## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 1, 2014

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

Subject:

Amended Labeling; Addition of CRP Packaging & Efficacy Claims, and Removal of RUP Status

LN Fipronil Trigger Sprayer for Dogs and Cats, EPA Reg. No. 87093-2

Your Submission Dated November 6, 2013 & E-Resubmissions Dated March 28, 2014 and

April 1, 2014

Dear Mr. Nouvel:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

Should you wish to add/retain a reference to the company's website, smart phone/tablet app and/or a QR code reader on your product label, please be aware that the website, smart phone/tablet app and/or a QR code reader becomes labeling under FIFRA and is subject to review by the Agency. If the website, smart phone/tablet app, and/or a QR code reader is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website, smart phone/tablet app, and/or a QR code reader is referenced on a product's label, claims made on the website, smart phone/tablet app, and/or a QR code reader may not be 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, smart phone/tablet app, and/or a QR code reader contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website, smart phone/tablet app, and/or a QR code reader will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

Copies of your label stamped "Accepted" along with copies of the child-resistant packaging (CRP) and efficacy reviews are enclosed for your records. If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u>.

Sincerely Yours

Richard J. Gebken Product Manager (10)

Insecticide Branch

Registration Division (7504P)

Enclosures:

Label Stamped "Accepted," dated April 1, 2014

Efficacy Review, dated March 27, 2014

Child-Resistant Packaging Review, dated April 24, 2014

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Information in [ ] is optional.

Optional text appears in brackets – the final label may include some or all of the optional text LN Fipronil Trigger Spray for Dogs and Cats [ABNs] [FIPROGUA'RDTM Spray for Dogs] **ACCEPTED** [FIPROGUA'RDTM Treatment for Dogs] April 1, 2014 [FIPROGUARD<sup>TM</sup> Spray Treatment for Dogs] Under the Federal Insecticide, Fungicide, [FIPROGUARD<sup>TM</sup> Flea and Tick Spray for Dogs] and Rodenticide Act, as amended, for the [FIPROGUARD<sup>TM</sup> Flea and Tick Treatment for Dogs] pesticide registered under: [FIPROGUARD<sup>TM</sup> Flea and Tick Spray Treatment for Dogs] [FIPROGUARD<sup>TM</sup> Spray for Dogs and Puppies] 87093-2 EPA, Reg. No:\_ [FIPROGUARD<sup>TM</sup> Treatment for Dogs and Puppies] [FIPROGUARD<sup>TM</sup> Spray Treatment for Dogs and Puppies] [FIPROGUARD<sup>TM</sup> Flea and Tick Spray for Dogs and Puppies] [FIPROGUARD<sup>TM</sup> Flea and Tick Treatment for Dogs and Puppies] [FIPROGUARD<sup>TM</sup> Flea and Tick Spray Treatment for Dogs and Puppies] [FIPROGUARD<sup>TM</sup> Spray for Cats] [FIPROGUARD<sup>TM</sup> Treatment for Cats] [FIPROGUARD<sup>TM</sup> Spray Treatment for Cats] [FIPROGUARD<sup>TM</sup> Flea and Tick Spray for Cats] [FIPROGUARD<sup>TM</sup> Flea and Tick Treatment for Cats] [FIPROGUARD<sup>TM</sup> Flea and Tick Spray Treatment for Cats] [FIPROGUARD<sup>TM</sup> Spray for Cats and Kittens] [FIPROGUARD<sup>TM</sup> Treatment for Cats and Kittens] [FIPROGUARD<sup>TM</sup> Spray Treatment for Cats and Kittens] [FIPROGUARD™ Flea and Tick Spray for Cats and Kittens] [FIPROGUARD<sup>TM</sup> Flea and Tick Treatment for Cats and Kittens] [FIPROGUARD™ Flea and Tick Spray Treatment for Cats and Kittens] [PRONYL OTC<sup>TM</sup> Spray for Dogs] [PRONYL OTC<sup>TM</sup> Treatment for Dogs] [PRONYL OTC<sup>TM</sup> Spray Treatment for Dogs] [PRONYL OTC<sup>TM</sup> Flea and Tick Spray for Dogs] [PRONYL OTC<sup>TM</sup> Flea and Tick Treatment for Dogs] [PRONYL OTC<sup>TM</sup> Flea and Tick Spray Treatment for Dogs] [PRONYL OTC<sup>TM</sup> Spray for Dogs and Puppies] [PRONYL OTC<sup>TM</sup> Treatment for Dogs and Puppies] [PRONYL OTC<sup>TM</sup> Spray Treatment for Dogs and Puppies] [PRONYL OTC<sup>TM</sup> Flea and Tick Spray for Dogs and Puppies] [PRONYL OTC<sup>TM</sup> Flea and Tick Treatment for Dogs and Puppies] IPRONYL OTC™ Flea and Tick Spray Treatment for Dogs and Puppies] [PRONYL OTC<sup>TM</sup> Spray for Cats] [PRONYL OTC<sup>TM</sup> Treatment for Cats] [PRONYL OTC<sup>TM</sup> Spray Treatment for Cats]

