon Manufacturers Association's (OSMA) guidance document submission entitled Clinical Trial Design for Hip Replacement Systems. The main focus of the submission was a proposed clinical study design for evaluating the safety and effectiveness of total hip joint replacement systems. The design includes a composite endpoint consisting of three objective performance criteria as a control for patient success with a benchmark for overall study success and a 4% delta for noninferiority.

At the August 31, 2004 meeting:

In the open session, the Panel deliberated on St. Francis Medical Technologies, Inc.'s PMA for the X Stop Interspinous Process Distraction System. The device is indicated for patients aged 50 years or older suffering from neurogenic intermittent claudication secondary to mild or moderate lumbar spinal stenosis, who have undergone a regimen of nonoperative treatment and experience relief in flexion from their symptoms of leg/buttock/groin pain, with and without back pain. After deliberations, the Panel recommended that the PMA be found not approvable. The Panel cited several concerns regarding the data; they discussed several options for the sponsor to put the PMA in an approvable form.

September 30, 2004
Date


Janet L. Scudiero
Executive Secretary

Orthopaedic and Rehabilitation Devices Panel Roster

Chairperson

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

Expertise: Orthopedic Surgery
Term: 11/13/02 - 8/31/05
Senior Associate Consultant and Associate Professor
Dept. of Orthopedic Surgery
Mayo Clinic and Graduate School of Medicine
200 1st Street SW
Rochester, MN 55905

Maureen A. Finnegan, M.D.

Expertise: Orthopedic Surgery
Term: 10/11/00 - 8/31/04
Associate Professor
Dept. of Orthopaedic Surgery
Univ. of Texas Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, TX 75390-8883

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
2270 Ashley Crossing Dr. Suite 110
Charleston, SC 29414

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
Univ. of California, San Diego
3350 La Jolla Village Dr., MC#112D
San Diego, CA 92161

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
510 20th St South FOT-Suite 940
Birmingham, AL 35294-3295

Executive Secretary

Janet Scudiero

Center for Devices and Radiological Health
Office of Device Evaluation/DGRND
9200 Corporate Blvd. HFZ-410
Rockville, MD 20850
(301) 594-1184 X 176
(301) 594-2358

Kinley Larntz, Ph.D.

Expertise: Biostatistics
Term: 11/13/02 - 8/31/05
Professor Emeritus
Dept. of Applied Statistics
University of Minnesota
6339 East Greenway, #102-172
Scottsdale, AZ 85254-6517

Stephen Li, Ph.D.

Expertise: Biomaterials; Materials Science
Term: 10/11/00 - 8/31/04
President
Medical Device Testing and Innovations
1469 Tallevast Road
Sarasota, FL 34243

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

Expertise: Orthopedic Surgery
Term: 11/13/02 - 8/31/06
Associate Professor of Orthopaedic Surgery
Dept. of Orthopaedics and Rehabilitation
Pennsylvania State Univ., Hershey Medical Ctr
500 University Dr.
Hershey, PA 17033

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
750 Washington Street
Box 306
Boston, MA 02111

****Sally Maher, ESQ**

Expertise: Bacteriology
Term: 12/31/00 - 8/31/04
Senior Director, Regulatory Affairs
Clinical Research
Smith & Nephew Endoscopy
150 Minuteman Road
Andover, MA 01810

** 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 February 3, 2004.

The meeting on February 3, 2004, included a closed session to permit a discussion of trade secret or confidential commercial information.

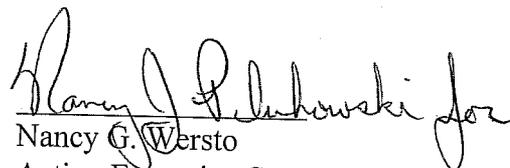
ACCOMPLISHMENTS

In the open session, the Panel discussed R2 Technologies, Inc.'s PMA for the ImageChecker CT CAD Software System. The device, a computer-aided detection (CAD) system, is designed to assist a physician in the identification of solid nodules in computerized topography (CT) images of the lung. It is intended to be a "second reader" that alerts the user to regions of interest that may have been initially overlooked. After deliberations, the Panel recommended that the application be found approvable with the following conditions: (1) a reanalysis of the data prior to approval to assess clinical significance; (2) the inclusion of strict rules for use in the labeling; (3) a requirement for formalized user training; and (4) post-market surveillance to continue collecting data on clinical significance.

