STEPHEN M. DOLLE
3908 ½ River Ave.
Newport Beach, California

October 8, 1998

Mr. James Dillard
Division of General and Restorative Devices
Office of Device Evaluation
HFZ-410, Room 350-D
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

Re: Response to and Request for Correction to (FDA's) Ruling on Citizen's Petition, for CNS Delta Shunt (PS Medical) and Anti-Siphon Device (Heyer-Schulte); Docket Number: 96P-0444.

Dear Mr. Dillard:

This communication is in reference to the Food and Drug Administration's ruling on the above-noted Petition, Docket No. 96P-0444, which I personally submitted November 1996. The FDA's ruling is dated Sept. 18, 1998, and is signed by D. Bruce Burlington, M.D.. You were identified as the person to contact in the event of any questions concerning this ruling.

I have found on page 2, paragraph 1, line 1, that there may be a typographical mistake in the wording, "denying parts (4) and (7)." Based on the paragraph's discussion, one would expect it to read, "denying parts (3) and (7)." Please make any necessary corrections, if needed, and forward me a copy.

Also in that same paragraph, there is a discussion of a search for a new test method that could identify these device's adverse effects as reported in the literature. I would like to report that I have developed such a system. It is an in-vivo non-invasive CNS shunt monitoring system, called the DiaCeph™ Test. Though still in development, it has been found to be accurate in its first clinical trial. It uses a computer program (decision tree) to interact with and process patient parameters specific to shunt performance, and provides for an accurate diagnosis, including, that of anti-siphon shunt insufficiency issues. I have attached a product summary, and would be happy to work with you on devising/implementing this new shunt test method.

As for informing all U.S. neurosurgeons and neurologists about the new warnings and labeling changes, and other professionals through the FDA Medical Bulletin (item numbers (5) and (6) respectively), I would strongly advocate such an open forum discussion.

Please note my address and telephone number have changed. Attached, please find a copy of the Sept. 18, 1998 ruling on the above-referenced Petition, and a product summary on my DiaCeph™ Shunt Monitoring System.

If I can answer any further questions at this time, please feel free to call.

Truly,

Stephen M. Dolle
Hydrocephalus Researcher

sd/
enclosures