

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

August 28, 2014

Iain Weatherston, Ph.D, Agent  
FidoPharm Inc.  
c/o J&T Associates, LLC  
4061 North 156<sup>th</sup> Drive  
Goodyear, AZ 85395

Subject: Label Amendment – Addition of Marketing Claims  
Product Name: LC-2010-4 Fipronil and S-Methoprene for Dogs  
EPA Registration Number: 85495-2  
Application Date: May 16, 2014  
Decision Number: 491536

Dear Dr. Weatherston:

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** supersede any of the pet mitigation and enhanced incident reporting requirements outlined in the Agency letters dated January 10, 2011 and June 26, 2013. You are reminded that this registration shall expire on June 26, 2015, unless the Agency receives a formal request to extend the registration for this product.

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.

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 with FIFRA section 6(e). If you have any questions, please contact Carlyn Petrella by phone at 703-347-0439, or via email at [petrella.carlyn@epa.gov](mailto:petrella.carlyn@epa.gov).

Sincerely,

A handwritten signature in black ink that reads "Richard J. Gebken". The signature is written in a cursive style with a large initial 'R' and a distinct 'G'.

Richard Gebken  
Product Manager 10  
Insecticide Branch  
Office of Pesticide Programs  
Date: August 28, 2014

**Master Label containing:**

**Sublabel A: Box Label**

**Sublabel B: Package Insert**

**Sublabel D: Labeling on the Pipette**

**Sublabel E: Stickers for Re-application Reminders**

[ ] -- alternate verbiage

“Pipette/Vial/Tube/Applicator” can be used interchangeably

**LC-2010-4 FIPRONIL and S-METHOPRENE FOR DOGS**

**ACTIVE INGREDIENTS**

Fipronil.....	9.80%
(S)-methoprene.....	8.80%
OTHER INGREDIENTS.....	81.40%
TOTAL.....	100.00%

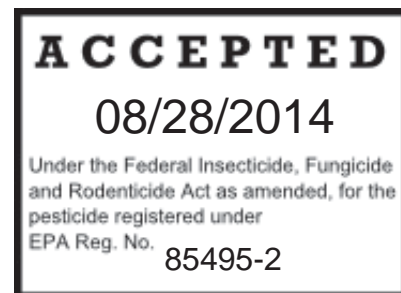
(Picture of dog that is appropriate for the size of dog for each weight range)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

Contains X-0.0XX fl.oz. (X.xx mL) pipette(s)

**EPA Reg. No. 85495-2**



## Sublabel A: Box Label

### [Front Panel of Box]

LC-2010-4  
For Dogs

3 (Drawing of pipette)  
[Alternate Packaging]  
[6 (Drawing of pipette)]  
[1 (Drawing of pipette)]  
[2 (Drawing of pipette/vial/tube)]  
[4 (Drawing of pipette/vial/tube)]  
[5 (Drawing of pipette/vial/tube)]  
[12 (Drawing of pipette/vial/tube)]  
[24 (Drawing of pipette/vial/tube)]  
Pipette[s]

- Kills fleas, flea eggs, ticks, chewing lice & mosquitoes
- Fast action
- Kills ticks, including ticks that may transmit Lyme Disease
- Waterproof
- Lasting control
- Direct to skin [applicator][tube][vial][pipette]
- Bonus
- Buy “x” get “y” free
- Get “x%” free
- “X%” More Free
- Clip, Part, Squeeze
- [For Small Dogs 5 to 22 lbs.] [For Medium Dogs 23-44 lbs.] [For Large Dogs 45-88 lbs.] [For Extra Large Dogs 89-132 lbs.]
- [Easy to use][applicator]
- Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **apply** directly to the skin
- Easier than ever applicator lets you **clip** the tip, **part** the fur [hair] and **squeeze** directly onto the skin
- Clean cut [open][applicator!]
- No mess [open][applicator]
- Clip-tip design [applicator][!]
- [Contains the same active ingredients used in FRONTLINE® Plus for Dogs. This product is not manufactured or distributed by Merial®, the makers of

FRONTLINE® Plus for Dogs. FRONTLINE® Plus for Dogs is a registered trademark of Merial®.]

- [[Brand name] is a registered trademark of Sergeant's Pet Care Products, Inc.]

[Only use on dogs and puppies 5- 22 lbs. 8 weeks or older]

Or

[Only use on dogs 23-44 lbs. 8 weeks or older]

Or

[Only use on dogs 45-88 lbs.]