Closed Committee Deliberations: On February 3, 2004, the meeting was closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future agency issues.

September 30, 2004

Date


Nancy G. Wersto
Acting Executive Secretary

Radiological Devices Panel Roster

Chairperson

Minesh P. Mehta, M.D.

Expertise: Radiotherapy; Brain or Nervous System Cancer

Term: 2/22/02 - 1/31/05

Professor & Chairman

Dept. of Human Oncology

University of Wisconsin-Madison

600 Highland Ave., K4/312 CSC

Madison, WI 53792

Executive Secretary

Nancy G., Acting Wersto

Center for Devices and Radiological Health

Office of Device Evaluation/DRAERD

9200 Corporate Blvd. HFZ-470

Rockville, MD 20850

(301) 594-1212 x144

(301) 480-4224

Wendie A. Berg, M.D., Ph.D.

Expertise: Radiology; Breast Cancer

Term: 4/21/00 - 1/31/04

Address not available

Baltimore, MD 21201

****Deborah J. Moore**

Expertise: Brain and Breast Cancer

Radiotherapy

Term: 2/1/04 - 1/31/08

Vice President, Regulatory & Clinical Affairs

Proxima Therapeutics, Inc.

2555 Marconi Drive Suite 220

Alpharetta, GA 30005--2066

*** Charles B. Burns, MSPH, RT(R)**

Expertise: Diagnostic Radiologic Physics

Term: 12/22/03 - 1/31/07

Professor, Div. of Radiologic Science

Dept. of Allied Health Sciences

Univ. of North Carolina School of Medicine

CB# 7130 Medical School Wing E

Chapel Hill, NC 27599-7130

Peter E. Shile, M.D.

Expertise: Breast Cancer

Term: 2/22/02 - 1/31/06

Medical Director

Susan G. Komen Breast Center

8800 North Route 91

Peoria, IL 61615

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

University of Pennsylvania School of Medicine

3400 Spruce Street

Philadelphia, PA 19104

****Ernest L. Stern, B.S.**

Expertise: Radiology

Term: 8/13/00 - 1/31/04

Chairman and CEO

Thales Components Corp.

40 G Commerce Way

P.O. Box 540

Totowa, NJ 07511-0540

Harry K. Genant, M.D.

Expertise: Acoustics; Ultrasound

Term: 4/21/00 - 1/31/04

Prof. Radiology, Medicine, Epidemiology

University of California, San Francisco

Dept. of Radiology

505 Parnassus Ave., M392

San Francisco, CA 94143-0628

Prabhakar Tripuraneni, M.D.

Expertise: Cancer Radiotherapy

Term: 2/22/02 - 1/31/06

Head, Division of Radiation Oncology

Scripps Clinic/ Scripps Green Hospital

10666 North Torrey Pines Road, MSB1

La Jolla, CA 92037

Geoffrey S. Ibbott, Ph.D.

Expertise: Medical Physics; Radiation

Dosimetry

Term: 8/20/01 - 1/31/05

Associate Professor & Section Chief

UT M.D. Anderson Cancer Center

Dept. of Radiation Physics

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Xiao-Hua A. Zhou, Ph.D.

Expertise: Clinical Trial Design; Biostatistics

Term: 7/13/04 - 1/31/08

Professor, Dept. of Biostatistics

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Elizabeth A. Krupinski, Ph.D.
Expertise: Radiology
Term: 7/13/04 - 1/31/08
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Dept. of Radiology
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*Consumer Representative
**Industry Representative



ANNUAL REPORT
OF THE
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
(renamed the Cellular, Tissue and Gene Therapies Advisory Committee)

For the period

October 1, 2003 through September 30, 2004

FUNCTION

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases. 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 two times during the reporting period. Meetings were held in Gaithersburg, Maryland and Silver Spring, Maryland.

