



U.S. Department of Health and Human Services

Food and Drug Administration

**THE MEDICAL DEVICE ADVISORY COMMITTEE
MEETING OF THE
DENTAL PRODUCTS PANEL**

**Holiday Inn Gaithersburg
Walker/Whetstone Salons
Gaithersburg, Maryland
Thursday, May 22, 2003**



U.S. Department of Health and Human Services

Food and Drug Administration

DRAFT MEETING AGENDA
DENTAL PRODUCTS PANEL
Holiday Inn Gaithersburg
Walker/Whetstone Salons
Gaithersburg, MD
Thursday, May 22, 2003

- 9:30 a.m. **CALL TO ORDER**
- 9:30 – 9:45 a.m. **OPEN SESSION -- Welcome and Introductory Remarks**
?? Michael E. Adjodha, Executive Secretary
?? Dr. Leslie B. Heffez, Chairman
- 9:45 - 10:15 a.m. **FDA Presentation – Reclassification of Tricalcium Phosphate Granules for Dental Bone Repair (21 CFR 872.3930)**
?? Dr. Kevin P. Mulry, Acting Chief, Dental Devices Branch, DAGID
?? Dr. Robert S. Betz, Lead Reviewer, Dental Devices Branch
- 10:15 - 11:15 a.m. **Sponsor Presentation – Petition to Reclassify 21 CFR 872.3930**
?? Dr. Vincent J. Morgan – The Petitioner
?? Mr. Thomas Driskell – Inventor
?? Dr. John R. Long – Chemist
- 11:15 - 12:15 p.m. **Open Public Hearing**
?? Dr. Gunter Uhr – Curasan AG
?? Dr. Thomas Arrowsmith-Lowe – Regulatory Consultant for Curasan AG
?? Dr. Barbara Boyan – American Academy of Dental Research
?? Dr. Mark A. Reynolds – American Academy of Periodontology

12:15 - 1:15 p.m.

LUNCH

1:15 - 2:15 p.m.

Panel Presentation/Discussion

2:15 - 2:30 p.m.

BREAK

2:30 - 4:00 p.m.

Panel Recommendation and Classification

?? Ms. Marjorie Shulman, Consumer Safety Officer, FDA

4:00 p.m.

CLOSED SESSION – Dental Branch Updates

4:30 p.m.

MEETING ADJOURNED

**The Medical Device Advisory Committee
Meeting of the Dental Products Panel**

Thursday, May 22, 2003

| CHAIR | EXECUTIVE SECRETARY |
|--|--|
| Leslie B. Heffez, DMD, MS Professor & Head, Oral/Maxillofacial Surgery University of Illinois, College of Dentistry Chicago, Illinois | Michael E. Adjodha, M.ChE. 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 |

PANEL MEMBERS

| Name | Affiliation | Role |
|---------------------------------|--|--|
| Richard G. Burton, D.D.S | University of Iowa, Department of Hospital Dentistry Iowa City, Iowa | Consultant Deputized to Vote |
| David L. Cochran, D.D.S., Ph.D. | University of Texas, Health Science Center San Antonio, Texas | Voting Member |
| Julianne Glowacki, Ph.D. | Brigham and Woman's Hospital Boston, Massachusetts | Consultant Deputized to Vote |
| Edmond R. Hewlett, D.D.S. | UCLA, School of Dentistry Los Angeles, California | Consultant Deputized to Vote |
| Elizabeth S. Howe | National Foundation for Ectodermal Dysplasias Auburn, Washington | Consumer Representative Non-voting Member |
| Mark R. Patters, D.D.S., Ph.D. | University of Tennessee, College of Dentistry Memphis, Tennessee | Consultant Deputized to Vote |
| E. Diane Rekow, D.D.S., Ph.D. | New York University, College of Dentistry New York, New York | Voting Member |
| Daniel R. Schechter, J.D. | Parkell, Inc. Farmingdale, New York | Industry Representative Non-voting Member |
| Jon B. Suzuki, D.D.S., Ph.D. | University of Pittsburgh, School of Dentistry Pittsburgh, Pennsylvania | Voting Member |

