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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Rm. 1-23, 12420 Parklawn Dr.
Rockville, MD 20857

Supplement to Petition for Reconsideration

Docket No. 01M-0210

In a letter dated May 1, 2001, a copy of which is attached as Exhibit #1, the undersigned petitioned the Food and Drug Administration to hold an open hearing on its decision to approve the TMJ Implants, Inc. Fossa-Eminence Prosthesis. Such letter was deemed by the Food and Drug Administration (FDA) to be a **Petition for Reconsideration**. The undersigned hereby submits this **Supplement to the Petition for Reconsideration** of the decision of the Commissioner of Food and Drugs in Docket No. 01M-0210.

A. Decision Involved

The decision involved is FDA's decision to approve the application of TMJ Implants, Inc. for premarket approval (PMA) of the TMJ Fossa-Eminence Prosthesis, Application No. P000035. The approval order was issued on February 27, 2001 in a letter from Bernard Statland, Ph.D., M.D., Director, Office of Device Evaluation, Center for Devices and Radiological Health, FDA, to Robert W. Christensen, D.D.S., President of TMJ Implants, Incorporated. A copy of the order approving the PMA is attached as Exhibit #2.

B. Action Requested

The petitioner respectfully requests that the Commissioner reconsider the approval order promulgated on February 27, 2001 and that the Commissioner withdraw approval of the TMJ Fossa-Eminence Prosthesis, Application No. P000035. Specifically, the petitioner seeks review of the approval order under Section 515 (g)(2) of the Food Drug and Cosmetic Act (the "Act") (21 U.S.C. 360e(g)(2)), whereby the Secretary shall refer the PMA subject to the order and

the basis for the order to an advisory committee of experts for a report and recommendation with respect to the order.

C. Statement of Grounds

Petitioner believes that the following criteria for withdrawal of approval under section 515(d) the Act are applicable:

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; [and]

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

The Dental Products Panel of the Medical Device Advisory Committee met in open session on Friday, October 6, 2000 to consider the application of TMJ Implants, Inc. for premarket approval of its TMJ Fossa-Eminence Prosthesis. After the hearing, the eight members of the Dental Products Panel who voted agreed unanimously that the application of TMJ Implants, Inc. was “**Not Approvable**” based on the lack of substantive safety and efficacy data for the indications presented in the PMA. The Panel also specified measures that it believed would be necessary to render the PMA approvable.

In the FDA’s *Summary of Safety and Effectiveness* (the “Summary”), the FDA acknowledges that “types of adverse events observed in the clinical use of the TMJ Fossa-Eminence Prosthesis System include: Postoperative pain, swelling jaw muscle spasm; Facial nerve and muscle weakness or paralysis; Ankylosis and fibrosis; Trauma; Nausea; Condylar dislocation; Malocclusion; Blurry vision; Suspected allergic reaction; Heterotopic bone formation; Decreased interincisal opening; Joint locking; Malocclusion [sic]; Hearing loss/problems; Degenerative joint changes; Poor fit of custom prosthesis; [and] Increased pain.” The FDA also acknowledges in the Summary that “In addition to the adverse events identified above, potential adverse events and complications. . .may require further treatment and include but are not limited to: Hematoma formation; Hemorrhage; Foreign body or allergic reactions to the device materials; Rejection of the device; Wear, displacement of the device or implant loosening; Fracture of the device/Surgical damage to anatomical structures adjacent to the TMJ; Patient discomfort; Speech problems; [and] Facial deformity.”

Other FDA statements in the Summary that are inconsistent with the FDA’s approval of the device as safe and effective are as follows:

Section V, WARNINGS, on Page 3 of 19: “The long-term effects of the TMJ Fossa-Eminence Prosthesis System on the natural mandibular condyle are unknown. Remodeling of the natural mandibular condyle has been observed. Other degenerative changes may be attributable to the TMJ Fossa-Eminence prosthesis.”

Section XIV, FDA DECISION, Page 18 of 19: “FDA balanced the scientific concerns related to the limited clinical data with the knowledge that there appears to be a group of patients, albeit poorly defined, for whom this device seems to provide a reasonable treatment option.” (Emphasis supplied.)

Vulnerable patients should not be asked to assume the risks of the device without further data establishing its safety and effectiveness, given the types of adverse events already observed in the clinical use of the TMJ Fossa-Eminence Prosthesis System; the potential adverse events and complications which the FDA identifies; the FDA’s admission that the long-term effects of the TMJ Fossa-Eminence Prosthesis System are unknown; and the FDA’s admission that a group of patients for whom this device seems to provide a reasonable treatment option is “poorly defined.” Petitioner also believes that the additional data submitted by the sponsor after the October 6, 2000 meeting are insufficient to assure safety and effectiveness of the device.

Based on the above grounds, the petitioner believes that the Dental Products Panel’s recommendations and other information contained in the administrative record were not adequately considered by the Commissioner.

Petitioner
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