The dates of those meetings were October 9-10, 2003 and March 18-19, 2004.

The meetings on October 9-10, 2003 included a closed session to permit discussion of matters of a personal nature.

ACCOMPLISHMENTS

October 9-10, 2003: The topics were allogeneic islet transplantation including Federal oversight of allogeneic islet transplantation, islet processing, islet characterization and quality, possible licensing of islet products, and updates of individual research programs in the Division of Cellular and Gene Therapies and the Division of Therapeutic Proteins. The issues from this meeting are currently under consideration by FDA. On October 10, 2003, the Committee held a closed session to discuss and make recommendations on personnel and program actions for the Laboratory of Immunology and Virology and the Laboratory of Biochemistry. 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.

March 18-19, 2004: The topics included cellular therapies for cardiac disease including cardiomyopathy and ischemic heart disease, autologous myoblast transplantation, bone marrow cell therapy for angiogenesis, hematopoietic and mesenchymal cell therapies, cardiac catheters for delivery of cell suspensions, and transcatheter myocardial cell delivery. These issues are currently under consideration by FDA.

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

9/30/04

Date

Gail Dapolito

Gail Dapolito

Executive Secretary

Biological Response Modifiers Advisory Committee

Chair

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

Expertise: Cellular Biology
Term: 05-22-01 - 03-31-05
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Jonathan S. Allan, D.V.M.

Expertise: Veterinary Medicine
Term: 09-30-02 – 03-31-06
Scientist
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Medicine
Department of Virology and Immunology
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Expertise: Pediatric Hematology
Term: 05-22-01 – 03-31-05
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David M. Harlan, M.D.

Expertise: Transplantation, Autoimmunity
Term: 09-30-02 – 03-31-06
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Chief, Islet and Autoimmunity Branch
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and Kidney Disease, NIH, DHHS
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Executive Secretary

Gail Dapolito

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Department of Genetics
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Expertise: Bioethics
Term: 01-05-04 - 03-31-07
President
The Hastings Center
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Expertise: Tumor Immunology / TC Clearance
Term: 01-05-04 - 03-31-07
Associate Center Director
Translation Science and Technology
Development
Michael McGillicuddy Endowed Chair
Melanoma Research and Treatment
H. Lee Moffitt Cancer Center and Research
Institute
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Joanne Kurtzberg, M.D.

Expertise: Pediatric Hematology
Term: 05/09/00 - 03/31/04
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Pediatric Bone Marrow and Stem Cell
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Alison F. Lawton**

Expertise: Industry Representative
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*Consumer Representative

**Industry Representative

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Expertise: Biostatistics
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Alice J. Wolfson, J.D.*

Expertise: Women's Health Law
Term: 05/09/00 - 03/31/04
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ANNUAL REPORT
OF THE
BLOOD PRODUCTS ADVISORY COMMITTEE

For the period

October 1, 2003 through September 30, 2004

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 December 11-12, 2003, March 18-19, 2004, and July 22-23, 2004.

The meeting on March 18-19, 2004 included closed sessions to permit discussion of trade secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

December 11-12, 2003: The topics included the American Association of Blood Bank's (AABB) abbreviated questionnaire, blood donor deferral for Leishmaniasis, West Nile Virus, and plasma collection nomograms. FDA is considering the validity of an abbreviated questionnaire for blood donors, the impact of blood donors exposed to Leishmaniasis on the blood supply, the effect of donor testing for West Nile Virus on the blood supply, and possible adjustments in nomogram standards.

