May 1, 2001

The Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
5630 Fishers Lane, Room 1061, HFZ-305
Rockville, Maryland 20852

RE: TMJ Implants, Inc. Fossa Eminence Prosthesis
PMA Number P000035

Attention: Dockets Management Branch Director

As a representative of the patient advocacy group, The TMJ Association, I formally petition the Food and Drug Administration to hold an open hearing on its decision to approve the TMJ Implants, Inc. Fossa-Eminence Prosthesis. I attended the Dental Products Panel meeting on October 6, 2000, in which the Panel unanimously voted that this device was not approvable because of significant concerns about safety and efficacy. The Panel concluded that not only were scientifically valid clinical studies to support the use of the device lacking, but also there were no clear indications for use. Further, clinical and/or testing data demonstrating the effect of the metal eminence on the natural mandibular condyle was not presented. I am concerned about the potential harm from this prosthesis as a treatment for patients with this ill-defined condition.

I am also concerned by the comments of Congressman Thomas Tancredo's aide, Mr. James Bergeron. His testimony was threatening and intimidating, intended to influence the agency and the Panel to approve this device.

It seems highly questionable that Dr. Bernard Statland concluded that the prosthesis was approvable after he met with TMJ Implants, Inc. attorneys, contradicting the conclusions of two Dental Products Panels and both the FDA Division of Biostatistics and the Division of Dental, Infection Control and General Hospital Devices.

We are alarmed by the formulation of a new FDA policy to accompany the marketing of the Fossa Eminence prosthesis regarding patient risk, responsibility, and understanding of these risks. When experts in the field have concluded that there is insufficient evidence of safety and efficacy of the TMJ Implants, Inc. device (for which criteria for use are unclear) it seems a violation of the FDA mandate to protect the public to assume that a suffering patient can make knowledgeable decisions regarding risk and use.

This petition has the unanimous support of the members of the board of The TMJ Association.

Sincerely,

Terrie Cowley
President