Or

[Only use on dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

#### ACTIVE INGREDIENTS

Fipronil.....	9.80%	
(S)-methoprene.....	8.80%	(Picture of dog that is appropriate for the size of dog for each weight range)
OTHER INGREDIENTS.....	81.40%	
TOTAL.....	100.00%	

#### **KEEP OUT OF REACH OF CHILDREN (1.5x1.5 cm Cat prohibition Icon)** **CAUTION**

[Contains 3-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.069 fl.oz.]

Or

[Contains 3-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.135 fl.oz.]

Or

[Contains 3-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.273 fl.oz.]

Or

[Contains 3-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.408 fl.oz.]

Or

[Contains 6-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.138 fl.oz.]

Or

[Contains 6-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.270 fl.oz.]

Or

[Contains 6-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.546 fl.oz.]

Or

[Contains 6-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.816 fl.oz.]

Or

[Contains 1-0.023 fl.oz (0.67 mL) pipette]

Or

[Contains 1-0.045 fl.oz. (1.34 mL) pipette]

Or

[Contains 1-0.091 fl.oz. (2.68 mL) pipette]

Or

[Contains 1-0.136 fl.oz (4.02 mL) pipette]

Or

[Contains 2-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.046 fl.oz.]  
Or  
[Contains 2-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.090 fl.oz.]  
Or  
[Contains 2-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.182 fl.oz.]  
Or  
[Contains 2-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.272 fl.oz.]  
Or  
[Contains 4-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.092 fl.oz.]  
Or  
[Contains 4-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.180 fl.oz.]  
Or  
[Contains 4-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.364 fl.oz.]  
Or  
[Contains 4-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.544 fl.oz.]  
Or  
[Contains 5-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.115 fl.oz.]  
Or  
[Contains 5-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.225 fl.oz.]  
Or  
[Contains 5-0.091 fl.oz. (2.68 mL) pipettes. Net weight 0.455 fl.oz.]  
Or  
[Contains 5-0.136 fl.oz (4.02 mL) pipettes. Net weight 0.680 fl.oz.]  
Or  
[Contains 12-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.276 fl.oz.]  
Or  
[Contains 12-0.045 fl.oz. (1.34 mL) pipettes. Net weight 0.540 fl.oz.]  
Or  
[Contains 12-0.091 fl.oz. (2.68 mL) pipettes. Net weight 1.092 fl.oz.]  
Or  
[Contains 12-0.136 fl.oz (4.02 mL) pipettes. Net weight 1.632 fl.oz.]  
Or  
[Contains 24-0.023 fl.oz (0.67 mL) pipettes. Net weight 0.552 fl.oz.]  
Or  
[Contains 24-0.045 fl.oz. (1.34 mL) pipettes. Net weight 1.08 fl.oz.]  
Or  
[Contains 24-0.091 fl.oz. (2.68 mL) pipettes. Net weight 2.184 fl.oz.]  
Or  
[Contains 24-0.136 fl.oz (4.02 mL) pipettes. Net weight 3.264 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

## **[Back Panel of Box]**

LC-2010-4 [or other approved alternate brand name] For Dogs

LC-2010-4 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes [ONLY on dogs and puppies weighing 5- 22 lbs. and 8 weeks or older.]

Or ... [ONLY on dogs weighing 23-44 lbs. and 8 weeks or older.]

Or ... [ONLY on dogs weighing 45-88 lbs.]

Or ... [ONLY on dogs weighing 89-132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.]

Do not use more than one tube/vial/pipette per dog per month.

[Label identifiers that will be used to identify each respective package size contained within the box.]

## **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 this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-4 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and 5-22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, flea eggs, ticks (including all stages of American Dog ticks, Brown Dog ticks, Deer ticks and Lone Star ticks), chewing lice and mosquitoes:

## **How to Apply**

Drawing of a pipette

Drawing of treating animal

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.
2. Snap the tip of the pipette away from you as shown
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-4 [or other approved

alternate brand names] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-4 [or other approved alternate brand names] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

### **Frequency of Application**

Fleas: According to research studies, adult fleas, flea eggs and flea larvae are killed for up to three months following an application of fipronil plus (S)-methoprene. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-4 [or other approved alternate brand name] For Dogs for thirty (30) days.