March 18-19, 2004: The topics included clinical trials for licensing Hepatitis B Immune Globulin Intravenous as a treatment to prevent Hepatitis B Virus (HBV) liver disease following liver transplantation in HBV positive recipients, supplemental testing for Human Immune Deficiency Virus (HIV) and Hepatitis C Virus (HCV), and product standards, quality assurance, and submission requirements for platelets, pheresis. FDA is currently evaluating the clinical trials for Hepatitis B Immune Globulin Intravenous, considering the effectiveness of supplemental testing methodologies for HIV and HCV, and evaluating a statistical quality control model for platelet pheresis. On March 19, the Committee held a closed session to permit discussion of personnel and program actions for the Laboratory of Hepatitis and Related Emerging Agents and 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.

July 22-23, 2004: The topics were dating of irradiated red blood cells, new standards for platelet evaluation, bacterial contamination of platelets, and Hepatitis B Virus Nucleic Acid Testing for donors of whole blood. FDA is considering the viability of red blood cells and how long irradiation cells can last in order to prevent graft vs. host disease. FDA is also evaluating the recommendations from the Committee regarding platelet standards. The Committee recommendations regarding NAT testing for donors of whole blood is currently under consideration by FDA.

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

9/30/04
Date

Paul Dapolito for
Linda A. Smallwood, Ph.D.
Executive Secretary

Blood Products Advisory Committee

Chair

Kenrad E. Nelson, M.D.

Expertise: Epidemiology
Term: 12/05/01 – 09/30/04
Professor
Department of Epidemiology
The Johns Hopkins University
School of Hygiene and Public Health
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James R. Allen, M.D.

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Term: 02/08/02 – 09/30/05
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American Social Health Association
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Charlotte Cunningham-Rundles, M.D., Ph.D.

Expertise: Immunobiology, Pathology
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Kenneth Davis, Jr., M.D.

Expertise: Trauma, Critical Care
Anesthesiology
Term: 02/08/02 - 09/30/05
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Anesthesia
Department of Surgery
Division of Trauma/Critical Care
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Executive Secretary

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Harvey G. Klein, M.D.

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Suman Laal, Ph.D.

Expertise: Immunology, Microbiology
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VA Medical Center
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Judy F. Lew, M.D.

Expertise: Infectious Disease, Molecular
Epidemiology
Term: 02/08/02 - 09/30/05
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University of Florida
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Donna M. DiMichele, M.D.

Expertise: Pediatric Hematology, Oncology
Term: 02/08/02 - 09/30/05
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Weill Medical College and Graduate
School of Medical Sciences
Cornell University
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New York, New York 10021

D. Michael Strong, Ph.D, BCLD (ABB)**

Expertise: Immunology, Hematology
Term: 02/13/03 – 09/30/04
Executive Vice President, Operations
Puget Sound Blood Center
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Samuel H. Doppelt, M.D.

Expertise: Orthopedic Surgery,
Transplantation
Term: 02/08/02 - 09/30/05
Chief, Department of Orthopedic Surgery
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* Consumer Representative

** Industry Representative



ANNUAL REPORT
OF THE
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
For the period
October 1, 2003 through September 30, 2004

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 four times during the reporting period. Meetings were held in Bethesda, Maryland. Two meetings were held by teleconference.

The dates of those meetings were February 18-19, 2004, March 17, 2004, May 6, 2004, and September 22-23, 2004.

The meetings on May 6, 2004, and September 22-23, 2004 included closed sessions to permit discussion of secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

February 18-19, 2004: The topic was the strain selection for the Influenza Virus Vaccine for the 2004-2005 season including strain characterization.

March 17, 2004 teleconference on the National Institutes of Health campus in Bethesda, Maryland: The topic was the influenza B component for the strain selection of the Influenza Virus Vaccine for the 2004-2005 season. FDA used the recommendations from the February and March meetings to make formal recommendations to industry for the composition of the 2004-2005 Influenza Virus Vaccine.

