

## **QUESTIONS FOR THE DENTAL PRODUCTS PANEL REGARDING A 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).

Beta-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 step 3. If no, go to question 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 step 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 question 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?