DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 18 1998

2273 '98 SEP 24 A11 :18

Docket Number: 96P-0444

Mr. Stephen M. Dolle
13191 Gwyneth Drive #A
Tustin, California 92780

Dear Mr. Dolle:

This letter is in response to your Citizen's Petition of November 6, 1996. In your petition, you requested the Food and Drug Administration (FDA) take action concerning Pudenz Schulte Medical Research Corporation (PS Medical) for its Central Nervous System (CNS) Delta Shunt with Siphon Control Device (SCD) and action concerning Heyer Schulte NeuroCare, L.P. for its Anti-siphon Device (ASD). Specifically, you requested FDA to: (1) require changes in manufacturers' labeling, (2) require a new package insert to warn of adverse events, (3) require manufacturers to conduct testing for adverse events under conditions of normal sleep and external pressure and make the results available to physicians and patients, (4) require the surgical section of the manufacturers' labeling to describe the adverse events, (5) inform all U.S. neurosurgeons and neurologists about the new warnings and labeling changes, (6) inform all other U.S. professionals through the FDA Medical Bulletin about the new warnings and labeling changes, and (7) impose restrictions in the use of these devices.

Based on our evaluation of your petition, the medical literature, and adverse effect reporting to the agency, we are in part granting your request (1), (2) and (4) relating to device labeling as indicated above. While it is not feasible at this time for FDA to mandate specific wording in the labeling of each of these devices, there is a long-standing statutory obligation on the part of the manufacturers to provide adequate information in labeling regarding the safe use of their products. This includes a description of the known risks to health from the use of the device. We have met with CNS shunt manufacturers to review their current labeling and directed them to re-evaluate their labeling to include appropriate warnings of adverse events. In response to (5) and (6), we are moving forward to have a broader evaluation of shunt devices in a public forum to see if any further public and/or health care provider notification is necessary. We intend to work closely with the medical device industry, the medical community, and consumers to address the public health issues that exist with CNS shunts.

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The agency is denying parts (4) and (7) of your petition. First, there is insufficient evidence to require CNS shunt manufacturers to conduct specific device testing at this time and to restrict the use of these devices. Secondly, there is no validated test method to simulate the failure modes you described. However, our Office of Science and Technology is reviewing current test methods and assessing an in vitro model to more rigorously test shunts and their components. Should this evaluation lead to the identification and validation of new methods which would increase the assurance of the safety of these devices, we would share them with the manufacturers, the public and work diligently to have them included in the consensus standard being developed for central nervous system shunts.

While we are unable to grant your petition in full at this time, we remain committed to following the issues that you raised and would greatly appreciate your continuing to share information on this subject with the agency. If you have any additional questions concerning this letter, please do not hesitate to call Mr. James Dillard, Deputy Director, Division of General and Restorative Devices, Office of Device Evaluation, at (301) 594-1184.

Sincerely yours,

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health