Animal & Veterinary

Vetoryl (trilostane) Capsules Letter - Veterinarians

September 11, 2009

Dear Veterinarian:

We are writing to you about the recent approval by the U.S. Food and Drug Administration (FDA) of Vetoryl (trilostane) Capsules for the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease) in dogs. Please see the approval announcement at http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm150265.htm.

Vetoryl, distributed by Dechra, Ltd., is available in the U.S. in 10, 30, and 60 mg strength capsules. It is the only FDA-approved animal drug that contains trilostane as the active ingredient. Now that VETORYL is approved and available for veterinary use in the U.S., trilostane should not be imported from other countries or compounded from bulk.

Each FDA-approved animal drug goes through a rigorous evaluation process, and prior to approval, is clinically tested for safety and effectiveness in the target animal species. In addition, the FDA thoroughly inspects and evaluates the adequacy of the manufacturing process to ensure that the drug's identity, strength, quality, and purity are preserved. The FDA continues to monitor the drug's quality and safety after it is approved. An animal drug that is compounded from bulk drug ingredients is not FDA-approved and the safety and effectiveness of the compounded drug, as well as the adequacy of the manufacturing process, have not been evaluated.

In prescribing FDA-approved VETORYL to treat Cushing's disease, you are providing your clients and their dogs with the only trilostane product that has demonstrated safety and effectiveness in dogs and whose manufacturing process met the FDA's standards for quality, purity, and potency.

You may have specific patients that require trilostane in strengths or forms that are not offered by Vetoryl. In these limited cases, trilostane can only be legally compounded by using FDA-approved VETORYL as the starting material. Additional requirements and information on legal animal drug compounding are available in Title 21, Code of Federal Regulations, Section 530.13 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=530&showFR=1).

At the FDA's Center for Veterinary Medicine (CVM), we are committed to

promoting and protecting animal health by ensuring that safe and effective drugs are available for veterinary use.

For more information, please contact the Communications Staff at CVM at 240-276-9300 or CVMHomeP@cvm.fda.gov.

Sincerely,

The FDA's Center for Veterinary Medicine