



Regulatory Compliance and POLYGLYCAN[®] Veterinary Medical Devices

The POLYGLYCAN[®] product is labeled for veterinary use only as a post-surgical lavage for synovial compartments and is designed to replace synovial fluid lost during surgery. The product contains naturally occurring components that play a central role in maintaining the homeostatic environment of the joint. The POLYGLYCAN[®] product contains a highly viscous aqueous solution of purified Hyaluronic acid, Chondroitin sulfates C4 and C6 in a 10% solution of N-acetyl-D-glucosamine. The product exhibits viscoelastic properties similar to synovial fluid.

Regulatory Compliance

The POLYGLYCAN[®] product is manufactured and legally marketed in strict US FDA compliance as a veterinary medical device. FDA does not require pre-market approval of devices used in veterinary medicine. It is FDA's position that it is the responsibility of the manufacturer and/or distributor of veterinary medical devices to assure that the devices are safe, effective, and properly labeled and marketed. (*see*, How FDA Regulates Veterinary Devices, October 28, 2009 (<http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm047117.htm>)).

POLYGLYCAN[®] is manufactured for ArthroDynamic Technologies Animal Health Division, Inc. (ADT) in the U.S.A., in a GMP-FDA approved facility. Under FDA law, medical devices include implants and similar articles which are intended to affect the structure or function of the body, which do not achieve their primary intended purposes through chemical action, and which are not dependent upon being metabolized to achieve their primary intended purposes. (21 U.S.C. § 321(h)). The primary intended purpose of the POLYGLYCAN[®] product is to provide intra-articular replacement of synovial fluid components lost during surgery (viscosupplementation), which qualifies it as a medical device.

Regulatory Precedent for Similar Medical Devices

Similar products have been affirmatively FDA approved as medical devices for use in humans, with analogous components and mechanical functions. For example, the SYNVISIC[®] Hylan G-F 20 product marketed by Genzyme Corporation was approved as a medical device, containing hyaluronic acid indicated for intra-articular administration for the treatment of pain of osteoarthritis in the knee. The VISCOAT[®] product marketed by Alcon Laboratories as a medical device, containing hyaluronic acid and chondroitin sulfate, is indicated for use as a surgical aid in anterior segment procedures including cataract extraction and intraocular lens implantation.

Safety and Efficacy

The POLYGLYCAN[®] product has demonstrated safety in trials conducted at Auburn University and Colorado State University (CSU), and IA efficacy in trials at CSU (*see*, www.arthrodynamic.com). The product has experienced over 3½ years of safe and effective clinical field use with over 750,000 doses. ADT has an adverse event reporting system to monitor safety, and has received fewer than fifty reports of mild allergic type reactions and only a few instances of joint flares. There have been no deaths or serious injuries reported.