### **Side Effects:**

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [FidoPharm or name of distributor] at 1-888-908-TICK

**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm Cat prohibition Icon]

FidoPharm, Inc.  
10077 South 134<sup>th</sup> Street  
Omaha, NE  
68138 USA

EPA Reg. No. 85495-2



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(Drawing of telephone receiver) Questions? Comments?  
1-888-908-TICK

Made in USA

**[Top Panel of Box]**

**LC-2010-4 [or other approved alternate brand name] For Dogs**

[Only use on dogs and puppies 5- 22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	[6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older]	[1 (Drawing of pipette)]
Or	pipette[s]
[Only use on dogs 45-88 lbs.]	[2 (Drawing of pipette/vial/tube)]
Or	[4 (Drawing of pipette/vial/tube)]
[Only use on dogs 89-132 lbs.]	[5 (Drawing of pipette/vial/tube)]
	[12 (Drawing of pipette/vial/tube)]
	[24 (Drawing of pipette/vial/tube)]

[Label identifiers that will be used to identify each respective package size contained within the box.]

**[Bottom Panel of Box]**

For Dog use only

**[Right side panel of Box]**

LC-2010-4 [or other approved alternate brand name] Fipronil and S-Methoprene For Dogs

[Only use on dogs and puppies 5- 22 lbs. 8 weeks or older]	3 (Drawing of pipette)
Or	[6 (Drawing of pipette)]
[Only use on dogs 23-44 lbs. 8 weeks or older]	[1 (Drawing of pipette)]
Or	pipette[s]
[Only use on dogs 45-88 lbs.]	[2, 4, 5, 12, or 24]
Or	
[Only use on dogs 89-132 lbs.]	

[Label identifiers that will be used to identify each respective package size contained within the box.]

**[Left side panel of Box]**

Lot Number: 3 (Drawing of Pipette)  
[6 (Drawing of pipette)]  
[1 (Drawing of pipette)]  
[2, 4, 5, 12, or 24]  
Pipette[s]

**Sublabel B: Package Insert**

**LC-2010-4 [or other approved alternate brand name] For Dogs**

**Only for use on dogs and puppies 8 weeks or older and 5-22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132lbs.]**

LC-2010-4 [or other approved alternate brand name] For Dogs is a topical application for fast action and lasting control of fleas, flea eggs, ticks, chewing lice, and mosquitoes.

**ACTIVE INGREDIENTS**

Fipronil.....	9.80%
(S)-methoprene.....	8.80%
OTHER INGREDIENTS.....	81.40%
TOTAL.....	100.00%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

LC-2010-4 [or other approved alternate brand name] For Dogs acts fast and is an effective, lasting, waterproof, and easy-to-use application for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, LC-2010-4 [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, and chewing lice and help to prevent reinfestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-4 [or other approved alternate brand name] For Dogs aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Specifically, LC-2010-4 [or other approved alternate brand name] For Dogs kills, controls and prevents infestations of:

- 1) Adult fleas, flea eggs, and flea larvae, including fleas which could cause flea allergy dermatitis, and can prevent the further development of fleas at the egg, larvae and pupae stages;
- 2) Brown Dog tick, the American Dog tick, the Lone Star tick, and the Deer tick (including ticks that may transmit Lyme Disease), at all stages;
- 3) Chewing lice infestations;
- 4) Kills mosquitoes.

LC-2010-4 [or other approved alternate brand name] For Dogs contains the active ingredient fipronil and the insect growth regulator (IGR) (S)-methoprene.

### **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 this product. READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE. CAREFULLY FOLLOW ALL PRECAUTIONARY STATEMENTS AND APPLICABLE USE DIRECTIONS. FOR USE ON DOGS ONLY. DO NOT USE ON RABBITS OR OTHER ANIMALS.

For topical application only. Do not allow your dog to ingest this product. Apply LC-2010-4 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and 5-22 lbs. [23-44 lbs.] [45-88 lbs.] [89-132 lbs.], including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, flea eggs, ticks, chewing lice, and mosquitoes:

### **How to Apply**

Drawing of a pipette

Drawing of treating animal

1. Open the child resistant package according to the directions on the back of the sealed inner package for each pipette.
2. Snap the tip of the pipette away from you as shown
3. Part the dog's hair and place the tip of the pipette behind the neck and between the shoulders. Ensure that the entire application of LC-2010-4 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the pipette thoroughly so that the entire contents are applied.

Do not apply the product superficially to the dog's hair. Use only one pipette during each application.

Do not touch the area where the application was made until it is dry.

LC-2010-4 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

### **Frequency of Application**

Fleas: According to research studies, adult fleas, flea eggs and flea larvae are killed for up to three months following an application of fipronil plus (S)-methoprene. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply once every month.

Ticks: Each application kills ticks for one month or longer. For best control of ticks, apply once every month.

Chewing Lice: Each application kills chewing lice for one month or longer. For best control of chewing lice, apply once every month.

