



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 15, 2018

Kevin Kutcel
KRK Consulting LLC
For America Vet Sciences LLC
5807 Churchill Way
Medina, OH 44256

Subject: PRIA Label Amendment – New CRP package: individual pouch with pipette
Product Name: Spot and Clear for Dogs
EPA Registration Number: 88082-6
Application Date: 30-Oct-17
Decision Number: 535418

Dear Mr. Kutcel:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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Decision No. 535418

with FIFRA section 6. If you have any questions, you may contact Dr. Breeden-Alemi at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kable Bo Davis', enclosed within a hand-drawn oval.

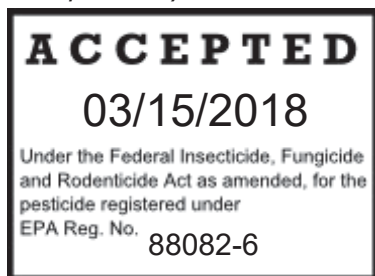
Kable Bo Davis, Product Manager 3
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

1. Carton Text – Front Panel, Carton Text – Back Panel,
2. Package Insert Text,
3. Carton Text – Side Panel,
4. Pouch Text,
5. Pipette Text

{NOTE TO REVIEWER: Optional Text (except ABN) is Placed in Brackets [], notes to reviewer are placed in braces { }, and text included on the label in parentheses () }

{A 1.5cm x 1.5cm cat prohibition icon in a box will be located at the lower right hand corner of the front panel in yellow with black images}



1. Carton Text – Front Panel



{NOTE TO REVIEWER: A large clear picture of a dog in the weight range for the product as packaged will appear on the front panel.}

Spot and Clear™ for DOGS
[ABN: Fipronix™ for DOGS]
[ABN: Smartguard for DOGS]

{Note to Reviewer: The word “dog” will be at least 75% the height of the largest letter in the product brand name.}

For use ONLY on [Small DOGS & PUPPIES 8 weeks [of age] and older and 5 to 22 lbs.] {or}
[For use ONLY on Medium DOGS 8 weeks [of age] and older and 23 to 44 lbs.] {or}
[For use ONLY on Large DOGS 8 weeks [of age] and older and 45 to 88 lbs.] {or}
[For use ONLY on Extra-large DOGS 8 weeks [of age] and older and 89 to 132 lbs.]

ACTIVE INGREDIENT:	
Fipronil.....	9.7%
OTHER INGREDIENTS:	
	90.3%
TOTAL:	
	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

See Package Insert for First Aid, Additional Precautionary Statements, and Complete Directions for Use.

NET CONTENTS:

{For 5-22 lbs.}

[0.023 fl. oz. (0.67 mL) (One pouch containing 0.023 fl. oz.)] *{or}*

[0.069 fl. oz. (2.01 mL) (Three pouches containing 0.023 fl. oz. each)] *{or}*

[0.138 fl. oz. (4.02 mL) (Six pouches containing 0.023 fl. oz. each)] *{or}*

{For 23-44 lbs.}

[0.045 fl. oz. (1.34 mL) (One pouch containing 0.045 fl. oz.)] *{or}*

[0.135 fl. oz. (4.02 mL) (Three pouches containing 0.045 fl. oz. each)] *{or}*

[0.270 fl. oz. (8.04 mL) (Six pouches containing 0.045 fl. oz. each)] *{or}*

{For 45-88 lbs.}

[0.091 fl. oz. (2.68 mL) (One pouch containing 0.091 fl. oz.)] *{or}*

[0.273 fl. oz. (8.04 mL) (Three pouches containing 0.091 fl. oz. each)] *{or}*

[0.546 fl. oz. (16.08 mL) (Six pouches containing 0.091 fl. oz. each)] *{or}*

{For 89-132 lbs.}

[0.136 fl. oz. (4.02 mL) (One pouch containing 0.136 fl. oz.)] *{or}*

[0.408 fl. oz. (12.06 mL) (Three pouches containing 0.136 fl. oz. each)] *{or}*

[0.816 fl. oz. (24.12 mL) (Six pouches containing 0.136 fl. oz. each)]

2. Carton Text – Back Panel

[1 Month Supply] [3 Month Supply] [6 Month Supply]

[1 Pouch] [3 Pouches] [6 Pouches]

[1 Dose] [3 Doses] [6 Doses]

[For Use Only on Small DOGS & PUPPIES 8 Weeks [of Age] and Older and 5 to 22 lbs.] *{or}*

[For Use Only on Medium DOGS 8 Weeks [of Age] and Older and 23 to 44 lbs.] *{or}*

[For Use Only on Large DOGS 8 Weeks [of Age] and Older and 45 to 88 lbs.] *{or}*

[For Use Only on Extra-large DOGS 8 Weeks [of Age] and Older and 89 to 132 lbs.]

READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE.

{Product Name} acts quickly, lasts up to 30 days. Controls fleas, ticks, chewing lice, mosquitoes and sarcoptic mange mites.

Best if used year-round. {Product Name} keeps working even after shampooing and rinsing with water and continues to work if dogs are outdoors and exposed to the sun or rain, or even after swimming.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON CATS OR OTHER ANIMALS.

{NOTE TO REVIEWER: A “Side Effects” box will appear immediately above the cat warning box.}

Side Effects. After application, check your dog for side effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea may occur. If you observe these signs in your treated dog, contact your veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Call 1-866-591-5777 for customer service.

{NOTE TO REVIEWER: A cat prohibition icon will be located immediately below the Side Effects box in the lower right-hand corner of the back panel. The box will include 1.5 cm X 1.5 cm cat prohibition icon and warning text in yellow and black images and text.}



DIRECTIONS FOR APPLICATION: See enclosed package insert for directions for application.

FREQUENCY OF APPLICATION: Monthly application kills fleas, ticks, chewing lice and mosquitoes and controls flea, tick, chewing lice and sarcoptic mange mite infestations. You can reapply {Product Name} once every 30 days.

LIMITATION OF WARRANTY AND LIABILITY: Before using this product, read the entire label including the Directions for Use, Conditions of Warranties and Limitations of Liability. If these terms and conditions are not acceptable, return the unopened product container at once. To the extent consistent with applicable law, by using this product, user or buyer accepts the Conditions, Disclaimer of Warranties and Limitations of Liability herein.

Manufactured by:
American Vet Sciences, LLC
6911 Bryan Dairy Road
Largo, FL 33777

EPA Reg. No. 88082-6
EPA Establishment No. XXXX-XX-X

[Optional Bar Code]

{NOTE TO REVIEWER: Lot number is stamped on back panel.}

3. Package Insert Text

Spot and Clear™ for DOGS
[ABN: Fipronix™ for DOGS]
[ABN: Smartguard for DOGS]

{NOTE TO REVIEWER: The word “dog” will be at least 75% the height of the largest letter in the product brand name}

READ ENTIRE LABEL BEFORE USE

For use ONLY on Small DOGS & PUPPIES 8 weeks [of age] and older and [5 to 22 lbs.] {or}
[For use ONLY on Medium DOGS 8 weeks [of age] and older and 23 to 44 lbs.] {or}
[For use ONLY on Large DOGS 8 weeks [of age] and older and 45 to 88 lbs.] {or}
[For use ONLY on Extra-large DOGS 8 weeks [of age] and older and 89 to 132 lbs.]

ACTIVE INGREDIENT:

Fipronil.....9.7%

OTHER INGREDIENTS:.....90.3%

TOTAL:.....100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
If on skin or clothing:	Take off contaminated clothing. Wash skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor immediately for treatment advice.
If swallowed:	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
If in eyes:	Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

HOTLINE NUMBER

For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide concerns), you may call 1-866-591-5777, twenty-four (24) hours per day, seven (7) days per week.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

CAUTION. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS OR OTHER ANIMALS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian. Do not use on puppies under 8 weeks of age or [5 lbs. for small dogs] [23 lbs. for medium dogs] [45 lbs. for large dogs] [89 lbs. for extra-large dogs]. Individual sensitivities, while rare, may occur after using ANY pesticide product. Some dogs may experience temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs. This product is not a substitute for prescribed heartworm preventative.

{NOTE TO REVIEWER: A "Side Effects" box will appear immediately above the cat warning box.}

Side Effects. After application, check your dog for side effects such as redness from skin irritation, scratching or other signs of discomfort. In some cases, vomiting or diarrhea may occur. If you observe these signs in your treated dog, contact your veterinarian. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Call 1-866-591-5777 for customer service.

{NOTE TO REVIEWER: A cat prohibition icon will be located immediately below the Side Effects box. The box will include 1.5 cm X 1.5 cm cat prohibition icon and warning text in yellow and black images and text.}

{CAT PROHIBITION ICON}

DO NOT USE ON CATS.

Keep cats away from treated dogs for 24 hours. If applied to or ingested by a cat, contact your veterinarian.

PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE. Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY.

Restrictions:

Do not allow children to apply product.

DO NOT USE ON RABBITS.

DO NOT USE ON CATS OR OTHER ANIMALS.

Avoid contact with treated area until dry.

Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

Do not get this product in your dog's eyes or allow your dog to ingest this product.

Do not bathe or allow dog to swim for 24 hours

Do not apply more than one pipette per treatment for one dog regardless of the dog's weight.

Do not reapply for 30 days.