[PRONYL OTC<sup>TM</sup> Flea and Tick Spray for Cats] [PRONYL OTC<sup>TM</sup> Flea and Tick Treatment for Cats]

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[PRONYL OTC<sup>TM</sup> Flea and Tick Spray Treatment for Cats]

[PRONYL OTC<sup>TM</sup> Spray for Cats and Kittens]

[PRONYL OTC<sup>TM</sup> Treatment for Cats and Kittens]

[PRONYL OTC<sup>TM</sup> Spray Treatment for Cats and Kittens]

[PRONYL OTC<sup>TM</sup> Flea and Tick Spray for Cats and Kittens]

[PRONYL OTC<sup>TM</sup> Flea and Tick Treatment for Cats and Kittens]

[PRONYL OTC<sup>TM</sup> Flea and Tick Spray Treatment for Cats and Kittens]

[ECTOADVANCETM Spray for Dogs]

[ECTOADVANCETM Treatment for Dogs]

[ECTOADVANCETM Spray Treatment for Dogs]

[ECTOADVANCETM Flea and Tick Spray for Dogs]

[ECTOADVANCETM Flea and Tick Treatment for Dogs]

[ECTOADVANCETM Flea and Tick Spray Treatment for Dogs]

[ECTOADVANCETM Spray for Dogs and Puppies]

[ECTOADVANCETM Treatment for Dogs and Puppies]

[ECTOADVANCETM Spray Treatment for Dogs and Puppies]

[ECTOADVANCE™ Flea and Tick Spray for Dogs and Puppies]

[ECTOADVANCETM Flea and Tick Treatment for Dogs and Puppies]

[ECTOADVANCETM Flea and Tick Spray Treatment for Dogs and Puppies]

[ECTOADVANCE<sup>TM</sup> Spray for Cats]

[ECTOADVANCETM Treatment for Cats]

[ECTOADVANCETM Spray Treatment for Cats]

[ECTOADVANCETM Flea and Tick Spray for Cats]

[ECTOADVANCETM Flea and Tick Treatment for Cats]

[ECTOADVANCETM Flea and Tick Spray Treatment for Cats]

[ECTOADVANCETM Spray for Cats and Kittens]

[ECTOADVANCETM Treatment for Cats and Kittens]

[ECTOADVANCE<sup>TM</sup> Spray Treatment for Cats and Kittens]

[ECTOADVANCETM Flea and Tick Spray for Cats and Kittens]

[ECTOADVANCETM Flea and Tick Treatment for Cats and Kittens]

[ECTOADVANCE™ Flea and Tick Spray Treatment for Cats and Kittens]

[For use on dogs, cats, puppies, and kittens][over 8 weeks of age]

[For Dogs & Puppies] [8 weeks or older]

[For Cats & Kittens] [8 weeks or older]

[Apply to puppies and kittens over 8 weeks old]

[Apply to puppies and kittens 8 weeks or older]

[Brand Name] provides [spray][treatment] [and] control of fleas and ticks on dogs and cats including puppies and kittens 8 weeks of age or older.

### [Fleas]

[Kills fleas]

[Kills newly emerged adult fleas before they lay eggs]

[Kills fleas for up to [4 weeks] [1 month] [30 days]!]

[If dog or cat is at high risk for flea reinfestation, apply once a month]

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[Kills fleas which may be a source of flea allergy dermatitis [or flea bite anemia]]

#### -Ficks]

[Kills ticks including those that may transmit Lyme disease]

[Kills ticks for up to [4 weeks] [1 month] [30 days]!]

