

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 29, 2016

Larry Nouvel President LNouvel, Inc. 4657 Courtyard Trail Plano, TX 75024-2114

Subject: PRIA Label Amendment – Addition of pest claims Product Name: LN Fipronil + Methoprene Spray for Dogs and Cats EPA Registration Number: 87093-8 Application Date: 1-March-2016 Decision Number: 514851

Dear Mr. Nouvel:

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

Sincerely,

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

Enclosure

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ACCEPTED

06/29/2016

Under the Federal Insecticide, Fungicide

[Optional text appears in [brackets] {and/or parenthesis} – the final printed label may include some or all of the optional text]

## LN Fipronil + Methoprene Spray for Dogs and Cats

(Spray/treatment) for control of fleas, ticks and chewing lice on dogs {(and) cats} [including [puppies] [and] [kittens] [8 weeks or older]].

[Use on dogs, cats, puppies, and kittens][8 weeks of age and older] [For Dogs & Puppies] [For Cats & Kittens] [8 weeks and older] [Apply to puppies and kittens 8 weeks and older]

[Fleas]

and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. [Kills fleas] 87093-8 [Controls fleas] [Prevents new flea infestations] [Apply monthly, for dogs (and/or cats) at high risk for flea reinfestation] [Stops existing infestations [and prevents new infestations]] [Kills fleas for up to [4 weeks] [1 month] [30 days]!] [Kills [newly emerged] fleas [before they lay eggs]] [LN Fipronil + Methoprene Spray for Dogs and Cats may protect dogs from fleas for up to 90 days] [Kills fleas which may cause flea allergy dermatitis] [Starts to kill existing fleas on dogs in 5 minutes] [Starts to kill new fleas on dogs in 5 minutes] [Controls existing flea infestations on dogs in 24 hours] [Provides control of new flea infestations on dogs in 24 hours]

### [Flea Eggs and Larvae]

[Controls flea reinfestation [for up to four weeks on cats.] [for up to six weeks on dogs.]] [Kills adult fleas, flea eggs, flea larvae, and prevents the development of pupae] [Kills all flea stages (adult fleas, flea eggs, flea larvae and prevents the development of flea pupae)] [Kills flea eggs [larvae] [and prevents the development of pupae]] [[Insect Growth Regulator][(S)-methoprene] [IGR] Breaks the Flea Life Cycle] Fipronil with (S)-methoprene [insect growth regulator] [IGR] Breaks the Flea Life Cycle]

[Stops Flea Eggs From Developing Into Biting Adults]

## [Ticks]

[Kills ticks] [Controls ticks] [Prevents new tick infestations] [Apply monthly, for dogs (and/or cats) at high risk for tick reinfestation] [Kills ticks for up to [4 weeks] [1 month] [30 days]!] [Kills [these stages (larva, nymph and adult) of] deer ticks [including those that may transmit Lyme

disease,] [for up to [4 weeks] [1 month] [30 days] [per application]]

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[Kills [three stages (larva, nymph and adult) of] deer ticks [including those that may transmit Lyme disease,] [for up to [4 weeks] [1 month] [30 days] [per application]] [Kills ticks [including deer ticks] for up to [4 weeks] [1 month] [30 days]] [Kills deer ticks that may transmit Lyme disease] [for up to [4 weeks] [1 month] [30 days]] [Kills American dog ticks [(Dermacentor variabilis)] for up to [4 weeks] [1 month] [30 days]!] [Kills [brown dog ticks] [Rhipicephalus sanguineus], [American dog ticks][Dermacentor variabilis] [and] [lone star ticks][Amblyomma americanum][,][and] [deer ticks][Ixodes scapularis] [for up to [4 weeks] [1 month] [30 days]] [Kills [these stages (larval, nymph and adult) 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 [-larva, nymph and adult] [Kills larval, nymph and adult ticks] [Kills ticks that may transmit [Lyme disease] [Rocky Mountain spotted fever] [ehrlichiosis] [babesiosis] [anaplasmosis] [haemobartonellosis]] [Starts to kill existing ticks on dogs in 5 minutes] [Starts to kill new ticks on dogs in 5 minutes] [Controls existing tick infestations on dogs in 24 hours] [Provides control of new tick infestation on dogs in 24 hours] [Multiple Infestations] [Kills fleas and ticks] [Controls fleas and ticks] [Prevents new flea, tick, and chewing lice infestations] [Kills fleas and ticks for up to [4 weeks] [1 month] [30 days]!] [Apply monthly, for dogs (and/or cats) at high risk for flea and tick reinfestation]

[[Kills ticks, fleas, flea eggs, larvae, and prevents pupae development][for 30 days]]

[Kills all flea stages (adult fleas, flea eggs, flea larvae and prevents the development of flea pupae) and kills ticks (larva, nymph and adult)]

[Kills all life stages of fleas (adults, eggs, larvae, and prevents pupae development) and tick adults, nymphs and larvae]