Do not apply to dogs or puppies less than 8 weeks of age or weighing less than [5] [23] [45] [89] lbs.

{Product Name} acts quickly, lasts up to 30 days. {Product Name} controls fleas, ticks, chewing lice, mosquitoes and aids in the control of sarcoptic mange mites. For use only on [small dogs and puppies weighing 5 to 22 lbs.] [medium dogs weighing 23-44 lbs.] [large dogs weighing 45-88 lbs.] [extra-large dogs weighing 89-132 lbs.] and 8 weeks of age or older. **Weigh your dog to be sure you are using the appropriate product size.** Best if used year-round. {Product Name} keeps working even after shampooing and rinsing with water 24 hours after application. {Product Name} continues to work if dogs are outdoors and exposed to the sun or rain, or even after swimming.

Apply {Product Name} when your dog is dry. {Product Name} is applied at a single point on the surface of the skin above the dog's shoulder blades at the base of the neck and rapidly covers the entire dog by localizing in the hair, on the surface of the skin and in the sebaceous glands. Soon after coming into contact with a treated dog, fleas, ticks, mosquitoes and chewing lice are killed. Allow treated area to dry thoroughly for 24 hours after application. Dogs can be bathed 24 hours after treatment. Do not reapply for 30 days.

FREQUENCY OF APPLICATION

Monthly application of {Product Name} controls flea, tick and chewing lice infestations. You can reapply {Product Name} once every 30 days.

Fleas {Product Name} adult fleas for up to three months unless the risk is high for reinfestation of fleas. If your dog becomes reinfested with fleas, or if your dog is in situations where reinfestation may occur, you may apply {Product Name} every 30 days.

Ticks: {Product Name} kills ticks for up to one month. Apply {Product Name} every 30 days to control all life stages of ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis and anaplasmosis.

Chewing Lice: {Product Name} kills chewing lice for at least one month. Apply {Product Name} every 30 days to control chewing lice.

Mosquitoes: Apply {Product Name} every 30 days to kill mosquitoes. Mosquitoes are killed within 48 hours for up to 28 days.

Sarcoptic Mange Mites: {Product Name} aids in the control of sarcoptic mange mite infestations. Apply {Product Name} every 30 days until mites are reduced on your dog.

HOW TO APPLY

{CRP package: individual pouch with pipette; SAUE opening instructions apply to the pouch and will not change in text or format from that used in testing or presented on this label; Whenever this package is used, the terms "pipette" and "pouch" will be used consistently throughout the label.}

1. Cut along dotted line, being careful not to cut pipette.



2. Open pouch and remove pipette.



3. Cut tip of pipette with scissors. Part the dog's hair above the shoulder blades, at the base of the neck. Place the pipette tip just above the skin and squeeze. Apply entire contents of the pipette in a single spot directly onto the dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

[Optional drawing of pipette being applied to dog]

{If any drawings are used of a dog, it will be in the weight range for the product as packaged.}

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

Store in original container in a cool, dry (preferably locked) place that is inaccessible to children and animals (pets). Do not remove pipette from the pouch until ready to use. Protect from direct sunlight.

PESTICIDE DISPOSAL and CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container.

If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-CLEANUP (1-800-253-2687) for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT: Before using this product, read the entire label including the Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, weather conditions, and other unknown factors, all which are beyond the control of the manufacturer and sellers. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, the manufacturer and sellers make no warranty, expressed or implied, of merchantability or of fitness for a particular purpose, or otherwise, concerning the use of this product other than as indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither the manufacturer nor the sellers shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.

Manufactured by:
American Vet Sciences, LLC
6911 Bryan Dairy Road
Largo, FL 33777

EPA Reg. No. 88082-6
EPA Establishment No. XXXXXXXX

4. Carton Text – Side Panel

{Product Name}

NET CONTENTS:

{For 5-22 lbs}

[0.023 fl. oz. (0.67 mL) (One pouch containing 0.023 fl. oz.)] *{or}*

[0.069 fl. oz. (2.01 mL) (Three pouches containing 0.023 fl. oz. each)] *{or}*

[0.138 fl. oz. (4.02 mL) (Six pouches containing 0.023 fl. oz. each)] *{or}*

{For 23-44 lbs}

[0.045 fl. oz. (1.34 mL) (One pouch containing 0.045 fl. oz.)] *{or}*

[0.135 fl. oz. (4.02 mL) (Three pouches containing 0.045 fl. oz. each)] *{or}*

[0.270 fl. oz. (8.04 mL) (Six pouches containing 0.045 fl. oz. each)] *{or}*

{For 45-88 lbs}

[0.091 fl. oz. (2.68 mL) (One pouch containing 0.091 fl. oz.)] *{or}*

[0.273 fl. oz. (8.04 mL) (Three pouches containing 0.091 fl. oz. each)] *{or}*

[0.546 fl. oz. (16.08 mL) (Six pouches containing 0.091 fl. oz. each)] *{or}*

{For 89-132 lbs}

[0.136 fl. oz. (4.02 mL) (One pouch containing 0.136 fl. oz.)] *{or}*

[0.408 fl. oz. (12.06 mL) (Three pouches containing 0.136 fl. oz. each)] *{or}*

[0.816 fl. oz. (24.12 mL) (Six pouches containing 0.136 fl. oz. each)]

