



## Comments on Extra Label Use of Veterinary Medical Devices

### Regulatory Status of Polyglycan®

The POLYGLYCAN® product is labeled for veterinary use only as an intra-articular post-surgical lavage of synovial compartments designed to replace synovial fluid lost during surgery (a viscosupplementation device). The POLYGLYCAN® product is manufactured and legally marketed in strict US FDA compliance as a veterinary medical device. The POLYGLYCAN® product is not promoted or marketed for extra label use and the product is not approved for use as a drug.

### Extra-label Uses Not Prohibited by FDA

The POLYGLYCAN® product label clearly states that it is indicated for intra-articular injection as a post-surgical lavage and to replace synovial fluid lost during surgery in a quantity to be determined by a veterinary surgeon. An “extra-label” use (aka “off-label” use) is one that is not indicated on the product labeling, but is often used by a veterinarian when they believe in their professional judgment that the product may be safely and effectively used in a different manner from that indicated on the label. Examples of extra-label uses include different indications, dosages, frequencies, durations, routes of administration, or in combination with other drugs and/or medical devices.

FDA has repeatedly recognized that extra-label uses are generally allowed and may become the standard of care in the medical profession. (FDA website, Unapproved New Uses for Approved Drugs and Approved or Cleared Medical Devices, January 2009). FDA does not limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. (21 U.S.C. §396 (2006)). Therefore, the fact that FDA has not approved labeling of a drug or device for a particular use does not necessarily bear on those uses that are established within the medical and scientific community as medically appropriate within the scope of a valid veterinarian-client-patient relationship and such uses are not considered improper or illegal.

The POLYGLYCAN® product is not promoted or marketed for any extra-label use. The makers of the POLYGLYCAN® product have and continue to sponsor university-based safety and efficacy investigatory veterinary clinical research into additional intravenous (IV) and intramuscular (IM) indications, as a candidate for future FDA approval for use as a drug. Currently, veterinarians must exercise their own professional judgment in deciding whether to use or prescribe the POLYGLYCAN® product in a manner not indicated on the product label, according to the above FDA guidelines. The above information should not be construed as legal advice or a solicitation to use POLYGLYCAN® other than as labeled.

