

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

53883-312

EPA Reg. Number:

Date of Issuance:

1

JUN 28 2013

NOTICE OF PESTICIDE:

X Registration

\_ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

CSI Fipronil + Novaluron Spot-On for dogs

Name and Address of Registrant (include ZIP Code):

Control Solutions, Inc. 5903 Genoa-Red Bluff Road Pasadena, TX 77507

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(B) provided that you:

- 1. Submit and/or cite all data required for registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data. You must comply with DCI ID# GDCI-129121-1305 issued on 3/14/2013. If you have questions about the Generic DCI issued, you may contact Susan Bartow from the Pesticide Re-evaluation Division.
  - 2. Make the following label changes before you release the product for shipment:
    - Revise the EPA Registration Number to read, "EPA Reg. No. 53883-312."

Signature of Approving Official:

John Hebert, Product Manager 07

Insecticide-Rodenticide Branch, Registration Division (7505P)

Date:

Jun 28,2013

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- 3. Submit Storage stability (830.6317) and corrosion characteristics (830.6320) data within 18 months from the date of this registration notice.
- 4. Submit one copy of the revised print-ready/marketed final printed label (as defined in 40 CFR 152.3) containing all graphics, colors, font sizes, marketing claims, etc. The label must be accepted by the Agency prior to sale and distribution.

#### **Other Conditions:**

This registration is time-limited and expires two years from the date this product is first released for shipment.

- A. You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.
- B. Consider limiting the formulations of each product to one basic confidential statement of formula. The Agency may require this in the future. It is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
- C. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on *October 1, 2013*.

The quarterly reports are due two months after each 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 Pesticide Re-evaluation Division (7504P), Immediate Office (attn: Ms. Kaitlin Keller).

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

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

If the Agency determines that future mitigation measures are necessary for all pet spot-on products, you will be informed, and be expected to comply. If mitigation measures are necessary, the Agency may take appropriate regulatory actions.

Please note that, should you wish to add/retain a reference to the company's website on your label, the website then 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 Assurance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. If you have any questions, please contact Autumn Metzger at 703-305-5314 or metzger.autumn@epa.gov.

A stamped copy of the label is enclosed for your records.

John Hebert Product Manager07 Insecticide-Rodenticide Branch Registration Division (7505P)

Enclosure

June 27, 2013

Information in [ ] is optional.

EPA Reg. No. 53883-GRE

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#### **FRONT LABEL**

## **CSI Fipronil + Novaluron Spot-On for Dogs**

[For use only on dogs 8 weeks of age or older]

[For use only on dogs 8 weeks old and older]

[For use only on dogs more than 8 weeks old]

[For use only on dogs [&][and] puppies 8 weeks or older and 6.5/6½ lbs. and over]

[For use only on dogs  $6.5/6\frac{1}{2}$  lbs. and over [and][&] over 8 weeks of age]

[Only apply to puppies over 8 weeks old]

[Only apply to puppies 8 weeks or older]

[Apply to dogs 8 weeks of age or older]

[Apply only to dogs 8 weeks of age or older]

[Apply to dogs > 8 weeks old]

[Apply only on dogs [and puppies] [>6.5/6½ lbs./more than 6.5/6½ lbs. [and/&] over 8 weeks old]

{One of following will be used on label}

[For use ONLY on dogs [&][and] puppies]

[ONLY for Dogs & Puppies 8 weeks or older [and][&] 6.5/6½[-] [to] 22 lbs]

[6.5/6½[-] [to] 22 lbs] [Only for Dogs 6.5/6½[-] [to] 22 lbs.]

[23[-] [to] 44 lbs] [Only for Dogs 23[-] [to] 44 lbs.]

[45[-] [to] 88 lbs] [Only for Dogs 45[-] [to] 88 lbs.]

[89[-] [to] 132 lbs] [Only for Dogs 89[-] [to] 132 lbs.]

[over 8 weeks of age]]

{or}

[Only for Dogs 6.5/6½-22 lbs. & Puppies (8 weeks or older)]

[Only for Dogs 23-44 lbs.]

[Only for Dogs 45-88 lbs.]

[Only for Dogs 89-132 lbs.]

# ACCEPTED

JUN 28 2013

Under the Pederal Insecticide, Pungicide, and Rodenticide Act, as exampled, for the pesticide Registered under EPA Reg. No. 53883-316

#### **ACTIVE INGREDIENTS:**

Fipronil	9.8%
Novaluron	
OTHER INGREDIENTS:	<u>70.2%</u>
TOTAL:	100.0%

{1.5 cm x 1.5 cm or as listed below/bottom right corner of front panel}



# KEEP OUT OF REACH OF CHILDREN CAUTION

[See [Back][or][Side] [Label[s]] [Panel[s]] [or] [insert] for Additional Precautionary Statements]

June 27, 2013

Information in [ ] is optional.