Do not reapply LC-2010-4 [or other approved alternate brand name] For Dogs for thirty (30) days.

Please note that there is no need to reapply following your dog's exposure to bathing or water immersion, as LC-2010-4 [or other approved alternate brand name] For Dogs remains effective in those conditions.

#### **Side Effects:**

Monitor your dog after application. Infrequent side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting and/or diarrhea have been reported. If these or other side effects occur, consult your veterinarian or XXXXX [FidoPharm or name of distributor] at 1-888-908-TICK.

### **Storage and Disposal**

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

**Storage.** Store unused application pipettes in the original child-resistant container and outer box only, out of reach of children and animals.

**Pesticide Disposal. If partly filled:** Call your local solid waste agency [or 1-800-CLEANUP] for disposal instructions. Never place unused product down any indoor or outdoor drain.

**Container Disposal.** Nonrefillable container. **If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

### **First Aid**

Have the product container or label with you when calling a poison control center or doctor, or if going for treatment.

**If Swallowed:** Immediately call a poison control center or doctor for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the 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 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

**If on Skin:** Rinse skin with plenty of soap and water. Get medical attention if irritation persists.

### **PRECAUTIONARY STATEMENTS**

#### **Hazards to Humans. Caution.**

Harmful if swallowed. Causes 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.

#### **Hazards to Domestic Animals.**

For external use only. Do not use on puppies under 8 weeks of age or less than 5 lbs. Sensitivities may occur after using ANY pesticide product for pets. While temporary irritation at the application area may occur, if signs of continued sensitivity occur, consult a veterinarian immediately. Should any unusual reactions to the application occur, do not reapply before consulting with a veterinarian. Certain medications can interact with pesticides. Consult with your veterinarian before using this product on medicated, debilitated, or aged dogs. Call 1-888-908-TICK for 24-hour assistance.

#### **Physical or Chemical Hazards**

**Flammable:** Keep away from heat and open flame.

#### **Application Options for Different Sizes of Dogs**

LC-2010-4 [or other approved alternate brand name] For Dogs comes in four different packages for different-sized dogs and puppies eight (8) weeks or older:

\* 5 to 22 lbs

\* 23 to 44 lbs.

\* 45 to 88 lbs.

\* 89 to 132 lbs. If your dog weighs more than 132 lbs., discuss dosing with your veterinarian.

Do not use more than one pipette/vial/tube per dog per month.

#### **Warranty**

To the extent consistent with applicable law, Sellers make no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer

assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5x1.5 cm. Cat prohibition Icon]

FidoPharm, Inc.  
10077 South 134<sup>th</sup> Street  
Omaha, NE  
68138 USA

EPA Reg. No. 85495-2

EPA Est. No. XXXXX-XXX-XX

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(Drawing of telephone receiver) Questions? Comments?  
1-888-908-TICK  
Made in USA

**Sublabel D: Labeling on the Pipette**

**Neck of pipette:** Contains: fipronil 9.80%  
s-methoprene 8.80%

**Body of pipette:** **FidoPharm**  
[0.023 fl.oz.]  
Or  
[0.0045 fl.oz.]  
Or  
[0.091 fl.oz.]  
Or  
[0.136 fl.oz.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

LC-2010-4 [or other approved alternate brand name] For  
Dogs

[For Dogs 5- 22 lbs. 8 weeks or older]

Or

[For Dogs 23-44 lbs. 8 weeks or older]

Or

[For Dogs 45-88 lbs.]

Or

[For Dogs 89-132 lbs.]

[Label identifiers that will be used to identify each respective package size contained within the box.]

[1.5x1.5 cm Cat prohibition Icon]

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See package insert for directions for use

**EPA Reg. No. 85495-2**

**Sublabel E: Stickers for Re-application Reminders [Optional]**

**LC-2010-4**  
[or other approved alternate brand name]  
**For Dogs**  
**Care Card**

Kills Fleas, Flea Eggs, Ticks, Chewing Lice, & Mosquitoes

Picture of Dog

Month 1

Drawing of paw
_____
Date of Application

Month 2

Drawing of paw
_____
Date of Application

Month 3

Drawing of paw
_____
Date of Application

[ Month 4

Drawing of paw
_____
Date of Application

Month 5

Drawing of paw
_____
Date of Application

Month 6

Drawing of paw
_____
Date of Application

]

Place sticker on your calendar or refrigerator to remind yourself to apply LC-2010-4 [or other approved alternate brand name] For Dogs to your dog

Pet's Name:

lbs.