



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

July 12, 2006

Dr. Fremont P. Wirth  
American Association of Neurological Surgeons  
5550 Meadowbrook Drive  
Rolling Meadows, Illinois 60008

Dear Dr. Wirth:

This is to correct the address to our previous acknowledgement letter dated 7/6/06 for docket number 2006P-0085/CP 1.

Your petition requesting the Food and Drug Administration to Exempt the Class II device Cranial Orthoses from Premarket Notification Requirements under section 510(m) (2) was received by this office on 07/06/2006. It was assigned docket number 2006P-0085/CP1 and it was filed on 07/06/2006. 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,

Gloria Ortega  
Division of Dockets Management  
Office of Management Programs  
Office of Management

cc: Catherine Jeakle Hill  
AANS/CNS Washington Office  
725 15<sup>th</sup> St., N.W., Suite 800  
Washington, DC 20005

2006P-0085

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