

The Government Liaison Committee requested clarification on estradiol use from FDA. FDA's response follows:

Thank you for your inquiry regarding FDA's policy for the use of estradiol 17 β in food producing animals. You asked the question, "...has there been any change in the FDA policy that would make it legal for a licensed veterinarian to prescribe estradiol 17 β for the off-label, or extra-label, use of controlling estrous for facilitating super-ovulation protocols (reproductive therapy) in food producing animals?"

In short, there are no changes in FDA policy for off-label or extra-label use of drugs. Please see 21 CFR Part 530.

Currently there is not an approved estradiol 17 β drug product. In order to legally use a product for off-label use or for extra-label use there would have to be an approved product.

As you have stated, the available estradiol preparations are those being compounded by various pharmacies. The FDA provides regulations and a Compliance Policy Guide 608.400 "Compounding of Drugs for Use in Animals" that you may refer to. Compounding that is consistent with the FDA Extra-Label Drug Use regulations is the customized manipulation of an approved drug(s) by a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a particular patient. Therefore, in order to legally compound a product, the compounding pharmacy is required to use an approved product with an approved active product ingredient (API) and then reformulate it to meet the needs of a patient. Legal compounding is not the formulation of preparations from bulk or raw active ingredients.

Currently, the Center for Veterinary Medicine at the FDA is taking an initiative to work with sponsors of unapproved new animal drugs to seek a New Animal Drug Approval (NADA). The initiative is to acquire evidence for the safety and effectiveness of some of these unapproved new animal drugs where no individual sponsor is developing an NADA. A sponsor can acquire this evidentiary package from the FDA and complete the NADA process.

Thank you,
Vito R. Del Vento, DVM, MS
Veterinary Medical Officer
HHS/FDA/OSC/HFV 216
7519 Standish Place
Rockville, MD 20855