FzioMed Files Citizen Petition with Commissioner of FDA for Reconsideration of Denial of Approval of Premarket Approval Application

The Associated Press

SAN LUIS OBISPO, Calif.--(BUSINESS WIRE)--Dec 3, 2012--FzioMed, a privately held medical device company based in San Luis Obispo, CA, has filed a petition for reconsideration with the U.S. Food and Drug Administration, under Section 515(g)(2)(a) of the Food Drug Cosmetic Act, Section 562 of the FD&C act and Part 10.33 of Title 21 Code of Federal regulations, which denied approval of its premarket approval application (PMA) for Oxiplex® Gel. Oxiplex is an absorbable, clear, viscoelastic gel that is applied during lumbar spine surgery immediately prior to wound closure. Based on four studies involving more than 500 patients, and nearly 10 years of commercial use benefitting more than 300,000 patients outside the U.S., Oxiplex has proven itself to be an effective surgical adjuvant that significantly reduces the effects of Failed Back Surgery Syndrome (FBSS) such as leg pain and neurological symptoms following surgery. Available in nearly 70 countries, including those in the European Union, Australia, Canada, Brazil, Mexico and South Korea, the United States is the only country to deny an application for approval of Oxiplex.

There have not been any reports of safety issues associated with the device among more than 300,000 surgical patients who have been treated with Oxiplex. Those safe, successful surgical procedures occurred in countries whose regulatory agencies are science-based and equally as stringent as the U.S. FDA.

“Patients and spine surgeons across the United States are eager to take advantage of the safe, pain-relieving benefits of Oxiplex and hope the FDA will reconsider its decision to deny access to U.S. patients,” said John Krelle, President and CEO of FzioMed, which recently celebrated 16 years in business. “FzioMed strongly believes that there are several significant issues of scientific dispute that warrant review by an independent advisory committee.” Mr. Krelle went on to say that should the FDA reverse its decision, the company would be in a position to add several hundred well-paying jobs to its U.S. operations. When the FDA first issued a Not Approvable letter in September of 2008, FzioMed was forced to downsize its California operations by 50 percent and to outsource jobs overseas.

About FzioMed FzioMed is a privately held medical device company founded in 1996. The company develops, manufactures and commercializes absorbable surgical biomaterials based on its patented polymer science. FzioMed adhesion barriers are used in many surgical applications including spine, orthopedics, hand, tendon, peripheral nerve, gynecology and general surgery. Its spine gel is the #1 adhesion barrier gel for spine surgery worldwide and is distributed by Medtronic, DePuy and other independent distributors. For more information, please visit www.fziomed.com FzioMed® and Oxiplex® are registered trademarks of FzioMed,

Inc.

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John Krelle, President & CEO 805-546-0610 KEYWORD: UNITED STATES NORTH AMERICA CALIFORNIA INDUSTRY KEYWORD: SURGERY HEALTH MEDICAL DEVICES FDA SOURCE: FzioMed, Inc. Copyright Business Wire 2012 PUB: 12/03/2012 06:00 AM/DISC: 12/03/2012 06:00 AM
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