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**Veterinary Biologics Memorandum 2006-04**

To: Veterinarians, Distributors and Manufacturers of Veterinary Biologics

**Subject: CFIA-VBS position statement on the 'extra-label' use of veterinary vaccines**

The purpose of this memorandum is to state the position of the Canadian Food Inspection Agency, Veterinary Biologics Section (CFIA-VBS) regarding the practice of administering veterinary vaccines to non-target species, or of using partial doses of veterinary vaccines, and the implications for official certification of vaccinated animals.

The CFIA-VBS is responsible for licensing veterinary biologics in Canada. To meet the licensing requirements, manufacturers must demonstrate that the product is pure, potent, safe and efficacious when used in the target species according to the label recommendations. The dose is established by the manufacturer, based on safety and efficacy studies in each target species. The manufacturer must demonstrate that the recommended dose confers the desired level of protection as indicated on the label. The manufacturer cannot change the vaccine formulation, antigen concentration and dose volume, or label recommendation without submitting additional supporting data to CFIA-VBS for approval. Therefore, due to the lack of safety and efficacy data to support uses other than those indicated on the approved label, CFIA-VBS does not recommend the use of a veterinary vaccine in a species other than the target species, or the administration of a partial dose of a veterinary vaccine.

In Canada, the regulation of the practice of veterinary medicine is under the authority of provincial veterinary licensing bodies. If veterinarians wish to use vaccines in an extra-label manner they must comply with the standards of the relevant provincial licensing body.

A vaccination certificate issued by a veterinarian to fulfill a CFIA regulatory requirement (e.g. for rabies or for other vaccines for export purposes) serves as a legal document confirming that the animal has received the specified vaccine for the purpose of achieving the desired level of protection against the indicated disease(s). Since there is no assurance that the desired level of protection will be achieved if label recommendations are not followed, a vaccination certificate must not be issued for any animal species other than the target species, or the target species vaccinated with less than the recommended dose of a particular vaccine as indicated on the label.

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