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Michael J. Ryan
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Dear Mr. Ryan:

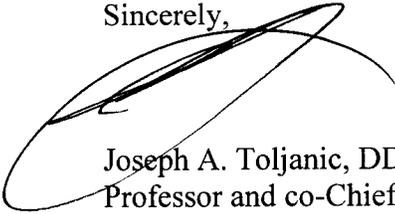
I am writing with regards your upcoming November 9, 2006 FDA Advisory Panel scheduled to review the use of rhBMP-2/ACS for oral and maxillofacial applications. As an clinical investigator, I have had the opportunity to critically assess the safety and efficacy of rhBMP-2 in two prospective multicenter clinical trials for use to correct alveolar defects of the jaws and to augment atrophic maxillae via sinus lift surgery. In each of these clinical trials, I was more than impressed with the ability of this device to induced significant bone volume in these deficient areas. This outcome permitted successful dental implant placement without the need for standard accepted bone grafting procedures. Based on these impressive results to date, I am aware that further clinical trials are being designed in order to make even more efficient use of the protein in conjunction with dental implants thus holding out the promise for rhBMP-2 to one day totally supplanting all bone graft materials currently used in implant rehabilitation.

By permitting this device to become commercially available, you will add a powerful new tool in the armamentarium of dental implant rehabilitation. With rhBMP-2, I anticipate that many more patients will undergo successful implant treatment without the need to harvest autologous bone or to rely on commercially prepared bone graft products that may have variable bone induction capabilities while creating attendant concerns regarding the source of these products and product safety. Speaking from the point of view of a practicing clinician, it is abundantly clear to me that the excellent long-term

clinical outcomes achievable with the use of rhBMP-2 will have a very positive impact on the care that I will be able to provide my private patients on a day to day basis.

If you have any questions regarding my experiences to date with rhBMP-2/ACS or have any questions regarding these comments, please do not hesitate to contact me. I look forward to a favorable review of this device.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joseph A. Toljanic', written over a large, loopy flourish that extends to the left and then curves back under the text.

Joseph A. Toljanic, DDS
Professor and co-Chief
Subsection of Dentistry