

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.

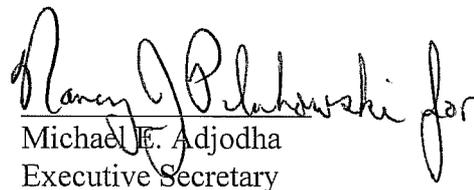
ACCOMPLISHMENTS

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