May 6, 2004 teleconference on the National Institutes of Health campus in Bethesda, Maryland: The topics was an overview of the Laboratory of DNA Viruses, Division of Viral Products, Office of Vaccines Research and Review. In the afternoon of May 6, 2004, the Committee held a closed session to make recommendations on personnel and program actions for the Laboratory of DNA. 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 22-23, 2004: The topics was Aventis Pasteur Inc.'s Tetavalent Meningococcal Conjugate Vaccine, Menactra, including clinical data, safety and efficacy, and an overview of the Thailand HIV Vaccine Phase 3 Trial. On September 23, 2004, the Committee held a closed session to permit a discussion and review of trade secrets and/or confidential information 5 U.S.C. 552b(c)(4). These issues are under consideration by FDA.

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

9/30/04
Date

Paul Dapocito for
Christine A. Walsh, R.N.
Executive Secretary

Vaccines and Related Biological Products Advisory Committee

Chair

Gary D. Overturf, M.D.

Expertise: Pediatrics
Term: 02/01/02 - 01/31/06
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Albuquerque, New Mexico 87131

Chair

David S. Stephens, M.D.

Expertise: Bacterial Pathogenesis
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Division of Infectious Diseases
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Expertise: Infectious Diseases
Term: 06/20/01- 05/28/04
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Pamela S. Diaz, M.D.

Expertise: Pediatrics, Infectious Disease
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Executive Secretary

Christine Walsh, R.N.

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Expertise: Neonatology
Term: 07/11/00 - 01/31/04
President Emeritus
Spelman College
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David M. Markovitz, M.D.

Expertise: Infectious Diseases
Term: 02/01/02 - 01/31/06
Professor
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Expertise: Bacterial Infectious Diseases
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Expertise: Biostatistics, Clinical Trials
Term: 07/11/000 - 01/31/04
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Ruth A. Karron, M.D.

Expertise: Pediatrics & Infectious Diseases
Term: 02/01/03 - 01/31/07
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Samuel L. Katz, M.D.

Expertise: Pediatrics, Infectious Disease
Term: 07/11/00 - 01/31/04
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Expertise: Molecular Biology
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Cindy Lyn Province, R.N., M.S.N.*

Expertise: Consumer Representative
Term: 04/10/03 - 01/31/05
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Expertise: Infectious Diseases / Neurology
Term: 02/01/03 - 01/31/07
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Expertise: Pediatrics & Infectious Diseases

Term: 06/20/01 - 01/31/05

Professor

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Term: 02/01/04 - 01/31/08

Assistant Professor of Pediatrics

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Houston, Texas 77030



ANNUAL REPORT

OF THE

Anti-Infective Drugs Advisory Committee

for the period

October 1, 2003 through September 30, 2004

FUNCTION

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and make 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 in Gaithersburg, Maryland and Rockville, Maryland.

The dates of those meetings were October 28 & 29, 2003, October 29 & 30, February 2, 2004, February 3 & 4, and June 9, 2004.

The meeting on October 28, 2003, 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

October 28-29, 2003: On October 28, 2003, the Anti-Infective Drugs Advisory Committee began with a closed session. The meeting was closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b (c) (4)). Following the closed session, the committee discussed clinical trial design issues for demonstrating the safety and efficacy of antimicrobials in the treatment of diabetic foot infections. The committee offered responses to agency questions to include: 1) the definition of “diabetic foot infection”, 2) considerations for clinical trials for ruling out osteomyelitis in patients in trials of diabetic foot infections, 3) how to determine drug efficacy for the diabetic foot infection in the setting of osteomyelitis and whether such patients should be considered clinical cures or failures, and 4) how to define clinical success or failure in patients in a clinical trial of diabetic foot infections. The Agency’s questions generated productive discussions of the issues, but the Committee was unable to reach consensus. Agency action: the agency obtained information from the advisory committee to revise the “Uncomplicated and Complicated Skin and Skin Structures Guidance” to include information on diabetic foot infections. On October 29, 2003, the Committee discussed clinical trial design of antimicrobials in the treatment of acute bacterial sinusitis. The agency obtained information from the advisory committee for review of the “Acute Bacterial Sinusitis Guidance Document”. The committee offered recommendations on the following: 1) how to ensure that patients in clinical trials of acute bacterial sinusitis have bacterial disease, 2) the methods of obtaining microbiologic data including sinus punctures and nasal endoscopy, 3) the strengths and limitations of placebo-controlled trials and non-inferiority trials, 4) determining a non-inferiority margin in non-inferiority trials for this indication, 5) the strengths and limitations of comparative microbiologic data, and 6) the issues of measuring outcomes in patients in trials of acute bacterial sinusitis, to include the measurement of time-to-resolution of symptoms as an endpoint compared to fixed endpoints. Agency action: This guidance document entitled “Acute bacterial Sinusitis- Developing Drugs for Treatment” has been rewritten and is currently undergoing internal agency review.