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## {Option 1: Net Contents related to specific CRP packaging}

NET CONTENTS: X fl oz [Y - X fl oz applicators]

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.023 fl oz (0.67 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][TwentyFour] 0.045 fl oz (1.34 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.091 floz (2.68 mL) applicators

[1][One][2][Two][3][Three][4][Four][5][Five][6][Six][12][Twelve][24][Twenty-Four] 0.136 fl oz (4.02 mL) applicators

{End Option 1}

### {Option 2: Net Contents related to specific CRP packaging}

NET CONTENTS: X fl oz [3 - X fl oz applicators]

[[Three] [3] 0.023 fl. oz. (0.67 mL) applicators]

[[Three] [3] 0.045 fl. oz. (1.34 mL) applicators]

[[Three] [3] 0.091 fl. oz. (2.68 mL) applicators]

[[Three] [3] 0.136 fl. oz. (4.02 mL) applicators]

{End Option 2}

{Front label may include various marketing statements, refer to Optional Marketing Language section}

#### **{END FRONT LABEL}**

{BACK LABEL}

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

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION: Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID		
If swallowed	<ul> <li>Immediately call a poison control center or doctor.</li> <li>Do not induce vomiting unless told to do so by a poison control center or</li> </ul>	
	<ul> <li>doctor.</li> <li>Have person sip a glass of water if able to do so.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>	

June 27, 2013 Information in [ ] is optional.

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#### HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. [You may also contact [XXX-XXXX] for emergency medical treatment information.]

HAZARDS TO DOMESTIC ANIMALS. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, known organ dysfunction, debilitated or aged dogs. [Call [XXX-XXX-XXXX] for 24-hour assistance.]

### **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 ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. Do not have contact or allow children contact with treated area until completely dry.

Do not use on puppies under  $6.5/6\frac{1}{2}$  pounds and 8 weeks of age. Do not allow your dog to ingest this product. Use entire contents of tube on each dog. Do not split one tube between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Do not treat your dog with more than one pesticide product at a time. Do not use on rabbits or animals other than dogs. Do not use on pregnant or lactating dogs. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Individual sensitivities, while rare, may occur after using any pesticide product. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating treatment. Certain medications can interact with pesticides. [Call [XXX-XXX-XXXX] for 24-hour assistance.]

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.

{1.5 cm x 1.5 cm or as listed below/bottom right corner of back panel}

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







[[Application Instructions] [How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]

Only For Dogs Weighing 6.5/6½[-][to]22 lbs. [including small dogs and puppies,] 8 weeks or older

[For cartons containing 0.023 fl. oz. (0.67 ml) applicator tubes]

Apply one [tube] [applicator] (0.023 fl. oz.) (0.67 ml) [as a spot [on][to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

Only for Dogs Weighing Between 23[-][to]44 lbs.

[For cartons containing 0.045 fl. oz. (1.34 ml) applicator tubes]

Apply one [tube] [applicator] (0.045 fl. oz.) (1.34 ml) [as a spot [on][to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

Only for Dogs Weighing Between 45[-][to]88 lbs.

[For cartons containing 0.091 fl. oz. (2.68 ml) applicator tubes]

Apply one [tube] [applicator] (0.091 fl. oz.) (2.68 ml) [as a spot[on][to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

Only for Dogs Weighing 89[-][to]132 lbs.

[For cartons containing 0.136 fl. oz (4.02 ml.) applicator tubes]

Apply one [tube] [applicator] (0.136 fl. oz.) (4.02 ml) [as a spot [on][to] the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail]. Do not use two tubes on dogs greater than 132 lbs.

FREQUENCY OF APPLICATION

Use [Brand Name] monthly for control of flea, tick, flea egg, [and] chewing lice [and mosquito] infestations. [Studies show that] [Brand Name] kills adult fleas for up to three months. Apply monthly if your dog is at high risk for flea reinfestation[, or in a highly infested environment]. [Apply monthly to kill mosquitoes within 24 hours.] Apply monthly to control ticks[,] [mosquitoes] and chewing lice. Do not reapply for [30 days][4 weeks].

[If you have questions or comments about this product, please write: CSI Consumer Response, 5903 Genoa-Red Bluff Road, Pasadena, TX 77507]

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Information in [ ] is optional.

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[In Case of Emergency, call: XXX-XXX-XXXX]
[For more information]
[Non-Emergency, call XXX-XXX-XXXX]
[Made in USA]

[Distributed by:][Manufactured by:] Control Solutions, Inc. 5903 Genoa-Red Bluff Road Pasadena, TX 77507

EPA Reg. No. 53883-GRE EPA Est. No. XXXXX-XXX

{END BACK LABEL}

# {FOLLOWING TEXT MAYBE FOUND ON SIDE PANELS, BACK PANEL AS SPACE PROVIDES OR PRODUCT INSERT}

# {Option 1: How to open label language related to specific CRP packaging} [Option 1a]

How to open: Remove product tube[s] [vial] from the package. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body of you and your dog. Use scissors to cut off the narrow end at the notches along the line.

