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January 22, 1999

Ms. Janine Morris
Center for Devices and Radiological Health
1350 Piccard Drive, HFZ-500
Rockville, Maryland 20850

Re: Follow-up to Food and Drug Administration
"Conference on Neurological Shunts."

Dear Janine:

I want to thank you and your staff for an excellent conference January 8, 1999. It was a very good format. My father and I were very pleased at the willingness by all to address the key issues. FDA staff were particularly kind to me.

Attached, you'll find my completed "evaluation sheet," and additionally, I have a few suggestions I will include in this letter.

I would advocate holding two (2) more such conferences - over the next two years. One in about 6 - 9 months, in which all would agree on drafted regulatory changes, and a status conference about 12 months after that to discuss and make any necessary final changes. I would advocate treating those in attendance as an "industry focus group" and direct subsequent inquiries to and within this group.

Some more specific recommendations are listed below:

1. Provide an executive summary response to each person in attendance, either via e-mail or through regular mail.
2. Provide a tentative concensus of determinations from each session.
3. Propose a projected timeline for propsective new technolgy as discussed at the conference.
4. Provide a prioritized timeline of the implementation of new patient and physician labeling, and discuss whether the labeling would be voluntary or mandatory.
5. Provide more specific recommendations for routine in-vivo shunting outcomes and shunt performance measurements.
6. Provide suggested manufacturer public affairs topics, that would include such activities as voluntary "device tracking" methods - which may be tied into sales and advertising packages for the manufacturer.
7. Present possible amendments to licensing and PMA guidelines for shunt products that define requirements that are commensurate with current scientific knowledge and practice, and permit specific patient labeling to play a larger role in their use.
8. Propose simplified alternatives to adverse event reporting by patients and professionals, including, new mechanisms for manufacturer reporting.

Sincerely,

Stephen M. Dolle

sd: enclosures