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**FOR IMMEDIATE RELEASE**

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**VETSULIN® PRODUCT ALERT: INFORMATION FOR VETERINARIANS**

LAKEWOOD, Colo. – Intervet/Schering Plough Animal Health and the Food and Drug Administration (FDA) have issued a Vetsulin® product alert after finding three batches of the product were out of specification in regards to the long-term stability of the crystalline, or long acting, component. The American College of Veterinary Internal Medicine (ACVIM) has compiled the following information for veterinarians:

- Vetsulin® is a combination of two types of insulin – amorphous and crystalline. In the three affected batches, the ratio of the two forms is out of their required range, with the crystalline portion being slightly elevated. According to the FAQ's provided by Intervet/Schering Plough Animal Health, due to the altered ratio, it is theoretically possible that diabetic patients on Vetsulin® may experience a delay in onset of action and peak activity and an overall extension of the duration of activity. The actual ramifications are not fully understood. When tested in normal dogs, Intervet/Schering Plough Animal Health has found no differences between batches with respect to change in blood glucose concentration, time of peak effect, or duration of action. Intervet/Schering Plough Animal Health has also reviewed their pharmacovigilance data and found no difference with respect to reports of adverse effects between affected and unaffected batches.
- Although the information provided is certainly helpful, whether the affected batches still perform the same as unaffected has not been conclusively proven. At this time, after a complete review of all steps of the manufacturing, storage and testing procedure, Intervet/Schering Plough Animal Health believes the problem may lie with the testing method used to determine the ratio of amorphous to crystalline insulin, rather than the manufacture of or the insulin itself.
- All Vetsulin® (and Caninsulin®, the same insulin but sold under another trade name in all countries besides the U.S.) is made in one factory in Germany. The questionable batches were within specification when they left the factory, but the problem was identified via follow-up testing done for quality control over the subsequent two years. At this time, the only drug regulatory body that has reacted to the information is the FDA; the agencies in all other countries where Caninsulin® is used have been notified but have not issued a warning or change in policy.

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- In the United States, Vetsulin® is not being recalled and the product will remain in limited distribution. All Vetsulin® should be viewed as potentially affected. The FDA is recommending that veterinarians transition all their patients currently receiving Vetsulin® to other insulins when the patient's current supply runs out. Intervet/Schering Plough Animal Health is asking that veterinarians not start any newly diagnosed patients on Vetsulin®. Intervet/Schering Plough Animal Health will reimburse owners and veterinarians for all unopened vials of Vetsulin® and any syringes; they should be returned to the source of purchase. At this time no reimbursement is being provided for opened vials or for the costs associated with transitioning a pet to different insulin.
- Due to the variability of pharmacokinetics of any insulin between patients, the physiological effects of using an affected batch could potentially cause either hypo- or hyperglycemia in any patient. Signs of hyperglycemia are those of unregulated diabetes mellitus – polyuria/polydipsia, polyphagia, etc. Signs of hypoglycemia include ataxia, disorientation, weakness, seizures and coma. It should be noted, however, that the presence of either hyper- or hypoglycemia can occur at any time in a diabetic patient with inadequate control. The existence of such clinical signs in a patient on Vetsulin® does not mean that the insulin is at fault. If any of the clinical signs of hyper- or, especially, hypoglycemia are noted, the veterinarian in charge of the case should be notified. Other insulin products that may be used are NPH insulin (many brands available), insulin glargine, insulin detemir or the newly approved insulin ProZinc™ (PZI insulin).
- Intervet/Schering Plough Animal Health and the FDA are working diligently toward resolving the issue and returning Vetsulin® to full distribution in the United States. The timeline for resolution of the problem is uncertain. In the near future, Intervet/Schering Plough Animal Health will continue to manufacture Vetsulin® using current protocols. Whether a period of complete non-availability will occur also remains to be determined.
- Although Intervet/Schering Plough Animal Health has not documented an increase in adverse events, they urge veterinarians to monitor their patients closely and report any concerns, and direct any questions, to 1-800-224-5318. More information can also be found at [www.Vetsulin.com](http://www.Vetsulin.com). Clients may also call the number with questions.

The ACVIM is the national certifying organization for veterinary specialists in large and small animal internal medicine, cardiology, neurology and oncology. Established in 1973, ACVIM's mission is to enhance animal and human health by advancing veterinary internal medicine through training, education, and discovery. To find an ACVIM Board-certified Specialist in your area, please visit [www.ACVIM.org](http://www.ACVIM.org).

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