

May 5, 2010

Re: Vetsulin[®] Critical-Need Program Available

Dear Doctor:

In response to the Vetsulin[®] product alert issued in November 2009, Intervet/Schering-Plough Animal Health (“Intervet”) has been working with the FDA to address an issue identified with our Vetsulin[®] (porcine insulin zinc suspension) product. Since that time, we have recommended that pets be transitioned to other insulin products as we anticipated a limitation on supply and eventual supply depletion. During the process of transitioning pets to other insulin products, we heard from a number of veterinarians and pet owners who expressed significant concerns that specific dogs and cats cannot be effectively managed on an insulin product other than Vetsulin.

After working with the FDA on this situation, Intervet can now offer a limited supply of Vetsulin to specific, critical-need pets, when in the veterinarian’s medical judgment these pets cannot be effectively managed on another insulin product. The availability of this supply will mean that truly critical-need patients can be maintained on Vetsulin. This Vetsulin[®] Critical-Need Program, which will be made available the week of May 24, 2010, is intended to apply only to a limited number of pets and includes only pets that currently are being treated with Vetsulin and those that veterinarians have tried to transition from Vetsulin. The program will require veterinarians to contact Intervet and request that their patients be enrolled in this program. The specifics of the program are:

- Veterinarians having potentially qualified patients will need to telephone Intervet’s Technical Services Department at 800-224-5318 and request that their patients be enrolled in the Vetsulin Critical-Need Program. Veterinarians will need to provide the patient’s name, species, breed, age, owner’s name, address and telephone number and the reason they conclude, in their medical judgment, that the particular patient cannot be effectively managed on any veterinary and human insulin products commonly used for dogs or cats.
- Veterinarians will then be faxed or emailed a form they will be asked to sign certifying that in their medical judgment, the named patient cannot be effectively managed on any insulin other than Vetsulin. An owner informed consent form will also be provided and will need to be completed and sent back along with the veterinarian’s certification statement.
- Once Intervet receives the two signed forms and a patient is enrolled in the program, supply of the product will be made through a designated third-party pre-selected to perform this specific activity. Due to the fact that supplies will have to be controlled and are subject to audit, we unfortunately cannot work through additional distribution channels.
- The designated distributor will set-up the Vetsulin order for direct delivery to the pet owner. The company will invoice the veterinarian for the product and delivery fee and, in turn, the veterinarian should invoice the pet owner at the retail price plus the home delivery fee. This procedure has been put into place to ensure that distribution of the product for these critical cases is done in a timely and efficient manner and that the product goes only to pets veterinarians have pre-qualified for the Critical Need Program.
- Veterinarians will need to advise the dog and cat owners of the potential for variability in vial-to-vial potency and instruct dog and cat owners to monitor carefully their pet after starting a new vial of Vetsulin and report any adverse events, including those related to effectiveness. This information will also be included in the owner consent form.

We have been working diligently to address the issues with this product and hope that the Vetsulin Critical-Need Program will only be a temporary measure. Our top priority is the health, safety and welfare of pets and we believe this program will help assist those pets most in need of Vetsulin in the coming months. We remind you that the Vetsulin Critical-Need Program is intended for use **only** with those patients that you as the treating veterinarian judge cannot be effectively managed on any other insulin product.

If you have any questions, please call Intervet Technical Services at 800-224-5318.

Sincerely,



Christopher Pappas, Jr., DVM, Director of Technical Services