[Only For Small DOGS & PUPPIES 8 weeks [of age] and older and 5 to 22 lbs.] *{or}*

[Only For Medium DOGS 8 weeks [of age] and older and 23 to 44 lbs.] *{or}*

[Only For Large DOGS 8 weeks [of age] and older and 45 to 88 lbs.] *{or}*

[Only For Extra-large DOGS 8 weeks [of age] and older and 89 to 132 lbs.]

5. Pouch Text

(picture of scissors)-----

1. Cut along dotted line, being careful not to cut pipette.
2. Open pouch and remove pipette.
3. Cut tip of pipette with scissors. Part the dog's hair above the shoulder blades, at the base of the neck. Place the pipette tip just above the skin and squeeze. Apply entire contents of the pipette in a single spot directly onto the dog's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

{Product Name}

For use ONLY on Dogs 8 weeks of age or older weighing [5-22] [23-44] [45-88] [89-132] lbs.

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read entire label including Directions for Use and Precautions before Using this Product

{NOTE TO REVIEWER: Optional language below pertaining to package size in the circle.}

Single dose

Fipronil 9.7%

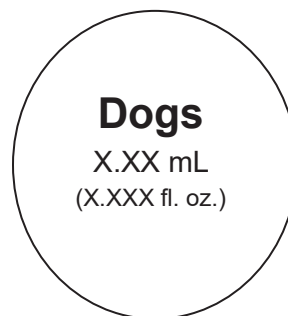
[0.67 mL (0.023 fl. oz.)] *{or}*

[1.34 mL (0.045 fl. oz.)] *{or}*

[2.68 mL (0.091 fl. oz.)] *{or}*

[4.02 mL (0.136 fl. oz.)]

EPA Reg. No. 88082-6



{NOTE TO REVIEWER: All of the text is on one side of the pouch. The lot # is on the box and on each pouch.}

6. Pipette Text

{Product Name}

For use ONLY on Dogs 8 weeks of age or older weighing [5-22] [23-44] [45-88] [89-132] lbs.

Fipronil 9.7%

[0.023 fl oz] {or}

[0.045 fl oz] {or}

[0.091 fl oz] {or}

[0.136 fl oz]

{NOTE to REVIEWER – A cat prohibition icon will appear on the pipette-itself}

EPA Reg. No. 88082-6

[Optional Marketing Claims]:

[Long-lasting]

[Waterproof] [Does not wash off]

{Product Name} is a topical application for waterproof, fast-acting and lasting control of fleas, ticks and chewing lice]

[For monthly control of fleas, ticks, chewing lice, mosquitoes and aids in the control of sarcoptic mange mites]

[Kills fleas] [Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Reduces existing flea infestations and prevents establishment of new infestations on dogs]

[Kills adult fleas which may cause flea allergy dermatitis]

[Kills ticks]

[Kills all life stages of ticks, including brown dog ticks [(*Rhipicephalus sanguineus*)], American dog ticks [(*Dermacentor variabilis*)], lone star ticks [(*Amblyomma americanum*)] and deer ticks [(*Ixodes scapularis*)]]

[Kills ticks that may transmit Lyme disease, Rocky Mountain Spotted Fever, ehrlichiosis, babesiosis and anaplasmosis]

[Kills ticks including those that may transmit Lyme disease]

[Kills brown dog ticks, American dog ticks, lone star ticks and deer ticks for up to one month]

[Kills mosquitoes] [Kills adult mosquitoes]

[Kills chewing lice] [Eliminates chewing lice infestations on dogs]

[Aids in control of sarcoptic mange mite infestations on dogs]

[Kills fleas, ticks, chewing lice and mosquitoes]

[1 Pouch] [3 Pouches] [6 Pouches]

[1 Dose] [3 Doses] [6 Doses]

[Optional picture of flea, tick, mosquito, chewing lice.]

{NOTE TO REVIEWER: When the following statements are used, they will be grouped together on the same panel.}

{Product Name} is not manufactured or distributed by Merial.]

[Contains the same active ingredient as in FIPAIRA™ FOR DOGS]

[FIPAIRA™ is a trademark of Merial.]