



October 30, 2012

Federal Trade Commission  
Office of the Secretary  
600 Pennsylvania Avenue, N.W.  
Room H-113 (Annex X)  
Washington, D.C. 20850

Re: Pet Medications Workshop, Project No. P12-1201

Dear Sir or Madam,

Novartis Animal Health US, Inc. ("NAH") appreciates the opportunity to comment in relation to the Federal Trade Commission's recent Pet Medications Workshop. NAH has for many years distributed its prescription veterinary medicines and products through licensed veterinarians. We have found that this method is an effective channel to protect pet owners and their companion animals, by ensuring that the owners understand the different options that are available for them to treat their pets as well as the appropriate methods for using these products. NAH therefore urges the FTC to consider carefully the possible difficulties that emerge from changing distribution methods industry-wide and or for all classes of veterinary medicine.

### **Introduction**

NAH is a division of Novartis AG. Novartis AG is a world leader in the research and development of products focused on the health and well-being of patients. Novartis' business is to find innovative ways to address unmet medical needs. At NAH, we extend this innovation to providing solutions which enhance the quality of life for our veterinary patients and meet the needs of pet owners and veterinarians.

Companion animal medications can be separated into different classes: parasiticides and therapeutics. Parasiticides are products that treat internal and external parasites such as fleas, ticks, gastro-intestinal parasites and heartworms, which can threaten the health of pets and the well-being of pet owners. Therapeutic medications are products that address medical conditions, such as arthritis, allergic dermatitis, Addison's disease and other conditions which can challenge a pet's quality of life. Today's therapeutic products provide treatments and solutions that pets did not enjoy decades ago, and reflect the increasingly important role that pets play in our lives. Although these medications are essential, they represent a minority of the market for animal health products. Importantly, animal health therapeutic products are by and large medications regulated by the Food and Drug Administration (FDA).

Parasiticides, especially flea and tick products, however, are regulated by different agencies and in range of forms. These products can be prescription, over-the-counter, oral or topical, regulated by the FDA, or regulated by the Environmental Protection Agency. These



products can be novel compounds developed for companion animal uses, or historical pesticides reformulated for use in or on companion animals. Across the industry there are a variety of effective ways of addressing the issues caused by these parasites. Accordingly, manufacturers' portfolio compositions can vary quite widely and many of the most successful treatments are non-prescription.

NAH's portfolio of parasiticides and therapeutics falls on the FDA-Prescription side of this spectrum. As a division of a globally respected health care company, NAH is a company with a strong FDA pedigree and dedicated to enhancing the quality of veterinary care through innovation. Consistent with this pedigree, NAH places the safety and health of pets at the center of its corporate mission.

This objective, and our medically-oriented product portfolio, underscores NAH's longstanding commitment to, and history of, delivering innovative medicine through the veterinary channel. NAH introduced the first commercially successful prescription flea medication in the 1990s. Since then, NAH's focus on FDA-regulated medicine has not changed, even though a small subset of NAH's products are no longer prescription. NAH continues to believe that distribution through the professional channel continues to present the best path to enhance animal well-being through innovation.

### **The Unique Challenge of Developing Therapeutic Products for Companion Animals**

Like human pharmaceuticals, prescription pet medications are cost-intensive to develop and bring to market. These medicines are essential, effective, quality-of-life enhancing, or lifesaving products, without which, pets will suffer diseases that can devastate pets and their owners. However, the market for these products is orders of magnitude smaller than in the human marketplace.

Thus, there is a business challenge in getting the word out about new and innovative treatments in a cost effective manner. As a result, NAH relies heavily on education of the veterinarian through personal visits to detail all relevant aspects of the product and accessible technical product support, as pet owners generally turn to their veterinarian when their pet has a problem. NAH relies very little on advertising to the general public, or even through professional media. The science behind our products and the data supporting our claims are the most important tools we have to help veterinarians use our products correctly and to the maximum benefit of our patients.

The vast majority, if not all, of our marketing practices are designed to educate the veterinarian and defer to his or her professional judgment when it comes to patients. We do not pay for prescriptions, or reward staff members who select our product over others. We believe that this interferes with the Veterinary Client Patient Relationship (VCPR). Rather, for a medication to earn a place in a clinic, a veterinarian must believe in the science, integrity and quality of the product and the company behind it. He or she will then overlay that information with their experience and the needs of their patients. His or her reputation is tied to the





recommendation as much as ours. This results in benefits for Novartis, the veterinarian, and the patient.

The impression that this business model somehow restricts access to medicine is false. In fact, this business model enhances access to a wide range of medicines that could not be developed without it. Much of the discussion at the Pet Medications Workshop centered around “blockbuster” drugs. But many of the life-saving medicines most important to the health of companion animals have extremely small markets. It is only by maintaining the VCPR that these medicines can be made available.