[Kills [all stages 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 [brown dog ticks], [(Rhipicephalus sanguineus)] [American dog ticks,] [and] [lone star

ticks][,][and deer ticks] [for up to [4 weeks] [1 month] [30 days]]

[Kills American dog ticks [(Dermacentor variabilis)] for up to [4 weeks] [1 month] [30 days]!]

#### [All Others]

[Fast Acting] [Long Lasting]

[Convenient spray treatment]

[Easy to Use [Apply]]

[Best if used year round!]

[For year-round protection, apply [Brand Name] monthly]

[Apply monthly]

[Prevents infestation of listed pests for [1 month][4 weeks]]

[Apply once every [4 weeks] [month] [30 days]!]

[A once monthly application required][Apply monthly]

[Waterproof]

[Effective after bathing and exposure to water and sunlight]

[Contains Fipronil[,] the same active ingredient used in Frontline® Spray Treatment\*]

[\*[Brand Name] is not manufactured by or distributed by Merial. Frontline® Spray Treatment is a registered trademark of Merial.]

[[Brand Name] is a trademark of [Company Name]]

[Stops and prevents infestation of listed pests for [4 weeks][1 month]

#### **ACTIVE INGREDIENTS:**

Fipronil	0.29%
OTHER INGREDIENTS:	
TOTAL:	100.00%

### KEEP OUT OF REACH OF CHILDREN **CAUTION**

See [Back] [Insert] [for] Additional Precautionary Statements

NET CONTENTS: [8 fl oz][12 fl oz][16 fl oz]

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS, CATS, PUPPIES, AND KITTENS OVER 8 WEEKS OF AGE.

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#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. 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 animal'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 on medicated, debilitated, aged, pregnant or nursing animals.

PHYSICAL AND CHEMICAL HAZARD. 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.
	HOTLINE NUMBER
_	act container or label with you when calling a poison control center or doctor, or ment. [For additional information on this product (including health concerns,
medical emerg	encies or pesticide incidents), you may call 1-800-781-4738, twenty four (24)
hours per day,	seven (7) days per week.][For emergency information concerning this product,
call the Nation	al Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week,

[Brand Name] controls infestations by killing fleas and ticks for up to [30 days][4 weeks][1 month]. [90 day flea protection for dogs.]

6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu).]

Stops and prevents infestation of fleas and ticks (brown dog ticks, American dog ticks, lone starticks, and deer ticks (which may transmit Lyme disease)). Apply [Brand Name] to dogs, cats, puppies and kittens (8 weeks or older) as follows:

#### **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 and cats. Do not use on rabbits. Do not use on any other animals.

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[How to Open CRP textual directions]

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]

- 1. Wear protective rubber gloves.
- 2. Hold bottle in upright position. Ruffle the animal's coat with one gloved hand while applying spray to the dog's or cat's back, sides, abdomen, legs, shoulders and neck.
- 3. For head and eye area, spray [Brand Name] on a gloved hand and rub gently into dog's or cat's hair.

Do not get this product in your dog's or cat's eyes or mouth. Apply spray until pet's hair is damp to thoroughly wet. Approximately 1 to 2 sprays (approximately 0.06 to 0.12 fl oz) per pound of the animal's body weight will be required. Dogs or cats with long or dense coats will require the higher rate.

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

For year-round protection, apply [Brand Name] monthly. No need to spray ticks directly onto their body for complete control. Do not reapply spray for 30 days.

[Brand Name] remains effective after bathing and exposure to water and sunlight.

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### LNouvel's Master Label

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### STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Store in a cool [below 77°F[/][25°C]] dry (preferably locked) place that is inaccessible to children and pets. Do not use or store near heat or open flame. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: 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.]

İn Case of Emergency, call: 1-800-xxx-xxxx

[Made in USA]

Non-Emergency call 1-800-xxx-xxxx [For more information]

Distributed by:

LNouvel's, Inc.

4657 Courtyard Trail

Plano, TX 75024

EPA Reg. No. 87093-2

EPA Est. No. XXXXX -XX -XXX

[BAR CODE AREA]

[Optional drawings/graphics that may or may not appear anywhere on finished label:]

