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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dr. Vincent J. Morgan  
President  
Bicon, Incorporated  
501 Arborway  
Boston, Massachusetts 02130

Re: Reclassification Order:  
Docket No. 2002P-0520  
Petition for Reclassification for Beta-Tricalcium Phosphate

Dear Dr. Morgan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for reclassification of tricalcium phosphate that is intended for use as a dental bone grafting material. FDA concludes that this device and substantially equivalent devices of this generic type, should be reclassified from class III into class II. This order, therefore, reclassifies tricalcium phosphate, and substantially equivalent devices of this generic type, into class II under the generic name, "bone grafting material", effective on May 31, 2005, the effective date of the final rule published in the Federal Register on April 28, 2005/70 FR 21947 (enclosed). This order also identifies the special control applicable to the device as FDA's "Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices" (enclosed).

FDA identifies this generic type of device, the subject of this reclassification, as follows:

Bone grafting material is a material such as hydroxyapatite, tricalcium phosphate, polylactic and polyglycolic acids, or collagen, that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Pub. L. 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

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The 1976 amendments broadened the definition of "device" in 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified all transitional devices, i.e., those devices previously regulated as new drugs, including tricalcium phosphate granules for dental bone repair, into class III. The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III (H. Rept. 808, 101<sup>st</sup> Cong., 2d sess. 26-27 (1990); S. Rept. 513, 101<sup>st</sup> Cong., 2d sess. 27 (1990)). Congress amended section 520(l) of the act (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices still remaining in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls). Accordingly, in the Federal Register of November 14, 1991 (56 FR 57960), FDA issued an order under section 520(l)(5)(A) of the act, requiring manufacturers of transitional devices, including tricalcium phosphate granules for dental bone repair, 21 CFR 872.3930, to submit to FDA a summary of, and a citation to, any information known or otherwise available to them respecting the devices, including adverse safety or effectiveness information which had not been submitted under section 519 of the act (21 U.S.C. 360i). Manufacturers were to submit the summaries and citations to FDA by January 13, 1992. However, because of misunderstandings and uncertainties regarding the information required by the order, and whether the order applied to certain manufacturers' devices, many transitional class III device manufacturers failed to comply with the reporting requirement by January 13, 1992. Consequently, in the Federal Register of March 10, 1992 (57 FR 8462), FDA extended the reporting period to March 31, 1992.

Section 520(l)(5)(B) of the act provides that, after the issuance of an order requiring manufacturers to submit a summary of, and citation to, any information known or otherwise available respecting the devices, but before December 1, 1992, FDA was to publish regulations either leaving transitional class III devices in class III or reclassifying them into class I or II. Subsequently, as permitted by section 520(l)(5)(C) of the act, in the Federal Register of November 30, 1992 (57 FR 56586), the agency published a notice extending the period for issuing such regulations until December 1, 1993. Due to limited resources, FDA was unable to publish the regulations before the December 1, 1993, deadline.

As you know, on November 12, 2002, as amended on December 9, 2002, FDA filed your petition requesting reclassification of tricalcium phosphate from class III into class II. The petition was submitted under section 520(l)(2) of the act (21 U.S.C. 360j(l)(2)), and 21 CFR 860.136 of the agency's regulations. In accordance with section 520(l)(1) of the act, tricalcium phosphate was automatically classified into class III because it was a transitional device, i.e., a device previously regulated as a new drug. In order to reclassify the tricalcium phosphate granules for dental bone repair into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the device for its intended use.

Pursuant to 21 CFR 860.125 and 860.136(b)(5), FDA consulted with the Dental Products

Panel (the Panel). The Panel unanimously recommended that the tricalcium phosphate granules for dental bone repair be reclassified from class III into class II because the Panel believed that special controls will provide reasonable assurance of the safety and effectiveness of the device. This recommendation was based on the information and data contained in the reclassification petition, on the summary and analysis of the data as set forth in the petition, on information presented during the open public hearing and open committee discussions of the meeting held on May 22, 2003, and on the Panel member's own personal knowledge of, and clinical experience with, the device.

