



Pet Spot-On Mitigation Plan

March 17, 2010

Risk Management

- Agency concluded, based on the analysis, that mitigation is necessary to prevent unreasonable adverse effects
- Regulatory Action Plan – EPA will pursue the following:
 - Product-specific, immediate further restrictions
 - Tighter regulation
 - Public outreach campaign

Risk Management: Further Restrictions

- Address dosing concerns
 - Pursuing label and/or packaging changes that would result in more narrow pet weight ranges per vial size

Risk Management: Further Restrictions

- Address concerns about cat exposure to dog products
 - Pursuing label changes that prohibit the use of the same brand names for both dog and cat products
 - Determining appropriate, clear labels statements to address concerns with cat exposure to dog products
 - as a result of direct application or
 - as a result of interactions between dogs and cats after application of dog products

Risk Management: Further Restrictions

- Address concerns about label clarity
- Address product specific concerns
 - Pursuing further label restrictions
 - Pursuing other changes, as needed, based on individual product assessments (DERs)

Risk Management: Further Restrictions

- Address uncertainties about inert ingredients
 - Pursuing disallowing alternate formulations
 - Determining whether additional information on certain inerts is needed and, if so, obtaining that information
 - When inerts with suspected toxic effects are identified, EPA will not allow the use of these chemicals in pet products

Risk Management: Tighter Regulation

- Pursue standardized adverse event reporting
 - Standard format
 - Standard content
 - Analysis of the information
 - Will allow EPA to efficiently continue post-market surveillance of these products

Risk Management: Tighter Regulation

- Pursue standardized sales reporting
 - Will allow EPA to accurately compare numbers of incidents between products

Risk Management: Tighter Regulation

- Revise Data Requirements - taking steps to bring data requirements in line with FDA's requirements for similar products
 - Will allow EPA to be consistent with FDA, including pre-market clinical trials
 - Will allow EPA to more thoroughly assess the safety of these products prior to registration
 - Will allow effective post-market surveillance

Risk Management: FDA and EPA Requirements

	Current EPA Requirements	Current FDA Requirements
Pre-Market Animal Safety Study	<p><u>Guideline No:</u> 870.7200</p> <p><u>Title:</u> Companion Animal Safety</p> <p><u>Number of Animals:</u> 6 per sex per dose</p> <p><u>Level of Concern:</u> 5X</p> <p><u>Other:</u> Harmonized with previous FDA/CVM Guidance #33</p>	<p><u>Guideline No:</u> 185 (VICH GL43)</p> <p><u>Title:</u> Target Animal Safety for Veterinary Pharmaceutical Products</p> <p><u>Number of Animals:</u> 4 per sex per dose</p> <p><u>Level of Concern:</u> 5X</p> <p><u>Other:</u> International harmonization</p>
Pre-Market Clinical Trials	<p><u>None</u></p>	<p><u>Guideline No:</u> 85 (VICH GL9)</p> <p><u>Title:</u> Good Clinical Practice</p> <p><u>Number of Animals</u> ~200 (where 1/2 are positive control). Represents populations of actual pets rather than only test beagles. Informs labeling and contributes to the overall approval decision.</p>
Post-Market Surveillance	<p>Aggregate summary reporting of summary numbers of adverse effects under FIFRA Section 6(a)(2). Generally only used to trigger a more detailed review.</p>	<p>Ten veterinarians and other professional staff evaluate detailed adverse events, particularly for new products. Findings may result in changes to product, label, insert, and communication with vets and the public.</p>

Risk Management: Tighter Regulation

- Conditional Registrations
 - Future pet spot-on registrations (new products) and amendments to existing registrations will contain appropriate conditions and time limitations
 - Will allow EPA to conduct appropriate post-market surveillance

Risk Management: Potential Implementation Mechanisms

- Anticipated further restrictions
 - Will be meeting with individual registrants to discuss individual products and product lines
 - Considering preparing a guidance document
- Tighter regulation
 - Will be discussing with Canada's PMRA
 - Will be discussing with FDA's CVM
 - Will be obtaining public input
 - May require changes to rules and guidelines or other regulatory process

Public Outreach Campaign

- The Agency is taking steps to initiate a multi-prong communication campaign
 - inform the public and other interested parties of the results of the investigation
 - steps the public can take to ensure safe use of pet flea and tick products

Next Steps

- Public Comment on Implementation of Mitigation Plan
- FR Notice
 - Docket: **EPA-HQ-OPP-2010-0229**
 - www.regulations.gov
 - 60-day public comment period

Contact information

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