US Environmental Protection Agency
Office of Pesticide Programs

Meeting Summary - Meeting with Registrants of Spot-On Flea and Tick Pesticide Products

May 5, 2009

Meeting Summary

Meeting with Registrants of
Spot-On Flea and Tick Pesticide Products

May 5, 2009, 1:00 pm to 3:00 pm
Room 1206, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attendees:

Representatives from the following companies (see also attached sign-in sheet):

- Summit Vet Pharm
- Central Life Sciences
- Hartz Mountain Corporation
- MGK
- TSG
- Exponent
- Fort Dodge Animal Health
- Bayer Animal Health
- Sergeant's PetCare
- Merial Limited
- AHI
- Pillsbury Law
- Intervet

Representatives from FDA's Center for Veterinary Medicine:

- John Baker
- Angela Clark
-

Representatives from Health Canada:

- Cheryl Chaffey
- Peter Chen
- Marion Law
- Brenda Linke

Representatives from EPA:

Office of Pesticide Programs:

- Byron Backus, RD
- Kate Bouve, ITRMD
- Julie Chao, RD
- Venus Eagle, RD
- Kit Farwell, HED
- Calvin Furlow, ITRMD
- Claire Gesalman, FEAD
- Masih Hashim, RD
- John Hebert, RD
- Samantha Hulkower, RD
- Meredith Laws, RD
- Tina Levine, HED
- Mary Manibusan, HED
- Autumn Metzger, RD
- Oscar Morales, ITRMD
- Kimberly Nesci, RD
- Anne Overstreet, SRRD
- Lois Rossi, RD
- Norman Spurling, ITRMD

Office of General Counsel:

- Michele Knorr

Meeting Summary:

The above-listed representatives from industry, EPA, FDA, and Health Canada met on May 5, 2009, to discuss reported adverse effects on pets associated with flea and tick products, ongoing agency actions related to the reported incidents, additional information needs, and a path forward for addressing the issue of pet incidents (see also attached slides).

The Agency presented historical information about pet incidents and discussed its April 16, 2009, advisory statement. The Agency discussed its ongoing communications with Health Canada, its intent to analyze the spot-on products and incidents seen more thoroughly, and its intent to consider whether the domestic animal safety studies currently required in the process of registering pet products are sufficient to protect the health of pets.

The Agency discussed what types of additional information would be helpful to EPA in further evaluating these products, including the following:

- information on market share;
- numbers of incidents per doses or packages sold; and
- additional information on each specific incident.

The Agency also discussed mitigation options and noted that mitigation options may include data requirements, revisions to labeling, or cancellation. A question and answer session followed.

Questions and Answers:

During the question and answer session, registrants asked questions about the additional information that would be helpful to EPA and the numbers of incidents being seen. During the meeting, the Agency committed to providing the registrants with further details concerning the additional information and numbers of incidents that have been reported to the Agency. This information was provided to the registrants in the form of an email message (see attachments).

The registrants also had questions about the use of statistics in the analysis of incident numbers. The Agency responded that we will be looking at information on individual incidents and not simply at total incident numbers.

Registrants asked whether the Agency's analysis of incidents will be subject to a public process. The Agency responded that its analysis will be released publicly.

Registrants commented that the overall effect of the message sent in the Agency's April 16, 2009, advisory and associated Web site has been dramatically negative. The Agency acknowledged the comment and committed to posting a complete list of all registered spot-on products, which EPA did on May 6, 2009.

Schedule/Next Steps:

The tentative schedule for the Agency's evaluation of these products was presented as well. The Agency has plans to complete its analysis of risk this fall, after which appropriate mitigation measures will be discussed. The Agency will also continue to update its Web page with additional information as it becomes available.

Attachments:

May 5, 2009, Agenda (2 pages)
May 5, 2009, Slides (7 pages)
Sign-In Sheet (3 pages)
Follow-Up email to participants (4 pages)

Agenda

Meeting with Registrants of
Spot-On Flea and Tick Pesticide Products

May 5, 2009, 1:00 pm to 3:00 pm
Room 1206, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

