



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Dear Panel Members,

Here is the agenda information for the upcoming meeting of the Neurological Devices Panel on September 16 and 17, 1999. The following four topics are on our agenda:

- **Tab 2:** Discussion of the "Draft Guidance Document for Dura Substitute Devices" and discussion questions;"
- **Tab 3:** Classification of processed human dura mater devices, the related guidance document "Guidance for the Preparation of a Premarket Notification Submission Application for Human Dura Mater," discussion questions, the summary minutes of the 1990 panel meeting, and one literature article;
- **Tab 4:** Discussion of the "Draft Guidance Document for Neurological Embolization Devices" and discussion questions; and
- **Tab 5 and a Separate Notebook:** Petition and references for the "Reclassification of the Totally Implanted Spinal Cord Stimulator for Pain Relief," a review memorandum, and discussion questions.

Tab 1 contains the draft agenda, panel roster, and medical device class information. There also is a copy of the Classification/ Reclassification Questionnaire and Supplemental Data Sheet that must be completed in the meeting for the classification and reclassification topics.

FDA is seeking your recommendations on the content of the guidance documents, in particular your comments on any important relevant considerations necessary to reasonably assure that cleared devices are safe and effective for their intended that we may have overlooked. For the classification agenda item, we are seeking your recommendation for the appropriate device class for processed human dura mater devices. For the reclassification agenda item, we are seeking your recommendation whether or not to reclassify the totally implanted spinal cord stimulator for pain relief from class III (premarket approval) into class II (special controls).

On the morning of Thursday, September 16th, there will be panel training and classification/ reclassification training beginning at 7:30 a.m. Even if you've had this training before, it is important for you to attend because the training program has been updated since last year. Also, the classification/ reclassification training is critical for those two topics. This is the only session we have together before the public meeting. We will have a light breakfast at the training session. The public meeting will begin at 11:30 a.m. and is expected to end at 6 p.m.

On the morning of Friday, September 17th, we will start with a half hour closed session at 8 a.m. so our Division management can brief you about panel track issues, including the two possible topics for the December 10th meeting. The public meeting will begin at 8:30 am and will adjourn about 3:30 p.m. However, in case it should last past 3:30 p.m., please have some backup reservations in mind. We believe the allotted time should be adequate for this agenda.

We will make a dinner reservation for Thursday evening and hope you will join us if possible. I'll let you know the details on September 16th.

If there is anything I can help you with concerning either the meeting agenda or logistics, please let me know. I may be reached at 301-594-1184 ext. 176, fax 301-594-2358, and em JLS@cdrh.fda.gov. Should you need to reach me at home, my home telephone number is ~~301-594-1184~~. I do work at home some if my schedule permits. I look forward to seeing you soon and having a productive meeting. Thank you for your participation on the panel. Have a safe trip here.

Sincerely yours,



Janet L. Scudiero
Executive Secretary
Neurological Devices Panel