Regulatory Challenges to Approval of Non-surgical Animal Sterilants – *Petrick*

Animal health products in the U.S., and most major countries around the world, require some level of data submission, review and subsequent approval before the product can be used in the marketplace. Non-surgical animal sterilants will most likely be classified in the U.S. and other countries as either drugs or biologicals, depending upon their mode of action, and will fall under a federal jurisdiction for that pre-market review and approval.

Defining what a product will do is a key factor. The proposed labeling will define the dose and consequently the level of efficacy and safety that the product can provide.

The cornerstones of approval are based on data collected to demonstrate that the product is safe, effective, and manufactured in a consistent manner that guarantees the quality of the product. Bringing a non-surgical sterilant to the market will face the same challenges as any new animal drug or biological product. If the use is destined for feral animal populations, some regulatory discretion may be available under the current regulations and directives.