I. Introductions & Opening Remarks

II. Background

III. Short-Term Actions

a. April 16th Advisory Statement
b. Canada's Registrant Meeting

IV. Mid- to Long-Term Actions

a. Analysis of the Incident Data
b. Domestic Animal Safety Studies

V. Next Steps

a. Information Needs (see back)
b. Mitigation Options
c. Schedule

VI. Open Discussion

VII. Meeting Summary

Data & Information Needs

- Market Share
- Incidents per dose sold
- Incident per package sold (number of doses per package)
- Additional information on incidents received to date
  - Product name
  - Registration # (very important)
  - Lot # if available
  - Formulation (Basic, Alternate #1, etc…) if available
  - Active ingredient(s)
  - Weight range for product
  - Date on which incident occurred.
  - State in which the incident occurred.
  - Registrant case #
  - Species: Dog, Cat, Other (specify)
  - Breed: (needs to be standardized)
  - Age: months or years
  - Sex: M, F, neutered
  - Weight: pounds
  - Route of Exposure: Dermal, Oral, Other Animal, Inhalation, Other
  - Body System: Neurological, Dermatological, GI, Respiratory, Ocular, Other
  - Signs noted with separate column for each sign, using standard terminology: (to be provided later)
  - Treated by Veterinarian: yes or no
  - Treatment provided:
  - EPA Severity Code: Death, Major, Moderate, Minor
  - Certainty Index: (criteria to be provided later)
  - Outcome: (died, recovered, still treated, unknown)
  - Time to Onset: hours, days
  - Duration of signs: < 1hr, 1-4 hr, 4-8 hr, 8-24 hr, 1-3 days, > 3 days
  - Any known precondition?
  - Was the product applied according to the label?
  - Was this the first time using this product?
  - How frequently was the product applied?
  - Was the pet being treated with other medications or other pesticides?
  - Spreadsheet cell with text narrative of incident.

EPA Meeting With Registrants of Spot-On Flea and Tick Products

May 5, 2009

Introductions

- Purpose of the meeting is
  - to discuss the pet incidents that we're seeing,
  - to discuss ongoing Agency actions and additional information needs, and
  - to discuss a path forward
- EPA is committed to working with registrants and stakeholders to best determine how to address this issue

Background

- Historical concerns about pet incidents
- Increase in number of incidents between 2007 and 2008
- Coordination with Canada; similar trend
- Spot-on products appear to contribute the most
- April 16, 2009, Advisory Statement

Short-Term Actions

- Response to April 16, 2009, advisory statement
  - Questions from the public
  - Removal & reposting of a list
  - Questions and Answers

Short-Term Actions

- Communications with Canada
  - Observed PMRA's meeting with Canadian registrants
  - Report from PMRA on the meeting with Canadian registrants
  - Will continue to coordinate with PMRA

Mid- to Long-Term Actions

- Analysis of the spot-on products
  - Establishment of a DVM team
  - Review of incident data
  - Review of domestic animal safety data
  - Review of additional information supporting the registration of these products and active ingredients

Mid- to Long-Term Actions

- Domestic Animal Safety Studies
  - Considering whether these studies are sufficient
  - Considering FDA's Center for Veterinary Medicine's testing guidelines
  - Reviewing domestic animal safety studies in house for these products

Next Steps

- Information Needs
- Mitigation Options
- Schedule

Next Steps – Information Needs

- Market Share
- Incidents per dose sold
- Incidents per package sold (doses per package)
- Additional information on individual incidents

Next Steps - Mitigation Options

- Action to reduce the numbers of incidents that we're seeing
- The analysis of spot-on products will inform that decision
- Sound science
- Options may include data requirements, revisions to labeling, cancellation

Next Steps – Tentative Schedule

- Obtain additional information by July 2009
- Complete our internal analysis by October 2009
- Initiate meetings to discuss mitigation by October 2009

Open Discussion

- Questions/Comments

Meeting Summary

- Points of Contact

  Kimberly Nesci, nesci.kimberly@epa.gov
  703-308-8059

  John Hebert, hebert.john@epa.gov
  703-308-8059

  Marion Johnson, johnson.marion@epa.gov
  703-305-6788

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May 5, 2009

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Anne Dienstreet	SRRD	
Byron Backus	EPA/RD	
Julie Chao	RD	
Claire Gesalman	FEAD	
John Baker, DVM	FDA/CVM	john.baker@fda.hhs.gov 240-453-6844
Kate Bouve	OPP/ITRMD	bouve.kate@epa.gov,

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May 5, 2009

Name	Affiliation	E-mail/Phone number
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Spot-On Registrants - Information request

Kimberly Nesci to: CHALEFD, COBBR, Cunningham, Dr. Karen, Timothy.Dotson, Kari.Blaho-Owens, Doug Spilker, Bruce Martin, RRosenwasser, LHemsarth, kellie.dixon, Rick Tinsworth, patricia.sheehy, JConti, WANGB, jazkatz, Becky Horton, KHoskins, Doug Spilker, lkchavez, Timothy.Dotson, jmcfadden, jedecto, janice.davis, warren.lehrenbaum, sspaulding, dave.carlson, jhall, bruce.martin.b, donald.schwartz, sveluvolu

05/26/2009 04:44 PM

Cc: "Baker, John D" <John.Baker@fda.hhs.gov>, Marion Law, Magy Bateh, Cheryl Chaffey, Brenda Linke, Dana Bruce, Anne Overstreet, Autumn Metzger, Byron Backus, Claire Gesalman, Clayton Myers, Deborah McCall, George Herndon, John Hebert, Kit Farwell, Lois Rossi, Marion Johnson, Marty Monell, Mary Manibusan, Meredith Laws, Michele Knorr, Norman Spurling, Oscar Morales, Richard Gebken, Samantha Hulkower, Tina Levine, Venus Eagle

Dear Registrants,

At our May 5, 2009, meeting with the registrants, we discussed how best to evaluate and characterize the increase in adverse incidents being reported to EPA under FIFRA section 6(a)(2). Below please find some guidance on how to provide the information on the enhanced reporting discussed at our meeting.

Please send the information to me at the following address:

Kimberly Nesci
Product Manager 11
Mail Code 7505P
1200 Pennsylvania Avenue, NW
Washington, DC 20460

or via email at nesci.kimberly@epa.gov.

Please note that we will be updating the website to provide meeting minutes from the Agency's May 5, 2009, meeting and the Agency's workplan for addressing animal incidents. I will send you all a link when that information is posted. In addition, I know that some of you were interested in obtaining the numbers that we presented during the meeting. They are as follows (please note that they have been rounded):

2007:
Death - 560
Major - 610
Minor/Moderate/Unspecified - 21000
Moderate - 1600
Minor - 5100
Unspecified - 140

2008:

Death - 640
Major - 740
Minor/Moderate/Unspecified - 8500
Moderate - 6700
Minor - 27,000
Unspecified - 130

If you have any questions, please contact me at 703-308-8059 or via email.

Thank you and best regards,
Kimberly Nesci

Kimberly Nesci, Product Manager 11
Insecticide Branch
Registration Division (7505P)
Office of Pesticide Programs
(703) 308-8059

Enhanced Reporting

Submission of the following enhanced incident data will help to better characterize the incident data which EPA receives in regard to the types of incidents, severity, circumstances of use, and possible sensitive populations. We want to distinguish misuse from proper use, but still want data on misuse in order to know the circumstances and consequences of misuse. It's not necessary to report information calls.

Listed below is the information we'd like in spreadsheet form. Registrants may submit their own database which contains information similar to that requested below. If the data are contained in a proprietary software program then it should be converted to spreadsheet form. We are not asking you to conduct any new evaluation of the information that you have that is the basis of your reports under FIFRA section 6(a)(2) and the implementing regulations at 40 CFR Part 159.

To assist the Agency in this process, we request that you be consistent, use standard terminology, and have the same person enter the data as much as possible. Standard terminology of clinical signs are used by companies providing adverse event management and regulatory reporting, by NIOSH SENSOR, and other sources.
If standardized terms have not already been used, we suggest the following key terms: Neurological (salivation, tremor, seizure, depression, excited/aggressive, ataxia, hiding, weak, paralysis, vocalizing), Dermal (skin irritation, pruritus, ulcer, hair loss, staining), Gastrointestinal (diarrhea, vomiting), Ocular (conjunctivitis, miosis, mydriasis, blinking, tearing).

The following is a list of information that would be helpful for EPA to better characterize these incidents:

EPA Registration # (very important).

Product name (brand name)
Lot # (if available)
Formulation (Basic, Alternate #1, etc…) if available
Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/YYYY)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: Dog, Cat, Other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Route of Exposure: Dermal, Oral, Other Animal, Inhalation, Other
How applied: base of skull, between shoulder blades, along back
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Duration of signs: < 1hr, 1-4 hr, 4-8 hr, 8-24 hr, 1-3 days, > 3 days
Treated by veterinarian: yes or no
Treatment provided: (name treatment)
First time product used: yes or no
Misuse: dog product on cats, overdose, too frequent dosing, other (describe)
Treated with other pesticide or drug: (name product)
Any known precondition
EPA Severity Code: Death, Major, Moderate, Minor.
Certainty Index: definite, probable, possible, unlikely
Outcome: died, recovered, still treated, unknown

Spreadsheet cell with text narrative of incident.

CERTAINTY INDEX

Definite

Confirmed by laboratory diagnosis (*e.g.* cholinesterase inhibition; or high concentrations of pesticide detected; etc).
At least one specific clinical sign consistent with toxicity from chemical.
Exposure pathway and timing consistent with toxicity from chemical.
No other cause of toxicity identified.

Probable

At least one specific clinical sign consistent with toxicity from chemical.
Exposure pathway and timing consistent with toxicity from chemical.
No other cause of toxicity identified.

Possible
Clinical sign(s) generally consistent with toxicity from chemical.
Exposure pathway and timing generally consistent but may be uncertainty.
Other health problems could be responsible for part of the clinical signs.
History may be incomplete.

Unlikely
Clinical signs generally inconsistent with toxicity from the chemical.
Or exposure pathway and/or timing are inconsistent.
Or another health condition is more likely the cause.
Or very incomplete history.