

86230-2

06/26/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Iain Weatherston, Ph.D.
Agent for LoradoChem, Inc.
J&T Associates LLC
4061 North 156th Drive
Goodyear, AZ 85395

JUN 26 2013

Subject: LC-2010-2 Fipronil for Dogs
EPA Reg. No. 86230-2
Amendment dated 5/27/2013 to incorporate pet spot-on mitigation label language
and transfer the product manufacturing site
EPA Decision No. 480201

Dear Dr. Weatherston,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the transfer of the manufacturer of LC-2010-2 Fipronil for Dogs to Sergeant's Pet Care Products, Inc. facility in Omaha, Nebraska and corresponding label changes are accepted. Additionally, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. Please submit final printed labels to the Agency within 30 days of the date of this letter. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants and may take regulatory action. The time-limited registration for this product is extended to one-year from the date of this letter. If a registration extension request is not received prior to that date, the registration of this product will expire. If a review of the previously submitted enhanced incident data indicates that there is a concern with this product, EPA may choose to take further regulatory action at that time.

Per the additional requirements of September 30, 2011 letter, you must continue to submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the attention of Kaitlin Keller, Pesticide Reevaluation Division, Mail Code 7508P.

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #

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

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
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)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.

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- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Label stamped "Accepted"

Master Label containing:

Sublabel A: Box Label
Sublabel B: Package Insert
Sublabel D: Labeling on the Pipette
Sublabel E: Stickers for Re-application Reminders

LC-2010-2 FIPRONIL FOR DOGS

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

KEEP OUT OF REACH OF CHILDREN
CAUTION
 Contains X-0.0XX fl.oz. (X.xx mL) pipette(s)

EPA Reg. No. 86230-2

ACCEPTED

JUN 26 2013
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under
 EPA Reg. No. 86230-2

Sublabel A: Box Label

[Front Panel of Box]

LC-2010-2
[Alternate Brand Names]
[PetArmor™]
[TrustGard™]
[Velcera® Fipronil]

FOR DOGS

3 (Drawing of pipette/vial/tube)
[Alternate Packaging]
[6 (Drawing of pipette/vial/tube)]
[1 (Drawing of pipette/vial/tube)]
[2 (Drawing 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]/Vial[s]/Tube[s] Kills fleas, ticks, chewing lice & Mosquitoes

- Fast action
- Kills ticks, including ticks that may transmit Lyme Disease
- Kills mosquitoes
- Waterproof
- Lasting control

[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 INGREDIENT

Fipronil.....9.7%

(Picture of dog)

OTHER INGREDIENTS.....90.3%

TOTAL.....100.0%

KEEP OUT OF REACH OF CHILDREN

(1.5x1.5 cm Cat prohibition Icon)

CAUTION

- [Contains 3-0.023 fl.oz (0.67 mL) pipettes]
- Or
- [Contains 3-0.045 fl.oz. (1.34 mL) pipettes]
- Or
- [Contains 3-0.091 fl.oz. (2.68 mL) pipettes]
- Or
- [Contains 3-0.136 fl.oz (4.02 mL) pipettes]
- Or
- [Contains 6-0.023 fl.oz (0.67 mL) pipettes]
- Or
- [Contains 6-0.045 fl.oz. (1.34 mL) pipettes]
- Or
- [Contains 6-0.091 fl.oz. (2.68 mL) pipettes]
- Or
- [Contains 6-0.136 fl.oz (4.02 mL) pipettes]
- 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]
- Or
- [Contains 2-0.045 fl.oz. (1.34 mL) pipettes]
- Or
- [Contains 2-0.091 fl.oz. (2.68 mL) pipettes]
- Or
- [Contains 2-0.136 fl.oz (4.02 mL) pipettes]
- Or
- [Contains 4-0.023 fl.oz (0.67 mL) pipettes]
- Or
- [Contains 4-0.045 fl.oz. (1.34 mL) pipettes]
- Or
- [Contains 4-0.091 fl.oz. (2.68 mL) pipettes]
- Or
- [Contains 4-0.136 fl.oz (4.02 mL) pipettes]
- Or
- [Contains 5-0.023 fl.oz (0.67 mL) pipettes]
- Or
- [Contains 5-0.045 fl.oz. (1.34 mL) pipettes]
- Or
- [Contains 5-0.091 fl.oz. (2.68 mL) pipettes]

