



Companion Animal
Parasite Council

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April 9, 2010

Ms. Lois Rossi
Registration Division Director
Office of Pesticide (7505C)
Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

Dear Ms. Rossi,

Last year the EPA issued a statement alerting consumers and health *care professionals of the seemingly increased incidence of adverse* events associated with Pet Spot-On type products. EPA held a follow-up meeting with manufacturers of these products and public session on March 17, 2010 to discuss the results and offer recommendations. The Companion Animal Parasite Council (CAPC) would like to take this opportunity to comment on the notice referring to a proposed mitigation plan referenced to in the Federal Register / Vol. 75, No. 52/Thursday March 14, 2010.

CAPC is an independent not for profit educational foundation committed to the elimination of disease and suffering of animals brought on by parasitic diseases. It is comprised of veterinary practitioners, academic parasitologists and representatives of organizations charged with ensuring public health. CAPC advocates strongly for the aggressive control of parasites including fleas and ticks through year round monthly administration or application of internal and external parasite control products. These recommendations include but are not limited to Spot-On type compounds.

While any adverse event associated with any compound is concerning and deserves to be reported and explored, not all adverse events are the same and not all formulas nor pet owners are the same.

An adverse event (AE) is defined as any unfavorable and unintended sign including an abnormal laboratory finding, clinical sign or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure.

Clearly this definition is intentionally inclusive but allows for very broad interpretation. Some adverse events are extremely vague *when* reported or interpreted by the untrained pet owner and minor while others are very severe, reported by veterinary professionals with training and knowledge who have seen and treated the pet and can clearly associate the event with the administration of a product. While any licensed product is expected to be safe no product or procedure is totally safe. The goal should be not simply to report the individual incidence of a problem but to evaluate the severity and the prevalence of an adverse event and to view the adverse events seen in the light of the benefits associated with the use of a product when used according to directions. There are several key issues missing from the various EPA generated documents.

What is the severity of the adverse event being counted? Is the event life threatening or even fatal or is it merely annoying as occurs when a product smells or feels unpleasant? EPA's documents offered on March 17 report that the number of major incidences and deaths from these products actually declined from 2007 to 2008.

Adverse events should not be consolidated together but should be classified from mild to serious with the statistical emphasis placed on serious adverse events such as those that are life threatening or require hospitalization or prolonged treatment or results in chronic incapacity. While less severe adverse events clearly deserve attention there is very real difference in the EPA reporting out of this data between such severe events and the annoyance of an unpleasant odor or topical discoloration.

Similarly adverse events should be classified as clearly associated with the administration of a product based on time span and pathophysiology. For instance, neurologic signs or even gastro-intestinal signs that occur shortly after administration are far different from a disease that occurs months after administration.

How many doses of a given product have been administered? In recent years, awareness and utilization of control and prevention products has increased in no small part due to the recommendation of the profession and organizations such as CAPC and the proliferation of parasite control products and manufacturers. EPA documents say that in 2008 two hundred seventy million doses were dispensed. The internet and major retailers have increased access to parasite control products and in particular to flea and tick control products. It stands to reason that increased utilization of products particularly without appropriate instruction would result in an increased number of adverse events even if the statistical percentage as determined based on total doses administered may not have changed.

Are adverse events reported in every 100 applications or every ten million doses?

It is unreasonable to lump adverse event statistics related to products sold in pet stores and dispensed with no supervision with products dispensed or at very least recommended by trained health care professionals. Many of the products in question are intended for use under the guidance of a licensed veterinarian and yet many similar or even identical products are available in retail outlets and on the internet where they can be purchased with no professional guidance and used with no professional advice. Are all topical products created equally? The EPA has failed to even estimate what percentage of adverse events are associated with products purchased from veterinarians versus retail outlets. There can be no certainty that the products were used as intended, at the intervals intended and at the dosage or even in the species intended.

Finally, the relative safety and value of a product should be evaluated with at very least consideration of the benefits derived from their use. There are two major concerns that would speak for the aggressive use of flea and tick control products. First is the fact that ecto-parasites cause great discomfort and associated skin diseases in animals and in humans alike. There can be no doubt that relieving discomfort associated with infestations is a very real benefit of the advent of these products undergoing scrutiny.

Second is the ever increasing awareness of diseases transmitted by fleas, ticks and mosquitoes that are significant pathogens of animals and humans. By preventing and controlling these ecto-parasites we do much to reduce the likelihood of transmission of these debilitating and even fatal diseases.

While CAPC is focused on the control and prevention of parasites we are also committed to the safety and wellbeing of animals and of pets in particular. We do not want unsafe products on the market and we advocate for appropriate precautions to reduce adverse events. However, it is vital that products be evaluated fairly and individually with regard to the nature and severity of adverse events and their relationship to products based on careful evaluation

Adding additional label precautions presumes that it is the lack of such precautions that leads to adverse events. We believe that it is the lack of direct professional involvement between veterinarian and pet-owner that increases the possibility of such events, not a current lack of adequate information on existing labels. Those pet-owners who do not read present label precautions will not be better informed by revised labels that they will also fail to read or fully understand. We strongly advocate that the veterinary professional be the source of information for the pet owning consumer and that only products specifically dispensed or recommended by trained professionals be used by pet owners. The review of and consideration being given to changes in the labels of the products in question is reasonable and appropriate provided the reasons for any label changes are based on scientific and statistical information and not just reaction to a select group of undesirable side effects of varying severity.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Paul, DVM". The signature is fluid and cursive, with the first name "Michael" being the most prominent part.

Michael Paul, DVM
Executive Director, CEO