



Food and Drug Administration
1350 Piccard Drive
Rockville MD 20850

Stephen M. Dolle
3908 1/2 River Avenue
Newport Beach, CA 92663

OCT 10 2002

Dear Mr. Dolle:

This responds to your letter, dated July 11, 2002, to David Feigal, M.D., MPH, Director, Center for Devices and Radiological Health (CDRH). In your letter, you stated that it had come to your attention that the CDRH had undertaken new postmarket surveillance procedures, under Section 522 of the Federal Food, Drug, and Cosmetic Act, as amended, for medical devices posing frequent and dangerous product failures. Your letter requested that CNS shunts be added to the postmarket surveillance list, or that CDRH hold a special meeting with industry to establish new postmarket surveillance mechanisms of performance and outcomes assessment measurement.

Thank you for your interest in this issue. I apologize for taking so long to respond to your request. As you point out in your letter, CNS shunts meet the basic criteria for postmarket surveillance, that is, they are a Class II device, and they are intended to be implanted into the body for more than one year. However, the Food and Drug Administration Modernization Act changed Section 522 to a discretionary requirement, to be implemented when the Agency believes that there is a need to obtain information about a significant postmarket public health issue. Postmarket surveillance is intended to address important unanswered surveillance questions about marketed devices. We do not believe that CNS shunts present unanswered surveillance questions that could be addressed through postmarket surveillance. We believe that some of the issues with CNS shunts are related to the state of the art in understanding the underlying disease condition, and designing devices to perform optimally in the intended environment. The available devices are a best attempt, given the state of the art in device materials, at providing some benefit to patients. The work that is needed is developmental in nature, that is, a better understanding of the disease nature, and better materials to address issues such as clogging. These are not the type of studies for which Section 522 Postmarket Surveillance was intended. The products currently on the market were cleared for market based on the benefit that they provide, and substantial equivalence to products already legally marketed.

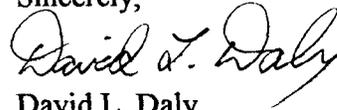
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Therefore, we see no benefit to ordering the manufacturers of CNS shunts to conduct postmarket surveillance under Section 522.

Sincerely,

A handwritten signature in black ink that reads "David L. Daly". The signature is written in a cursive style with a large, looped initial "D".

David L. Daly
Director, Issues Management Staff
Office of Surveillance and Biometrics
Center for Devices and Radiological Health

00N-1367_emc-000002

From: Stephen Dolle [diaceph@adelphia.net]
Sent: Wednesday, August 14, 2002 1:08 AM
To: fdadockets@oc.fda.gov
Subject: Following Up to "Written Request" on Postmarket Surveillance Docket No. 00N-1367

Dear CDRH Staff:

On July 11, 2002, I wrote Dr. David Feigal (per CDRH instructions) with my request that you add "CNS Shunts" to the problem devices list that will be covered by your new Post-Market Surveillance, Docket No. 00N-1367. The docket states this more stringent surveillance will apply to approximately 30 devices under CDRH, but does not identify by type or name the devices that shall apply.

As CNS shunts are one of the most high-failing devices under CDRH, and with extensive market research and understanding of post market QA difficulties and failures, my request is a highly qualified request. After submitting my request, I think it is reasonable that CDRH provide a response within your appropriate response period. I was told that time period is 2 to 3 weeks.

After not receiving a response, I telephoned Mr. David Daly's office and was transferred to Linda at (301) 594-2812. Upon speaking to Linda, I then faxed a copy of my July 11, 2002, Letter of Request to add CNS shunts to this new post market surveillance. Linda was to telephone me after receiving the facsimile of my letter. Regretfully, Linda and that department has not contacted me.

Please forward this email on to David Daly's office, as well as all other persons who may handle correspondence regarding Docket No. 00N-1367.

Thank You,

Stephen Dolle

Email: diaceph@adelphia.net