October 29-30, 2003: On October 29, 2003, the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee met to discuss the clinical risk management of hypothalamic pituitary adrenal (HPA) axis suppression in children with Atopic Dermatitis being treated with Topical Corticosteroids and the agency reported to the Subcommittee on Adverse Event Reporting as mandated in section 17 of the Best Pharmaceuticals for Children Act (BCPA). The products discussed during this portion of the meeting included ZYRTEC (cetirizine), BUSULFEX (busulfan), COZAAR (losartan), NOLVADEX (tamoxifen), ACCUPRIL (quinapril), and SERZONE (nefazodone).

The Subcommittee felt that use of topical corticosteroids was a relevant concern for pediatric patients. Several risk management approaches were discussed to include; the conduct of additional studies in children, to include, epidemiological studies relating to steroid exposure and effect on risk, studies to look at cortisol levels in patients under conditions of high stress, educational items that provide practical information such as that included in the Patient Package Insert, and education materials that provide information on issues on the topic that are actively being discovered. Agency action: The agency is taking the advisory committee recommendations under consideration.

On October 30, 2003, the Subcommittee met to discuss how to approach long-term monitoring for cancer occurrence among patients treated for atopic dermatitis with topical immunosuppressants. The Subcommittee felt that education and training, additional studies and possible labeling changes may be necessary to address long term monitoring for cancer occurrence among patients treated for atopic dermatitis with topical immunosuppressants. Agency action: The agency is taking the advisory committee recommendations under consideration.

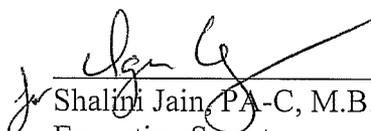
February 2, 2004: On February 2, 2004, the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee met with the Psychopharmacologic Drugs Advisory Committee to discuss reports of the occurrence of suicide (both suicidal ideation and suicide attempts) in clinical trials for various anti-depressant drugs in pediatric patients with major depressive disorder (MDD). The Committee considered optimal approaches to the analysis of data from these trials, and the results of analyses conducted to date, with regard to the question of what regulatory action may be needed pertinent to the clinical use of these products in pediatric patients. The Committee also considered further research was needed to address questions on the topic. Agency action: The agency had a follow-up joint advisory committee meeting with participation by the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee on September 13 and 14, 2004, to discuss reports of the occurrence of suicide (both suicide ideation and suicide attempts) in clinical trials for various antidepressant drugs in pediatric patients with major depressive disorder and other psychiatric disorders. This meeting was announced in the Federal Register of August 4, 2004 (69 FR 47157-47158).

February 3-4, 2004: On February 3, 2004, the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee met and the agency reported to the Subcommittee on Adverse Event Reporting as mandated in Section 17 of the Best Pharmaceuticals for Children Act (BPCA). The products reported were Paxil (paroxetine), Celexa (citalopram), Pravachol (pravastatin), and Navelbine (vinorelbine). The Subcommittee then discussed the use of imaging drugs in conjunction with cardiac imaging procedures in the pediatric population. On February 4, 2004, the Subcommittee met to continue the discussion of the use of imaging drugs in conjunction with cardiac imaging procedures in the pediatric population. Agency action: The agency is taking the advisory committee recommendations under consideration.