The report and recommendation of the Panel were published in the Federal Register of June 30, 2004, 69 FR 39377 (enclosed), and interested persons were invited to comment by September 28, 2004. FDA received one comment in response to the notice of panel recommendation. The comment said that tricalcium phosphate granules should remain in class III (premarket approval) and that all other bone grafting materials for dental indications should be regulated in class III because the commenter believed the special controls (composition, physical properties, and compliance with ASTM composition standards) described in the draft guidance document were not sufficient to provide a reasonable assurance of safety and effectiveness for these devices. The comment states that only evidence from clinical studies is sufficient to provide a reasonable assurance of safety and effectiveness for these devices.

FDA disagrees in part with the comment. In most cases, FDA believes that there is sufficient human experience with the dental bone grafting material devices being reclassified and classified into class II to establish a special controls guidance to provide reasonable assurance of safety and effectiveness through the 510(k) process without the submission of clinical data. FDA has determined that this experience supports the conclusion that information on composition, physical properties, and compliance with ASTM composition standards in a 510(k) will provide adequate information for FDA review of the device, if there is no change in the formulation, design, technology, or indication for use of the device. In cases in which there is such a change, however, the special controls guidance clearly states that FDA recommends the submission of clinical data in the 510(k) to support a substantial equivalence determination. If the manufacturer cannot demonstrate that the new device is substantially equivalent, the device will be found not substantially equivalent and a premarket approval application may be required. This approach is consistent with the general recommendations of the Dental Products Panel in 1995 and in 2003. Therefore, FDA believes that special controls, in addition to general controls, will provide a reasonable assurance of the safety and effectiveness of these devices and these devices can be classified in class II. Bone grafting material devices that contain a drug that is a therapeutic biologic will remain in class III and continue to require a premarket approval application.

FDA agrees with the Panel's recommendation to reclassify the tricalcium phosphate granules for dental bone repair from class III into class II with the following identified special control, namely FDA's "Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices." This decision is based on the administrative record which consists of the

reclassification petition, the transcript and minutes of the May 22, 2003, meeting of the Panel, the Panel member's individual data sheets containing their recommendations, and all other information identified in this letter.

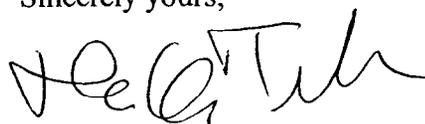
After review of the information submitted in the petition and consultation with the Panel regarding the reclassification petition, FDA has determined that tricalcium phosphate granules for dental bone repair as described and identified herein can be reclassified from class III into class II with the establishment of special controls. FDA believes that class II with special controls, in the form of a guidance document, provide reasonable assurance of the safety and effectiveness of the device. The special controls guidance document contains recommendations with regard to the information and testing that should be included in a premarket notification. The guidance document addresses the following topics: material characterization, biocompatibility, sterilization, and labeling. Adequate characterization of the composition, physical properties, and in vivo performance can address the risk of ineffective bone formation. Adequate biocompatibility can address the risk of adverse tissue reaction. Sterilization can address the risk of infection, and labeling can address the risk of improper use.

The device type is subject to the general control sections of the act and any special controls identified under section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)), including any performance standards promulgated under section 514 of the act (21 U.S.C. 360d). Thus, persons who intend to market this device type must submit to FDA a premarket notification submission containing information on the tricalcium phosphate they intend to market prior to marketing the device.

The final rule announcing the reclassification of tricalcium phosphate granules for dental bone repair as well as the availability of the guidance document that will serve as the special control for the class II devices, was published in the Federal Register on April 28, 2005, 70 FR 21947.

If you have any questions concerning this reclassification order, please contact Mr. Michael Adjodha at 301-827-5283, ext. 123.

Sincerely yours,



Donna-Bea Tillman, Ph.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures