U.S. Department of Health and Human Services
Food and Drug Administration

C·D·R·H Center for Devices and Radiological Health

MEDICAL DEVICES ADVISORY COMMITTEE MEETING OF THE DENTAL PRODUCTS PANEL

DRAFT

MEETING AGENDA

Thursday, November 9, 2006

Holiday Inn
Walker/Whetstone Room
Two Montgomery Village Avenue
Gaithersburg, MD

Protecting and Promoting Public Health

BACKGROUND

Medtronic Sofamor Danek has submitted an original Premarket Approval Application (PMA) to the FDA for a device called "InFuse Bone Graft." InFuse Bone Graft is a collagen sponge bone void filler that is intended to be combined with rhBMP-2, a bone morphogenetic protein, intended to be used for sinus augmentation, extraction socket augmentation, vertical and horizontal alveolar ridge augmentation, and cystic defects.

In accordance with the procedures for review set forth in 21 CFR 814.44, FDA has referred the PMA to the Dental Products Panel of the Medical Devices Advisory Committee for the Panel's recommendation

PANEL ACTION

At this meeting, the Dental Products Panel will discuss and/or vote on the following:

- Whether the device is approvable, approvable with conditions, or not approvable, and
- The basis for the recommendation above.

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

DRAFT

MEETING AGENDA

DENTAL PRODUCTS PANEL

Thursday, November 9, 2006

Holiday Inn
Walker/Whetstone Room
Two Montgomery Village Avenue
Gaithersburg, MD

8:00 a.m.	**CLOSED SESSION – Dental Devices Branch Updates** *This portion of the meeting is closed to public participation. The committee will discuss commercial information regarding future device applications.*
8:30 a.m.	**CALL TO ORDER**
8:30 - 8:45 a.m.	**OPEN SESSION -- Welcome and Introductory Remarks** • Dr. Richard G. Burton, Chairman • Mr. Michael J. Ryan, Executive Secretary
8:45 – 9:15 a.m.	**Open Public Hearing** *Public attendees, who have contacted the Executive Secretary prior to the meeting, will address the Panel and present information relevant to the agenda. Speakers are asked to state whether or not they have any financial involvement with sponsor of the product(s) being discussed or with their competitors*

DRAFT MEETING AGENDA continued

9:15 - 10:15 a.m.	**Presentation by the Sponsor – InFuse Bone Graft (P050053)**
10:15 - 10:30 a.m.	**BREAK**
10:30 - 11:30 p.m.	**Presentation by the FDA – InFuse Bone Graft (P050053)** • Dr. Peter L. Hudson, Biologist, Division of General, Restorative, and Neurological Devices • Dr. Robert S. Betz, Periodontist, Dental Devices Branch • Dr. Zhiwei Zhang, Statistician, Office of Surveillance and Biometrics
11:30 - 12:30 p.m.	**LUNCH BREAK**
12:30 - 2:30 p.m.	**Panel Deliberations**
2:30 - 2:45 p.m.	**BREAK**
2:45 - 3:15 p.m.	**Open Public Session** *This portion of the meeting is open to public observers. Public observers may not participate except at the specific request of the Chairperson***.**
3:15 – 3:30 p.m.	**Summation** • **FDA** • **Sponsor**
3:30 - 4:45 p.m.	**Panel Recommendation and Vote**
5:00 p.m.	**MEETING ADJOURNED**

Draft Questions for Panel Consideration

1. Given the conditions studied, please discuss whether the information provided by the sponsor provides a reasonable assurance that the device is safe[1] for all indications requested.

2. Please discuss the effectiveness results obtained for sinus augmentation. In your discussion please comment on:

    a) The results of the primary and secondary endpoints.

    b) The results as compared to autogenous bone grafting.

3. Given the conditions studied, does the information provided by the sponsor provide a reasonable assurance that the device is effective[2] for sinus augmentation?

4. Support for the sponsor's extraction socket indication consists of a dosing study where the primary objectives were to find the appropriate dose and to evaluate bone growth in terms of height and width. Given the conditions studied, does the information provided by the sponsor provide a reasonable assurance that the device is effective[2] for extraction socket augmentation?

[1] There is a reasonable assurance that a device is **safe** when it can be determined, based upon valid scientific evidence, that the probable benefits to health from the use of the device for its intended uses and conditions for use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of the device shall adequately demonstrate the absence of unreasonable risk associated with the use of the device for its intended uses and conditions for use.

[2] There is a reasonable assurance that a device is **effective** when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

DENTAL PRODUCTS PANEL

November 9, 2006

CHAIRMAN	EXECUTIVE SECRETARY
Richard G. Burton, DDS Vice-Chair, Hospital Dentistry Institute, University of Iowa Hospitals and Clinics Iowa City, Iowa	Michael J. Ryan Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Office of Device Evaluation Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGID)

PANEL MEMBERS AND CONSULTANTS

Name	Affiliation	Role
Salomon Amar, DDS, PhD	Professor and Associate Dean of Research Boston University, School of Dental Medicine Boston, Massachusetts	Voting Member
Mason Diamond, DDS	Vice President of Clinical and Regulatory Affairs TyRx Pharma, Inc. Monmouth Junction, New Jersey	Non-Voting Member, Device Industry Representative
Michael Fleming, DDS	Dentist Private Practice Durham, North Carolina	Non-Voting Member Consumer Representative
Kurt C. Gunter, MD	Medical Director, Cellular Therapy Hospira, Inc. Lake Forest, Illinois	Non-Voting Member, Drug Industry Representative
Janine E. Janosky, PhD	Assistant Professor, Division of Biostatistics University of Pittsburgh, School of Medicine Pittsburgh, Pennsylvania	Consultant
Yiming Li, PhD	Professor and Director of Center for Dental Research Loma Linda University School of Dentistry Loma Linda, California	Voting Member Non-voting for this meeting
William J. O'Brien, MS, PhD	Professor, Biologic and Materials Science University of Michigan, School of Dentistry Ann Arbor, Michigan	Voting Member
Mark R. Patters, DDS, PhD	Associate Dean for Academic Affairs Department of Periodontology University of Tennessee, College of Dentistry Memphis, Tennessee	Consultant
John R. Zuniga, PhD, DMD	Professor and Chair, Oral and Maxillofacial Surgery University of Texas Southwestern Medical Center Dallas, Texas	Consultant

OTHER PARTICIPANTS

FDA
Robert S. Betz, DDS, Captain, USPHS Dental Officer Dental Devices Branch DHHS/FDA/CDRH/ODE
Peter L. Hudson, PhD Biologist Division of General, Restorative, and Neurological Devices DHHS/FDA/CDRH/ODE
Zhiwei Zhang, PhD Statistician Division of Biostatistics DHHS/FDA/CDRH/OSB

SPONSOR
TBD
TBD