| FDA PARTICIPANTS |
|--|
| M. Susan Runner, D.D.S., M.A., Captain, USPHS Interim Division Director, DAGID DHHS/FDA/CDRH/ODE |
| Kevin P. Mulry, D.D.S., M.P.H. Acting Branch Chief Dental Devices Branch DHHS/FDA/CDRH/ODE |
| Robert S. Betz, D.D.S., Captain, USPHS Dental Officer Dental Devices Branch DHHS/FDA/CDRH/ODE |
| Marjorie Shulman Consumer Safety Officer Premarket Notification Staff DHHS/FDA/CDRH/ODE |
| Michael E. Adjodha, M.ChE. Chemical Engineer Dental Devices Branch DHHS/FDA/CDRH/ODE |

| SPONSOR PARTICIPANTS |
|--|
| Vincent J. Morgan, D.M.D. President Bicon, Inc. Boston, Massachusetts |
| Thomas Driskell Inventor Westerville, Ohio |
| John R. Long, Ph.D. Director of Technology GFS Chemicals, Inc. Columbus, Ohio |

BACKGROUND

Dr. Vincent J. Morgan, President of Bicon, Inc., Boston, Massachusetts, submitted a petition to the FDA on November 12, 2002, to reclassify beta-tricalcium phosphate for dental indications. Beta-tricalcium phosphate and all other forms of tricalcium phosphate, i.e., alpha, amorphous, etc., are transitional devices and are currently regulated for dental indications as a Class III devices under 21 CFR 872.3930, "Tricalcium Phosphate Granules for Dental Bone Repair." As modified on December 9, 2002, Dr. Morgan's petition requests that beta-tricalcium phosphate be regulated as a Class II device. Copies of the petition are available on FDA's docket. See <http://www.fda.gov/ohrms/dockets/dailys/02/Dec02/121702/02p-0520.pdf>.

To address the petitioner's request, the FDA has arranged to meet with a classification panel on May 22, 2003, in accordance with the procedures set forth for transitional devices (21 CFR 860.136), to reclassify 21 CFR 872.3930, the regulation to which beta tricalcium phosphate belongs. For the purposes of this meeting, all forms of tricalcium phosphate, are subject to the proposed reclassification.

PANEL ACTION

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

- ?? Dr. Morgan's petition,
- ?? The risks of tricalcium phosphate (as defined in 21 CFR 872.3930),
- ?? Any recommended controls for this device,
- ?? A reclassification of the device, and
- ?? Any recommended changes to the labeling and indications for use.

QUESTIONS FOR THE DENTAL PRODUCTS PANEL REGARDING THE PETITION TO RECLASSIFY TRICALCIUM PHOSPHATE.

Dr. Vincent J. Morgan of Bicon, Inc., has submitted a petition to reclassify beta-tricalcium phosphate from Class III (Pre-Market Approval) to Class II (Special Controls).

Tricalcium phosphate is regulated as a Class III device under 21 CFR 872.3930, product code LPK, "Tricalcium Phosphate Granules for Dental Bone Repair." Please consider the following questions for Panel discussion.

1. Does the petition, as filed, adequately describe the risks to health of the device and provide for appropriate controls for these risks? If yes, proceed to 3. If no, go to 2.

2.
 - a) What modifications would you make to the risks to health presented by the device?
 - b) What controls for these risks would provide a reasonable assurance of safety and effectiveness? Proceed to 3.

3. Please complete the Classification Questionnaire and Supplemental Data Sheet for the device. Completion of these forms will provide a formal recommendation for the reclassification of "Tricalcium Phosphate Granules for Dental Bone Repair." (21 CFR 872.3930). Proceed to 4.

4. Given your recommended classification, what changes, if any, would you recommend be made to the labeling (includes directions for use, indications, and contraindications) of these devices?