- Or
- [Contains 5-0.136 fl.oz (4.02 mL) pipettes]
- Or
- [Contains 12-0.023 fl.oz (0.67 mL) pipettes]
- Or
- [Contains 12-0.045 fl.oz. (1.34 mL) pipettes]
- Or
- [Contains 12-0.091 fl.oz. (2.68 mL) pipettes]
- Or
- [Contains 12-0.136 fl.oz (4.02 mL) pipettes]
- Or
- [Contains 24-0.023 fl.oz (0.67 mL) pipettes]
- Or
- [Contains 24-0.045 fl.oz. (1.34 mL) pipettes]
- Or
- [Contains 24-0.091 fl.oz. (2.68 mL) pipettes]
- Or
- [Contains 24-0.136 fl.oz (4.02 mL) pipettes]

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

Compare to Frontline® Top Spot same active ingredient*

*This product is not manufactured by Merial, the makers of Frontline®

[Back Panel of Box]

LC-2010-2 [or other approved alternate brand name] For Dogs
 LC-2010-2 [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, 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-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and ≥ 5 lbs., including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, 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. Remove product tube/vial from the package
2. [Separate one tube/vial from the others.] Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
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-2010-2 [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-2010-2 [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 are killed for up to three months following an application of fipronil. 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-2010-2 [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 [LoradoChem 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]

LoradoChem, Inc.
PO Box 1060
Yardley, PA
19067-9060 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

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

Made in XXXXX

[Top Panel of Box]

LC-2010-2 [or other approved alternate brand name] FIPRONIL FOR DOGS

- [Only use on dogs and puppies up to 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
[Only use on dogs 89-132 lbs.]

[4 (Drawing of pipette/vial/tube)]
[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-2010-2 [or other approved alternate brand name] Fipronil 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-2010-2 [or other approved alternate brand name] For Dogs.

Only for use on dogs and puppies 8 weeks or older and \geq 5 lbs.

LC-2010-2 [or other approved alternate brand name] FOR DOGS is a topical application for fast action and lasting control of fleas, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENT

Fipronil.....	9.7%
OTHER INGREDIENTS.....	90.3%
TOTAL.....	100.0%

Compare to Frontline® Top Spot same active ingredient*

KEEP OUT OF REACH OF CHILDREN

CAUTION

LC-2010-2 [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, ticks, chewing lice, and mosquitoes on dogs and puppies. When used as directed, LC-2010-2 [or other approved alternate brand name] For Dogs can stop infestations of fleas, ticks, chewing lice, and mosquitoes and help to prevent re-infestation on dogs and puppies, including on breeding, pregnant and lactating bitches. LC-2010-2 [or other approved alternate brand name] For Dogs also aids in the control of sarcoptic mange infestations. Apply monthly to eliminate sarcoptic mange mites.

Specifically, LC-2010-2 [or other approved alternate brand name] For Dogs kills, controls and prevents infestations of:

- 1) Newly emerged adult fleas prior to egg-laying, including fleas which could cause flea allergy dermatitis;
- 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-2010-2 [or other approved alternate brand name] FOR DOGS contains the active ingredient fipronil.

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-2010-2 [or other approved alternate brand name] For Dogs ONLY to dogs and puppies aged 8 weeks or older and ≥ 5 lbs., including on breeding, pregnant, and lactating bitches, as indicated below for control of fleas, ticks, chewing lice, and mosquitoes:

How to Apply

Drawing of a pipette/vial/tube

Drawing of treating animal

1. Remove product tubes/vials from the package
2. {separate one tube/vial from the others. Hold the tube/vial with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.
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-2010-2 [or other approved alternate brand name] For Dogs is contained in a single spot on the dog's skin. Be sure to squeeze the applicator 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-2010-2 [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 are killed for up to three months following an application of fipronil. If, however, your dog or puppy is susceptible to flea allergy dermatitis, or if you believe there is a risk of reinfestation, apply 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-2010-2 [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-2010-2 [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 [LoradoChem 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 < 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-2010-2 [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.

This product is not manufactured or distributed by Merial, the makers of Frontline® Top Spot

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]

LoradoChem, Inc.
PO Box 1060
Yardley, PA
19067-9060 USA

EPA Reg. No. 86230-2

EPA Est. No. XXXXX-XXX-XX

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

Sublabel D: Labeling on the Pipette

Body of pipetyte/vial/tube:

Contains: fipronil (9.7%)

LoradoChem

[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-2010-2 [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

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[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. 86230-2

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

LC-2010-2

[or other approved alternate brand name]

For Dogs

Care Card

Kills Fleas, Ticks, Chewing Lice, & Mosquitoes

Picture of Dog

Month 1

Month 2

Month 3

Drawing of paw

Date of Application

Drawing of paw

Date of Application

Drawing of paw

Date of Application

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[Month 4

Month 5

Month 6

Drawing of paw

Date of Application

Drawing of paw

Date of Application

Drawing of paw

Date of Application

] Place sticker on your calendar or refrigerator to remind yourself to apply LC-2010-2 [or other approved alternate brand name] For Dogs to your dog

Pet's Name: _____ lbs.