

Dear Distinguished Panel Member:

Thank you for agreeing to participate in the January, 2007 meeting of the Neurological Devices Advisory Panel. I would like to take this opportunity to tell you about a new initiative which the Center for Devices and Radiological Health (CDRH) will be launching during this panel meeting.

As you know, the advisory panel process is crucial to CDRH and our evaluation of new medical devices. We often bring our most novel and challenging pre-market submissions before a panel for a recommendation. It is not uncommon for an advisory panel to recommend to CDRH that the PMA application be found approvable with conditions and that the sponsor be required to perform a post-approval study as a condition of approval (CoA). These studies are intended to address pre-market data limitations and may be designed to assess issues such as the long-term safety and/or effectiveness of the device, effects of re-treatments, effectiveness of training programs, or use in the general medical community. These studies are designed to give FDA and the clinical community a more complete picture and understanding of the performance of the device after approval.

As part of our postmarket transformation initiative, CDRH will now regularly update advisory panels on the status of post-approval studies for approved PMAs which were previously brought before that particular panel. The sponsor of the PMA will be invited to make a brief presentation to the panel regarding their post-approval study and experience. Staff from CDRH's Office of Surveillance and Biometrics or Office of Device Evaluation will also make a short presentation and the panel will be given time to ask questions and discuss the information presented. The studies may be ongoing or completed and at times CDRH may have specific questions for the panel to address.

This initiative will begin with the January Neurological Devices Advisory Panel meeting. The supplemental panel pack provides you with basic background information on the post-approval studies for the two products which will be presented during that meeting:

1. VNS Therapy System (Vagal Nerve Stimulator) for treatment-resistant chronic or recurrent depression by Cyberonics, Inc.; and
2. DuraSeal Dural Sealant System for use as an adjunct to sutured dural repair during cranial surgery to provide watertight closure by Confluent Surgical, Inc.

Please add this background material to the binder sent to you in December for this meeting.

Thank you for your willingness to participate in this panel meeting and this new CDRH initiative. We look forward to hearing your feedback on the value of this effort.

Susan N. Gardner, Ph.D.
Director
Office of Surveillance and Biometrics
Center for Devices and Radiological Health