



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

March 13, 2000

Mr. C. Michael Schuch, CPO, FAAOP  
President  
American Orthotic & Prosthetic Association  
1650 King Street  
Suite 500  
Alexandria, Virginia 22314

Dear Mr. Schuch:

Your petition requesting the Food and Drug Administration to classify the cranial helmet was received by this office on 03/13/00. It was assigned docket number OOP-1085/CP 1 and it was filed on 03/13/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe

Dockets Management Branch

OOP-1085

ACK 1