[Kills adult fleas, flea eggs, flea larvae, and adult ticks, tick nymphs, and tick larvae] [Starts to kill existing fleas and ticks on dogs in 5 minutes]

[Starts to kill new fleas and ticks on dogs in 5 minutes]

[Stops (and/or) prevents infestation of listed pests for [4 weeks][1 month][30 days]]

## [Others]

[Lice][Stops chewing lice infestations] [[Insecticide] [Insecticidal] Spray [For [Dogs,] [Cats,] [Puppies,] and [Kittens]] [Convenient spray treatment] [Easy to [Use] [Apply]] [Recyclable] [No CFCs] [Apply monthly] [For year-round protection, apply [LN Fipronil + Methoprene Spray for Dogs and Cats] monthly]

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### [4 Week Protection]

#### [Use LN Fipronil + Methoprene Spray for Dogs and Cats monthly]

[Apply once every [4 weeks] [month] [30 days]!]
[Use year round for best results]
[Waterproof]
[Continues to work after bathing and exposure to water and sunlight]
[Fast Acting] [Long Lasting]

[Fast-acting, Long-lasting, waterproof treatment and control of fleas [and][&] ticks]

#### [Trigger Spray]

[Each bottle of **LN Fipronil + Methoprene Spray for Dogs and Cats** contains multiple treatments for your [dog] [and] [cat]] [Each bottle of **LN Fipronil + Methoprene Spray for Dogs and Cats** contains multiple monthly [dog] [and] [cat] treatments]

### [Bag on Valve]

[Bag on valve]
[Quietly sprays]
[No hiss, no scare sprayer]
[Continuous spray]
[Sprays evenly on pet's coat (or hair)]
[Thoroughly covers pet's coat (or hair]
[No pumping]
[Spray can works in any direction]
[Sprays upside down]
[[Contains] 13 [Treatments] [Applications] <sup>†</sup> ( <sup>†</sup> Cats weighing 10 lbs) [6.5 oz can]]
[[Contains] 18 [Treatments] [Applications] <sup>†</sup> ( <sup>†</sup> Cats weighing 10 lbs) [9.0 oz can]]
[[Contains] 25 [Treatments] [Applications] <sup>†</sup> ( <sup>†</sup> Cats weighing 10 lbs) [12.3 oz can]]
[[Contains] 10 [Treatments] [Applications] <sup>†</sup> ( <sup>†</sup> Dogs weighing 15 lbs) [6.5 oz can]]
[[Contains] 10 [Treatments] [Applications] <sup>†</sup> ( <sup>†</sup> Dogs weighing 20 lbs) [9.0 oz can]]
[[Contains] 10 [Treatments] [Applications] <sup>†</sup> ( <sup>†</sup> Dogs weighing 25 lbs) [12.3 oz can]]
[[Contains] Fipronil [(0.29%)][and][+][plus] (S)-methoprene [0.27%]]
[LN Fipronil + Methoprene Spray for Dogs and Cats is a trademark of LNouvel, Inc.]

#### **ACTIVE INGREDIENT:**

Fipronil	0.29%
(S)-methoprene	
OTHER INGREDIENTS:	
TOTAL:	$1\overline{00.00\%}$

#### KEEP OUT OF REACH OF CHILDREN CAUTION

See [Insert][Booklet][Back][Side] for First Aid and Other Precautionary Statements

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## **NET CONTENTS:**

[Bag on Valve]

[6.5 oz. [(184 g)] / 7.9 fl. oz. [(232.9 ml)] [9.0 oz. [(255 g)]] / 10.9 fl. oz. [(322.8 ml)] [12.3 oz. [(349 g)]] / 14.9 fl. oz. [(441.8 ml)]

### [Trigger Spray]

[8 fl oz][12 fl oz][16 fl oz]

### READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON [DOGS,] [CATS,] [PUPPIES] [AND] [KITTENS] [8 WEEKS OF AGE & OLDER]

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS. CAUTION**. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing spray. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Persons applying this product must wear [protective] rubber gloves.

**HAZARDS TO DOMESTIC ANIMALS.** For external use only. Do not use on [kittens] [and] [puppies] under 8 weeks of age. Causes moderate eye irritation. Take care not to spray in the pet's eyes or facial area. Individual sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing animals.

#### PHYSICAL OR CHEMICAL HAZARDS

[Bag on Valve]

EXTREMELY FLAMMABLE: Contents under pressure. Keep away from fire, sparks and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

[Trigger Spray]

Flammable. Keep away from heat and open flame.

FIRST AID				
If in eyes:	• Hold eyes 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 immediately for treatment advice.			
If on skin or	Take off contaminated clothing.			
clothing:	• Rinse skin immediately with plenty of water for 15-20 minutes.			
	• Call a poison control center or doctor for treatment advice.			

LNouvel, Inc. Master Label					
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If inhaled:	Move per	son to fresh air.			
• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.					
	• Call a poison control center or doctor for further 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 to an unconscious person.				
HOT LINE NUMBER					
Have the product container or label with you when calling a poison control center or doctor, or					
going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-781-4738.					