June 9, 2004: On June 9, 2004, the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee met and the agency reported to the Committee on the adverse event reporting as mandated in section 17 of the Best Pharmaceuticals for Children Act. The products discussed included HYCAMTIN (topotecan), TEMODAR (temozolomide), EFFEXOR (venlafaxine), MONOPRIL (fosinopril), ALLEGRA (fexofenadine), DURAGESIC (fentanyl), CILOXAN (ciprofloxacin), and VIGAMOX (moxifloxacin). Following this, the agency provided an update on neonatal withdrawal syndrome and congenital eye malformations reported in infants whose mothers used selective serotonin reuptake inhibitors (SSRIs) during pregnancy. An overview of the Pediatric Research Equity Act, which was signed into law on December 3, 2003, was presented. The agency provided an overview of the Institute of Medicine report entitled "Ethical Conduct in Pediatric Clinical Trials." The committee was updated by the agency on the subpart D, institutional review board referral process. Agency action: The agency is taking the advisory committee recommendations under consideration.

09/30/2004

Date



Shalini Jain, PA-C, M.B.A.
Executive Secretary

**ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH**

CHAIR

James E. Leggett, Jr., M.D.
Expertise: Infectious Diseases
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CHAIR

Ellen R. Wald, M.D.
Expertise: Pediatric Infectious Diseases
Term: 02/23/00 – 11/30/03
Chief, Allergy, Immunology and Infectious Diseases
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EXECUTIVE SECRETARY

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MEMBERS

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Term: 12/1/00 – 11/30/04
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Expertise: Infectious Diseases
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Chief, Division of Infectious Diseases
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David M. Bell, M.D.
Expertise: Pediatric Infectious Diseases
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Expertise: Industry Representative
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***Consumer Representative**

****Industry Representative**



ANNUAL REPORT
OF THE
Anesthetic and Life Support Drugs Advisory Committee
for the period
October 1, 2003 through September 30, 2004

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 Gaithersburg, Maryland.

The dates of that meeting were: November 18 & 19, 2004.

The meeting on November 19, 2004 included a closed session to permit discussion or presentation of trade secret or confidential commercial information where disclosure would constitute a clearly unwarranted invasion of personal privacy.

ACCOMPLISHMENTS

On November 18, 2003, the committee met to discuss the assessment and management of risk related to QTc prolongation by Droperidol (Inapsine) Akorn, Inc., indicated for nausea and

vomiting in surgical and diagnostic procedures, premedication, and neuroleptanalgesia. There have been cases of Torsade de Pointes reported following the use of droperidol at doses within and below the labeled doses. These events are consistent with the pharmacologic effects of droperidol reported in preclinical models and in human studies at 0.1 mg/kg and higher.

Data demonstrating safety and efficacy at droperidol doses lower than approved, yet commonly used, have not been submitted to the Agency. Agency Action: The labeling is still pending with respect to this product.

On November 19, 2003, the meeting was closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). During the closed session, the Committee received an annual update on the activities and decisions from the Division of Anesthetic, Critical Care and Addiction Drug Products. The committee was briefed discussed a number of New Drug Applications under review in the division.

09/30/2004

Date



Johanna M. Clifford, M.S., R.N.
Executive Secretary

ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE

Executive Secretary

Johanna Clifford, M.S., RN, BSN
Advisors and Consultants Staff (HFD-21)
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10/25/04

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

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* Consumer Representative

** Industry Representative



ANNUAL REPORT

OF THE

Nonprescription Drugs Advisory Committee

for the period October 1, 2003 through September 30, 2004

FUNCTION

The Committee shall review and evaluate 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

See attached Roster

MEETINGS

The committee met 3 times during the reporting period in Gaithersburg, Maryland and in Rockville, Maryland.

The dates of the meetings were: December 16, 2003, May 6-7, 2004, and May 7, 2004.

The meeting on May 7, 2004 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 December 16, 2004, the Committee met in joint session with the Reproductive Health Drugs Advisory Committee to discuss the proposed over-the-counter (OTC) use of Plan B (levonorgestrel), Women's Capitol Corporation, for reducing the chance of pregnancy after unprotected sex. The Committee voted in favor of approval of the application. On May 6, 2004, the Agency issued a Not Approvable letter for Plan B.

