

BioSpotVictims.org

May 15, 2010

Office of Pesticides Program (OPP) Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

RE: Pet Spot-On Analysis and Mitigation Plan Available for Public Comment; Availability
(Document ID EPA-HQ-OPP-2010-0229-0001)

Dear Sir or Madam:

The EPA's long-anticipated evaluation of pet spot-on products, and plan to increase their safety, falls short of action that is required to prevent the needless suffering and death of pets, and the anguish, guilt, and expense that is borne by pet owners as the result of adverse incidents.

To reduce the harmful effects of pet spot-on products, BioSpotVictims.org urges EPA to adopt the following measures:

- **Pet spot-on products should be labeled according to FDA requirements.** EPA's labeling requirements, including warnings concerning the potential for adverse reactions in pets and risks of exposure to children are woefully inadequate. Labels should explicitly state, "Warning: Do not use on aged, sick, debilitated, or underweight pets. Children should not come in contact with the application site for 24 hours after application."
- **Pyrethroid-based spot-on products should be removed from the over-the-counter market.** Spot-on products for dogs that contain a high concentration of permethrin, phenothrin, cyphenothrin, or etofenprox can result in serious injury or death if applied to or ingested by cats, and should be banned from the market or available only through licensed veterinarians. Label revisions to prevent accidental poisoning in cats have been attempted for the past 15 years and have proven to be ineffective.
- **Companion animal safety studies should include diverse breeds and acute oral toxicity tests.** The studies should include several animals whose weight is at the low end of a product's weight/dose range. It should also test 3x and 5x doses as a single application (not as 1x doses applied every hour until a 3x or 5x dose is achieved).
- **Registrants should be prohibited from collecting and reporting adverse incident data.** Incidents should be required to be reported directly to the EPA, or an entity that has no financial relationship with the product registrants, such as the National Pesticide Information Center.

BioSpotVictims.org also urges EPA to adopt pre-market clinical trials and post-market surveillance based on FDA data requirements, conditional registrations for new products, and require products to provide narrower dose ranges (not to exceed 1.5x the minimum effective dose).

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If the EPA is unable or unwilling to provide greater safety for pets by adopting the FDA's data requirements for product labeling, pre-market clinical trials and post-market surveillance, it should consider transferring regulatory authority of pet spot-on products to the FDA. Some flea and tick products, including spot-on products similar to those regulated by the EPA, are already regulated by the FDA.

There would be many advantages to having all pet spot-on products regulated by a single agency (FDA). It would eliminate redundancy and ensure that all spot-on products are required to meet the same standards for safety and effectiveness. It would also eliminate confusion among many pet owners who mistakenly assume that all spot-on products available from veterinarians are FDA-approved and held to a higher safety standard. Spot-on products are also heavily marketed as effective in preventing diseases in animals and humans, which is prohibited by FIFRA. Transferring regulatory authority to FDA would also prevent future Administrations from undoing the risk mitigation plan that is currently being proposed by EPA.

The FDA has a history of protecting human and animal health by recalling products, even in the absence of adverse events. They act out of an "abundance of caution." The EPA, on the other hand, has a history of foot-dragging when it comes to protecting people and pets from dangerous pesticide products. It took over 5 years for the EPA to negotiate the relabeling and voluntary cancellation of Hartz phenothrin-based spot-on product for cats, and despite tens of thousands of reports of adverse incidents involving Sergeant's cyphenothrin-based spot-on products, EPA has refused to order a recall.

Here is EPA's Cyphenothrin Summary Document for Registration Review:

http://www.biospotvictims.org/EPA-HQ-OPP-2009-0842-0005_2_.pdf

Excerpt from page 14:

"There have been several reported pet incidents involving the use of cyphenothrin pet treatments on dogs. From January 2006 to November 2009, there were 149 reported mortalities, 367 major reported incidents, 13,455 moderate reported incidents and 32,713 minor reported incidents. From all reported pesticide related pet incidents, cyphenothrin products account for 10% of the total reported pet mortalities, 13% of all major incidents, 54% of all moderate incidents, and 65% of all minor incidents. Some of these incidents resulted from cyphenothrin products co-formulated with pyriproxifen, and it is unclear whether one active ingredient or the other, or an emergent effect from the formulation is responsible for these incidents."

When you consider that Sergeant's products #2517-80 and #2517-85 are the ONLY cyphenothrin pet treatments on the market, that is simply astounding.

Sincerely,

James TerBush
Website Administrator