By way of example, Novartis’ Clomicalm product was found by the FDA to be “medically necessary” in 2011. NAH’s total annual sales of this product in 2012 are projected to be just over \$2 million through distribution to veterinary clinics. It is essential to the quality of life of many pets; however, its demand is simply not sufficient to justify marketing it to the public at large. We see no leakage in to other channels or requests from large retailers for products like this.

### **The Importance of the VCPR for the Health of Companion Animals**

Prescription medications, by definition, must be administered with regard to their efficacy and their safety for a particular patient. It is therefore essential to ensure that these products are prescribed by trained professionals, educated on the risks and benefits of these innovative technologies. The unique circumstances of a particular pet can impact the administration, efficacy and safety of these medications. Only a veterinary-trained professional can assess these variables and ensure that the client is properly counseled.

Therefore, the VCPR plays a critical role in the use of products from an FDA-focused company like NAH. Appropriate therapies require familiarity with pharmacology, education on the medication, and a thorough understanding of the unique circumstances of the patient. Our veterinary customers have been excellent stewards of our products, and have consistently demonstrated high levels of professionalism and understanding of the intricate product detail regarding the safety and efficacy of these products. Veterinarians care deeply about providing accurate and thorough instructions and follow-up care. This professionalism is the cornerstone of good animal care. The expertise, training and compassion possessed by veterinarians has been essential to helping NAH achieve its objective of preserving and enhancing the quality of life of companion animals and ensuring the optimal application of innovative treatments.

Accordingly, NAH brings its products to consumers and their pets exclusively through practicing veterinarians. NAH considers these highly skilled professionals to be our partners in addressing unmet medical needs. We have found no better, more effective way to ensure that innovative science is best directed to the benefit of pets. By distributing these treatments through veterinarians, pet owners receive the information necessary to use our products in the most safe and effective manner for the benefit of their companion animal.





NAH understands that many of the issues raised in the Pet Medications Workshop may impact consumers greatly, and that the FTC seeks to better understand distribution practices and to analyze how these may affect consumer choice and price competition. Some have questioned whether all pet medications should be required to be made available to consumers in different ways than they are now.

NAH does not purport to have an answer regarding the best distribution practices for all companies and all products. For products that are not FDA-regulated and non-prescription, the veterinary channel may create higher logistical and sales costs without a corresponding health benefit. But as a company with an FDA pedigree, that was founded to develop innovative solutions to unmet medical needs, NAH believes that doing so in the context of the VCPR creates efficiencies which serve our objective of preserving and enhancing the quality of life for our patients.

For one thing, by educating and distributing our products to practicing veterinarians, NAH has built relationships and developed a knowledge base with these veterinary professionals, which has helped sharpen our focus on the safety and health of companion animals. Working directly with the veterinarians who administer our products has driven innovation that has resulted in products that deliver therapies for previously unmet medical needs in pets.

Today's veterinary medications are quite advanced at treating various disease states. In particular, therapeutics, such as cox-2 inhibitors, offer extraordinary ability to enhance the quality of life in an elderly pet. Today's pets enjoy treatments that were not available ten years ago. However, with better medications comes enhanced risk. Many of these drugs have potentially acute side effects that can be exacerbated by many elements of a pet's lifestyle, pedigree and individual circumstances. NAH believes that veterinarians are uniquely trained and qualified to plan for these varied medical situations.

Veterinarians understand patient history and drug interactions and serve as a control point for dispensing medications, which is key to supporting proper drug usage. Contact points such as treatment, prescription, dispensing and follow up appointments with pets and pet owners create a base of experience and opportunities for feedback that are unmatched. These contacts, and the continuity of care fostered by a strong VCPR, are critical to the effective administration of animal health care. When this continuity is broken, the health and safety of companion animals are threatened. It is our position that nothing should interfere with this relationship or these contact points.

Over the past two decades, this market has evolved, and it continues to evolve. Manufacturers have embraced a variety of distribution channels. Market forces have created innovative solutions, such as veterinary home delivery services, which preserve this continuity and maintain the VCPR, while creating additional convenience and logistical efficiencies. The most successful market innovations, we have observed, have been those that preserve these contact points between veterinarians, pets and pet owners.



### **Conclusion**

NAH believes that delivering innovative solutions in the context of the VCPR enables pet owners and their companion animals to be the beneficiaries of this expertise and compassion. NAH's objective is not to control distribution, limit competition or support inefficient businesses. Rather, our driving goal is to address unmet medical needs through innovation and thus ensure the health and quality of life of companion animals. Embracing the VCPR as a point of education and expertise for innovative prescription and generic medications has proven itself to be the most effective way of ensuring access by pet owners to quality care for their animals at affordable prices through their chosen veterinarian. This model ensures that both innovation and pet health are served in an effective way. We urge the FTC to consider carefully the potentially adverse consequences to the health of companion animals and the ability of pet owners to make informed choices in the event an alternative distribution method is required industry-wide.

Respectfully submitted,

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Vice President/General Counsel  
Novartis Animal Health US, Inc.