



PETITION REVIEW SUMMARY

To: The Record
From: Robert S. Betz DDS

Date Summary Prepared: 04/07/2003

Subject: Petition for Reclassification
Beta Tricalcium Phosphate

Petitioner: Dr. Vincent Morgan D.M.D.
Filing Date: 10 December, 2002

On November 12, 2002 Dr. Vincent Morgan, President of Bicon Dental Implants submitted a petition for the reclassification of beta tricalcium phosphate (?TCP). A revision of this petition dated 05 April, 2002, was reviewed by the Dental Branch of the Office of Device Evaluation. On June 4, 2002 a letter and a disk, revising the petition, was received by FDA. On August 5, 2002 a letter and a hard copy of the revised petition, submitted because the disk submitted in June, was not readable. On 09 December, 2002, the petition was modified to request that ?TCP be classified as a Class II device, instead of requesting that it be changed to an unclassified status.

The final version of this petition contains eleven sections, including appendices. Section I is the Specification Section. The Specification section describes ?TCP, giving its physical properties, such as formula weight (310.20), density (3.15 gm/cm³), and melting point (1670°C), as well as identifying its Chemical Abstract Service (CAS) number (7758-87-4).

Section II is the Statement of Action. The Statement of Action is a request to reclassify ?TCP.

Section III is an FDA Supplemental Data Sheet, FDA Form 3247. The Indication for Use was identified as a bone substitute, and identified risks included infection and pyrogenic response. The information upon which the request of reclassification is based are that ?TCP has been successfully used in medicine and dentistry for over twenty years and that its properties are known to be beneficial when used as a bone substitute.

Section IV (Appendix II) is the FDA General Device Classification Questionnaire, FDA Form 3429. The questionnaire states that the submitter believes that there is sufficient information available to provide a reasonable assurance that general controls for this device are sufficient to assure safety and effectiveness, and that this device should be sold only on the prescription of a dentist or physician.

Section V is the Basis for Disagreement with the present classification. It includes the following:

1. Miter Inc. has successfully marketed ?TCP for over twenty years for dental purposes.
2. ?TCP is classified Class III for dental purposes and not when it is used for orthopedic purposes.

Section VI contains the Reasons for Reclassification. The sponsor reiterates the statements present in Section V and refers the reader to Appendix III, which has articles from the dental literature that he states support claims of safety and effectiveness for the intended use of ?TCP as a bone substitute.

Appendix III includes:

1. A 6 month report of three cases where ?TCP was used to treat “extensive periodontal pathology”.
2. A study compared calcium hydroxide (Cavit) with ?TCP (Synthograft) in the treatment of endodontic perforations in Sprague Dawley rats.
3. A study of 17 selected cases having 1 wall, 2 wall, crestal, and furcation defects. Sites in ten of these selected patients were reentered.
4. A report of three cases where ?TCP was used in extraction sockets in an attempt at preservation of alveolar bone

Section VII is titled Unfavorable Data. The submitter states that there is no unfavorable data known to them.

1. Section VIII is a Summary of New Information, which is in Appendix IV. This information is from a Medline search of data three years old or less. Four clinical studies and reviews of them are present.

Section IX Source Documents stated that there were no source documents to be submitted relevant to this document.

Section X was the Financial Certification/Disclosure Statement, which stated that Dr. Morgan did “not own any equity position in Bicon, Inc., and has not received any compensation for any clinical studies associated with this product, nor will he have an equity interest in the product.”

Section XI was labeled Appendices, which were included and reviewed as parts of Sections III, IV, VI, and VIII .

Comment and Recommendation:

A review of recent article abstracts, both review and original studies, indicates that ?TCP generally resorbs at a rate somewhere between Plaster of Paris and hydroxyapatite, and that it is biocompatible in orofacial locations. Bone formation is reported to occur as ?TCP is resorbed. No adverse reports related to ?TCP were found. Because of the lack of adverse

events reported in the dental literature over approximately twenty years, this reviewer believes that device safety is not an issue. Clinical and histological reports indicate that this device is osteoconductive, providing a scaffold onto which host osteoblasts may lay down new osteoid material that is subsequently calcified. The effectiveness of ?TCP in assisting in the formation of new bone does not appear to be greater or less than other osteoconductive alloplastic bone grafting materials.

This petition has merit for several reasons:

1. ?TCP has been classified Class II for orthopedic uses for several years without reports of significant adverse events. This includes craniofacial indications.
2. ?TCP has been used in dentistry at a concentration less than 40% for many years without significant problem. These devices have been cleared under 510(k) regulations.
3. ?TCP is a calcium phosphate salt that has the same intended uses, and is similar (physical and many chemical properties) to legally marketed dental grafting materials such as
 - a. Plaster of Paris (like Capset; K955096),
 - b. Hydroxyapatite (like Hapset; K910423),
 - c. Ceramics (like Bio Oss Ceramic; K873763), etc.
4. There is no available rationale as to why ?TCP should remain Class III for dental, oral, or maxillofacial indications, and that special controls would not assure adequate device safety and effectiveness.

This petition provides a reasonable basis for reclassification of ?TCP (absence of adverse data and successful use as a Class II device in Orthopedics). It is hereby recommended that this petition be approved.