



Texas Back Institute

**** Sent via Federal Express ****

June 23, 2008

Mr. Ronald P. Jean
Center for Devices and Radiological Health (HFZ-410)
Food and Drug Administration
9200 Corporate Blvd
Rockville, MD 20850

Dear Mr. Jean:

My name is Richard Guyer and I am an orthopedic spine surgeon practicing in Plano, Texas. I am very active in a variety of medical organizations including the North American Spine Society (NASS) where I am the immediate past president. Although I am not speaking as an official representative of NASS, I would like to express my support for the approval of Oxiplex. By way of disclosure, I have no financial or other interest in the products being discussed before the panel.

I have been performing spinal surgery for over 25 years and one of the problems that we spinal surgeons face is the recurrence of pain following decompressive laminectomy and discectomy procedures, particularly with those patients that present with both leg and back pain. We are not entirely sure what causes this post-surgical residual pain although many clinicians are convinced that epidural adhesions and nerve root trauma are two potential causes. In fact, many articles in the literature discuss this as part of a larger discussion of Failed Back Surgery Syndrome. An ideal solution would be a product that coats and protects the nerve roots and the dura during healing and prevents the normal scarring and adhesions. It is known that nucleus pulposus tissue, inflammatory toxins and fibrosis are associated with post surgical pain. A product that would hopefully result in less scar formation, less pain for patients and easier and safer access to the neural structures in the case of revision surgery would be beneficial to spine surgeons and their patients. There are no products approved for use in the US today that accomplish this.

Having reviewed the Oxiplex data from a number of the European clinical studies and recently seeing a poster of the data from the US clinical study at the SpineWeek meeting in May at Geneva, Switzerland, it is clear to me that this product is safe and will help many of my patients. I urge the panel to approve this product as soon as possible.

Regards,

Richard D. Guyer, M.D.