MEMORANDUM

SUBJECT: Analysis of Incident Reports for Adams Flea & Tick Dip with Dursban (for Dogs)*

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During the review of incident reports for Adams Flea & Tick Dip with Dursban (for Dogs), it was noticed that the majority of adverse reactions, including deaths, were the result of misusing the product in cats. An analysis of the incident reports is attached. Of 29 reports included in the analysis, 19 involved cats with adverse effects reported in 25 cats. Clinical signs of toxicity involving the nervous system were seen in 18 cats; death was reported in 3.

The product label contains the statement DO NOT USE ON CATS under Precautionary Statements, Hazards to Humans and Domestic Animals. However, it appears that the labeling has not been effective in this regard. Several of the incident reports stated that the precautionary warning was not prominently placed on the label. One report noted that the price sticker was over the warning. Therefore, it is recommended that an additional warning be placed on the label where the pet owner is more likely to read it.

Recommendation: In insure compliance with the label warning, it is recommended that the precautionary warning DO NOT USE ON CATS also be placed in the Directions for Use section of the label.

*Registration Number: 45087-26-622
Analysis of Incident Reports for
Adams Flea & Tick Dip with Dursban (for Dogs)*

Number of Cases in IDS system: 32
Number Analyzed: 29 (3 cases have not been received in HED)
Species Involved in Each Report: Dogs - 4
   Cats - 19 (1 report involved dogs and cats)
   Humans - 2
Total Number of Each Species Involved: Dogs - 4
   Cats - 25
   Humans - 2

Lack of Efficacy: 5
Signs Reported in Each Species (multiple signs may be reported for each animal):

<table>
<thead>
<tr>
<th></th>
<th>Dogs</th>
<th>Cats</th>
<th>Humans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>4</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>Death</td>
<td>1</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Neurological Signs</td>
<td>2</td>
<td>18</td>
<td>2*</td>
</tr>
<tr>
<td>Gastrointestinal Signs</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>OP Toxicity Signs⁵</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Generalized Signs⁶</td>
<td>0</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory Signs</td>
<td>0</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>No adverse Signs</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

* Numbness in hands
⁵ Two reports summarized the signs seen as consistent with OP toxicity
⁶ The classification used to describe non-specific signs of illness such as lethargy, anorexia, depression, etc.