

CVM Update
FDA Announces Availability of Vetsulin for Critical Needs Dogs and Cats

The Food and Drug Administration (FDA) announced today a plan to address concerns regarding the supply of Intervet/Schering Plough Animal Health's (Intervet) Vetsulin (porcine insulin zinc suspension), a product used to treat diabetes in dogs and cats. FDA is allowing Intervet to offer a limited supply of Vetsulin through their Vetsulin Critical-Need Program. The supply is only to be used for a critical-need dog or cat that, in the medical judgment of the pet's veterinarian, cannot be effectively managed on another insulin product.

In November 2009, FDA announced its concerns about the stability of Vetsulin and recommended that diabetic dogs and cats currently receiving Vetsulin be switched to other insulin products. After publicizing this recommendation, FDA and Intervet heard from many veterinarians and pet owners who expressed significant concerns about specific diabetic dogs and cats which could only be controlled with Vetsulin.

As a result of these concerns, FDA is recommending veterinarians with qualified patients contact Intervet's Technical Services Department at 800-224-5318, to request enrollment of the patient in the Vetsulin Critical-Need Program. The veterinarian will need to provide the medical rationale for why the patient cannot be effectively controlled using another insulin product.

Intervet continues to work with FDA to address FDA's concerns associated with the manufacture of Vetsulin. Because Vetsulin may have varying amounts of crystalline zinc insulin in the formulation, it could cause a delay in insulin action and an overall longer duration of insulin activity. Insulin products that do not remain within specification throughout the entire shelf life could potentially result in unpredictable fluctuations in the glucose levels of diabetic patients. Use of Vetsulin under the Critical-Need Program will require close monitoring of the patient, all of which will be described in an owner consent form.

For additional information, please see:

<http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm188752.htm>

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