## Appendix A

## BENEFITS OF THE REGULATORY AMENDMENT AS DESCRIBED IN RESPONSE TO HEALTH CANADA'S CONSULTATION LETTER DATED NOVEMBER 2, 2004

**VDD Stakeholders have identified the following benefits of the proposed regulatory amendment:**

***Expert advice and monitoring***
"More stringent control should be considered with the use of veterinary drugs in food-producing animals to protect public and animal health."

"Veterinary involvement in the use of unapproved drugs will ensure that the decision to do so is science-based. Veterinarians in Canada have access to gFARAD, a global system of data and expertise that provides the science behind the decision. In addition, the documentation and rationalization that is part of the service can provide the science-based evidence for future drug approvals. Finally, the use of these processes can improve any risk communications that may be required by VDD, or other stakeholders, to assure their clients that due diligence in use of unapproved drugs has been exercised."

***Antimicrobial Resistance***
"This proposal is in line with the recommendations in the report "*Advisory Committee on Animal uses of Antimicrobials and Impact on Resistance and Human Health*", and more specifically recommendation # 9 : *Stop the importation, sale and use of antimicrobials not evaluated and registered by Health Canada."*

The continued use of unapproved drugs imported for own use ... "undermines the credibility of national and international strategies to control antimicrobial resistance."

We "support this regulation for the purposes of managing antimicrobial resistance risk."

***Human, Public, Animal and Environmental Health***
"The [Canadian drug] approval process assures consumers and the agricultural community that veterinary drugs are efficacious and safe (for both animals and people) when used in the prescribed manner. End users of veterinary drugs are assured that the drug and the concentration in the product are as the label indicates. Unapproved drugs cannot offer these assurances."

"Acute adverse physiological reactions to drug residues in foods of animal origin are extremely rare, however there have been a number of incidents reported in international literature where unapproved drugs or active pharmaceutical ingredients have caused serious illness in humans. ..."

"Unapproved drugs imported for own use are also potentially hazardous to the environment as well as those handling the drugs."

"The prohibition of unapproved drugs for personal use in livestock would help mitigate the risk

of such pharmaceuticals significantly contaminating the Canadian environment. The impacts of such contaminants are only beginning to undergo recognition and evaluation."

"The successful implementation of this regulation will minimize the risk that drugs banned in Canada because of animal health and welfare issues will be used."

***Food Safety***

"The safety of the Canadian food supply is well respected both internationally and within Canada. (We) understand the requirement for this proposed amendment in order to strengthen the safety of the supply system.

"On-farm drug use is identified as a food safety hazard in all National On-Farm Food Safety Programs. ... National On-Farm Food Safety Programs do not list requirements for the purchase of unapproved veterinary drugs. The practice is not acceptable to industry from an on-farm food safety perspective. ...The on-farm use of unapproved drugs would damage the reputation of On Farm Food Safety; programs that are based on internationally accepted food safety principles. While some producers will argue that they have used these products safely for many years in other countries, or know of producers in other countries that use these products without any problems, their efficacy and safety has not been proven in Canada. The prohibition of importation of unapproved drugs for 'own use' in livestock would remove this hazard to food safety."

***Incentive for further drug research and development***

Veterinarians are also concerned about the impact the volume of personal use importations will have on certain sectors of the veterinary pharmaceutical industry in Canada. Consider the time, effort and cost associated with having a new veterinary drug approved for use in food-producing animals and then compare that to having significant quantities of similar, but unapproved products sourced from outside Canada. Given this scenario, submissions to approve new veterinary drugs may stop or be greatly due to lack of incentive for veterinary pharmaceutical companies."