[Reviewer note: final printed label may be for dog and cat use, dog use or cat use. Labeling will reflect specific use.]

**LN Fipronil + Methoprene Spray for Dogs and Cats** kills fleas, ticks, and chewing lice to control infestations for at least [30 days][4 weeks][1 month]. [May provide 90 day flea protection for dogs.] [Stops and prevents infestation of fleas and ticks [brown dog ticks, American dog ticks, lone star ticks, and deer ticks, which may transmit Lyme disease].]

### **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 PET, **READ ENTIRE LABEL AND ATTACHED DIRECTIONS BEFORE EACH USE.** Follow all directions and precautionary statements carefully. Use only on dogs or cats. Do not use on rabbits. Do not use on any other animals.

#### [Bag on Valve]

[How to remove cap: Refer to top of cap] [CRP graphic on top of cap:]



Pinch N′ Pull™

- 1. Wear [protective] rubber gloves.
- 2. Hold canister in any position. Ruffle the pet's hair with one gloved hand while applying spray to the pet's back, sides, abdomen, legs, shoulders and neck.

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3. For head and eye area, spray LN Fipronil + Methoprene Spray for Dogs and Cats on a gloved hand and rub gently into pet's hair.

[Label graphics options]





Wear protective rubber gloves.

Pinch N'Pull™



Hold canister in any position. Ruffle the dog's hair with one gloved hand while applying spray to the dog's back, sides, abdomen, legs, shoulders and neck.



eye area, spray [Brand Name] on a gloved hand and rub gently into dog's hair.



rubber gloves.



Pinch N'Pull™



Hold canister in any position. Ruffle the cat's hair with one

gloved hand while

applying spray to

abdomen, legs, shoulders and neck.

the cat's back, sides,



For head and eye area, spray [Brand Name] on a gloved hand and rub gently into cat's hair.

Spray 1 to 2 seconds per pound of the dog's or cat's body weight. Use higher rate to control lice. Replace cap securely after each use.

[Trigger Spray How to Open CRP textual directions] How to Open

- 1. When opening, do not hold or pull the trigger.
- 2. To open, lift up on the nozzle tab and turn the nozzle a quarter turn.
- 3. To close, turn the nozzle a quarter turn back to the locked position.

[graphic of gloves]

[graphic of spraying product on dog and/or cat]

[graphic of dog and/or cat head and gloved hand rubbing dog and/or cat]

How to Apply

- 1. Wear protective rubber gloves.
- 2. Hold bottle in upright position. Ruffle the pet's hair with one gloved hand while applying spray to the pet's back, sides, abdomen, legs, shoulders and neck.

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3. For head and eye area, spray LN Fipronil + Methoprene Spray for Dogs and Cats on a gloved hand and rub gently into pet's hair.

Spray approximately 1 to 2 sprays (approximately 0.06 to 0.12 fl oz) per pound of the pet's body weight. Use higher rate to control lice.

Do not get this product in your pet's eyes or mouth.

Apply spray until pet's hair is damp to thoroughly wet. Pets with long or dense hair require the higher rate.

As with any flea control product, wash hands and exposed skin thoroughly with soap and water after use. Dispose of gloves after use.

Apply LN Fipronil + Methoprene Spray for Dogs and Cats monthly, for year-round protection. Application directly onto ticks is not required for control. Do not reapply spray for 30 days. LN Fipronil + Methoprene Spray for Dogs and Cats remains effective after bathing and exposure to water and sunlight.

### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Store in original container. Keep away from fire, sparks and heated surfaces. Store in a cool, dry place inaccessible to children and pets.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING: [Bag on Valve:** Do not puncture or incinerate!] **Non-refillable 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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

### [WARRANTY

Read the entire Directions for Use and Warranty before using this product. By using this product, user or buyer accepts the following warranty. The directions for use of this product are believed to adequate and must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. The seller is committed to providing high quality products. To the extent consistent with applicable law, the seller makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent consistent with applicable law, the manufacturer or the seller shall not be liable for indirect, special, incidental or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[Call][For more information][or questions about flea, tick, and chewing lice control] [Emergency: X-XXX-XXX-XXX] [Non-Emergency: X-XXX-XXXX]

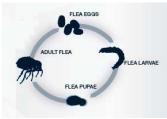
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[Distributed by:] LNouvel, Inc. 4657 Courtyard Trail Plano, TX 75024 EPA Reg. No. 87093-8 EPA Est. No. XXXXX -XX –XXX

[BAR CODE AREA]

[Graphics below may or may not appear anywhere on final label printing] [Flea life cycle diagram] [Flea Life Cycle]



Torn	Adult Flea	
-756-	Flea eggs	<b>€</b>
っ	Flea Larvae	3
	Flea Pupae	
×	Ticks	
-	Brown Dog Tick	8
×.	Deer Tick	8
*	American Dog Tick	
*	Lone Star Tick	