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Lisa Simpson, Director
Regeneration Technologies, Inc.
P.O. Box 2650
11621 Research Circle
Alachua, Florida 32616-2650

Re: Docket No. 2006P-0334

Dear Ms. Simpson:

This is an interim response to your petition dated August 10, 2006, which was filed by the Food and Drug Administration (FDA) on August 17, 2006. In your petition, you requested that FDA reclassify "Bone Heterografts" from class III to class II. You also asked that the specific reference to cervical spine be removed.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and consideration by Agency officials. This interim response is provided in accordance with FDA regulations on citizens petitions (21 CFR 10.30 (e) (2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Deborah Wolf of our Regulation Staff at (240) 276-2348.

Sincerely yours,

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health

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