

## **DRUGS AND DEVICES**

**Neurosurgical Devices Forum.** Member of the AANS and CNS Neurosurgical Forum on Drugs, Devices and Biologics, led by Drugs and Devices Committee Chairman, Richard Fessler, MD, continue to meet with representatives from the FDA. We are currently negotiating a Memorandum of Understanding (MOU) between FDA and AANS and CNS, to comply with what appear to be new FDA requirements for holding such meetings. Forum members will meet with FDA staff on April 16, 2007, during the AANS annual meeting in Washington, DC. The agenda includes a presentation on Vagus Nerve Stimulation in children, discussion of neurosurgical representation on FDA panels, and an overview of the device evaluation process.

**Unique Device Identification.** On November 9, 2006, the AANS and CNS joined a collation of members of the Alliance of Specialty Medicine in a letter to Acting FDA Commissioner Andrew C. Eschenbach, MD, in support of the development of the FDA's Unique Device Identification (UDI) project. The FDA published a notice in the Federal Register on August 11, 2006, asking for comments on the issue. The UDI development follows a January 2004 final rule in which FDA required bar coding for certain drug and biological projects to help reduce medication errors in hospitals and other health care settings. The 2004 bar code rule does not apply to medical devices and FDA is exploring the possibility of similar regulations to devices.

**Cranial Band FDA Petition.** On December 26, 2006, the FDA published a notice in the Federal Register stating that the agency had decided to deny the petition submitted by the AANS, CNS, and the Joint Section on Pediatric Neurosurgery to exempt cranial helmets from Class II device requirements. The AANS/CNS Drugs and Devices Committee had worked with FDA staff for several years to address the unintended consequence of a "de novo" approval of a 1998 cranial helmet application. On February 9, 2006, AANS, CNS, and the AANS/CNS Section on Pediatric Neurological Surgery sent a letter drafted by Mark Proctor, MD, to the FDA asking that the FDA exempt cranial helmets from Class II requirements. Several Pediatric Section leaders sent in comments in favor of the petition. Groups opposing the petition included Powell Goldstein, LLP, a law firm acting on behalf of a large device manufacturer, and Cranial Therapies, Inc. On November 22, 2006, the AANS and CNS submitted a letter written by Dr. Proctor that addressed and refuted each of the objections raised by the manufacturers. However, the FDA did not feel that sufficient information exists to warrant a change of status for the cranial helmets and therefore the agency denied the petition.

**FDA Neurological Devices Panel.** On January 26, 2007, the FDA Panel on Neurological Devices met to discuss and make recommendations on a 510 (k) application from Neuronetics, Inc for the NeuroStar Transcranial Magnetic Stimulator (TMS) System for the treatment of major depression. 510 (k) applications, in which the manufacturer has to show substantial equivalence to a device already on the market, are not typically sent to the panel for review. The panel's conclusion was very mixed and panel members concluded that they would like to see further study on the device. One panel member, Robert Coffey, MD, a neurosurgeon representing industry, spoke against the panel's recommendation for further study and expressed concern that deliberations took place without additional input from neurosurgery, as neurosurgeon panel members were not able to attend the panel meeting.

In addition to considering the NeuroStar device, the panel received reports from industry and FDA staff on post FDA approval studies of the Cyberonics Vagal Nerve Stimulator and the Confluent Surgical, Inc. Dural Sealant System. During the open public comment period which proceeded the presentation on post-approval studies of VNS, Jeffery Cozzens, MD, gave a statement in support of VNS technology for treatment resistant depression in appropriately selected patients. Preliminary data from Cyberonics continues to show efficacy over conventional treatment of TRD. Following the presentation of VNS data, Confluent Surgical, Inc., presented preliminary data from post approval studies on the Dural Sealant System.