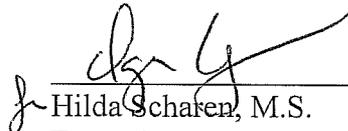
On May 6 and 7, 2004 the Committee met in joint session with the with the Dermatologic and Ophthalmic Drugs Advisory Committee to discuss efficacy and labeling issues for over-the-counter drug products used in the treatment of tinea pedis (interdigital) in patients 12 years of age and over. Recommendations were made concerning the lowest acceptable rate of cure that is clinically meaningful for a topical drug product for the treatment of tinea pedis, labeling, and drug development protocols.

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

At the closed session of the May 7, 2004 meeting, the Division of Over-the-Counter Drug 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. 552b(c) (4)).

09/30/2004

Date



Hilda Scharen, M.S.
Executive Secretary

**NONPRESCRIPTION DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH**

Chair

Louis R. Cantilena, Jr., M.D., Ph.D.

Expertise: Clinical Pharmacology

Term: 06/01/00 - 05/31/04

Director, Division of Clinical Pharmacology
and Medical Toxicology

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Term: 02/02/04 - 10/31/07

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Neal L. Benowitz, M.D.

Expertise: Clinical Pharmacology, Poison Control

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Chief, Division of Clinical Pharmacology

Departments of Medicine, Biopharmaceutical Sciences
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University of California, San Francisco

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Terrence F. Blaschke, M.D.

Expertise: Clinical Pharmacology/Drug Modeling
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Division of Clinical Pharmacology, Room S-009

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Term: 08/20/01 - 05/31/05

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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

Julie A. Johnson, Pharm.D.

Expertise: Cardiovascular Pharmacotherapy and
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College of Pharmacy, University of Florida

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* Consumer Representative

** Industry Representative



ANNUAL REPORT
OF THE
Dermatologic and Ophthalmic Drugs Advisory Committee
for the period
October 1, 2003 through September 30, 2004

FUNCTION

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disease states and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The committee met four times during the reporting period in Rockville and Bethesda, Maryland.

The dates of those meetings were February 26 & 27, 2004, May 6 & 7, 2004, July 12, 2004 and August 27, 2004.

The meeting on May 7, 2004 included a closed session to permit discussion of trade secret and/or confidential commercial information regarding pending and future issues within the Review Division.

ACCOMPLISHMENTS

February 26, 2004: Effectiveness of the isotretinoin risk management program for the prevention of fetal exposure to Accutane and its generic equivalents and consideration of whether changes to this isotretinoin risk management program would be appropriate. A new Risk Management Plan was developed and is in the process of implementation.

May 6 & 7, 2004: The committee discussed NDA 21-662, LAMISIL AT Spray Powder, 1% (terbinafine hydrochloride), Novartis Consumer Health, Inc. for the Over-the-Counter treatment of tinea pedis (interdigital) and tinea cruris in patients 12 years of age and over. On May 7th, the committee held a closed session to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c) (4)). The issue is under consideration by FDA.

July 12, 2004: The committee discussed oral tazarotene 1.5mg and 4.5 mg capsules (proposed trade name Tazorol), Allergan, Inc., proposed for the treatment of moderate to severe psoriasis, including risk management options to prevent fetal exposure. The issue is under consideration by FDA.

August 27, 2004: The committee discussed pegaptanib sodium injection (proposed trade name is Macugen) by Eyetech Pharmaceuticals, Inc., indicated for the treatment of exudative (wet) age-related macular degeneration. The information gathered is still under consideration. The issue is under consideration by FDA.

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

09/30/2004
Date



Kimberly Littleton Popper
Executive Secretary

Dermatologic and Ophthalmic Drugs Advisory Committee

Chairman

Roselyn E. Epps, M.D.

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Section Head

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Senior Vice President

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Professor and Chairman

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Dermatologist

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