How to apply: Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. [Do not apply more often than once every 4 weeks.] [Repeat application may be made if necessary, but do not apply more often than once every 30 days.] [Repeat application [may][can] be made every four weeks.]

## [Option 1b]

## How to open

- 1. Remove product tube[s] [vial] from the package.
- 2. [Separate one tube from the others.] Hold the tube [vial] with notched end pointing up and away from the face and body of you and your dog. Use scissors to cut off the narrow end at the notches along the line.

#### How to apply

- 1. Invert tube over dog and use open end to part dog's hair.
- 2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot [on][to] the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

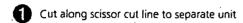
#### {End Option 1}

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{Option 2: How to open label language related to specific CRP packaging}

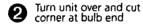
### DIRECTIONS FOR OPENING PACKAGING:

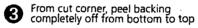


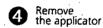


















#### {End Option 2}

[Brand Name] contains fipronil and the insect growth regulator (IGR) novaluron. [Brand Name] effectively targets fleas and ticks. [Brand Name] features a sustained release formula created to act fast and provide [long lasting] control of fleas, ticks, flea eggs, [mosquitoes] and chewing lice for up to [1 month] [[four] [4] weeks] [30 days]] on dogs.

#### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Do not remove tube from the pack until ready to use. Store in a cool [below 77°F[/] (25°C)] dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: If empty: Non-refillable container. Do not reuse or refill this container. 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.

#### [LIMITATION OF WARRANTY AND LIABILITY

Read the entire direction for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once. By using

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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 risk associated with the use of this product. Animal injury, ineffectiveness or other unintended consequences may result because of such factors as presence of other materials, or the manner of use or application, all of which are beyond the control of Control Solutions, Inc. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Control Solutions, Inc. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Control Solutions, Inc. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Control Solutions, Inc. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: 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 or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Control Solutions, Inc. election, the replacement of product.]

[If you have questions or comments about this product, please write: CSI Consumer Response, 5903 Genoa-Red Bluff Road, Pasadena, TX 77507]

[In Case of Emergency, call: XXX-XXX-XXXX]
[For more information]
[Non-Emergency, call XXX-XXX-XXXX]
[Made in USA]

[Distributed by:][Manufactured by:] Control Solutions, Inc. 5903 Genoa-Red Bluff Road Pasadena, TX 77507

EPA Reg. No. 53883-GRE EPA Est. No. XXXXX-XXX

[Look at the Label [Look at the Label icon] 6 Step [Spot-On] [Squeeze-On] [Topical] Checklist

- Read the label completely and follow directions
- Weigh your dog
- Do NOT use Dog products on Cats

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- Do NOT treat with more than one pesticide product at a time
- Separate animals after treatment for at least 24 hours to avoid chance of ingestion
- Do NOT split tubes between Dogs [and use the ENTIRE tube contents].]

#### [Brand Name]

[1][2][3][4][5][6][12][24] [Month [Treatment] [Application] Tracker]

[Monthly reminder card]

[Apply [Brand Name] monthly for continuous protection against fleas, ticks, flea eggs [and] chewing lice [and mosquitoes].]

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

[Pet's Name (Empty blank for owner to fill in name)]

 $[First][1^{st}][Second][2^{nd}][Third][3^{rd}][Fourth][4^{th}][Fifth][5^{th}][Sixth][6^{th}][Seventh][7^{th}][Eighth][8^{th}][Ninth][9^{th}][Tenth][10^{th}][Eleventh][11^{th}][Twelfth][12^{th}]$ 

[Dose] [Treatment] [Application]

[(Empty blank for owner to fill in date)(Date: MM/DD/YY)]

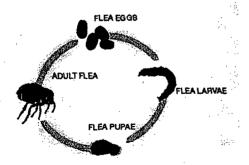
[Calendar stickers with brand name] [Place stickers on your calendar as a reminder to reapply [brand name] in 30 days.]

[Monthly Application Reminder Magnet]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button to start the clock. After 30 days the magnet will flash (and beep) reminding you to reapply [Brand Name]. This application reminder can be used for future treatments. Just press the reset button and in another 30 days the reminder magnet will flash (and beep) reminding you to reapply.]

{END: TEXT THAT MAYBE FOUND ON SIDE PANELS, BACK PANEL AS SPACE PROVIDES OR PRODUCT INSERT}

{Optional graphics below may or may not appear anywhere on finished label}



[Flea life cycle diagram] [Flea Life Cycle]
[Sample coloring and layout may be different on final label]

June 27, 2013 Information in [ ] is optional.

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	fleas
767	11003

flea eggs

Adult Flea

ticks

Deer Tick

Brown Dog Tick

Lone Star Tick

American Dog Tick

chewing lice

mosquitoes

Mite

fleas



flea eggs



Adult Flea



ticks



Deer Tick



Brown Dog Tick



Lone Star Tick



American Dog Tick



chewing lice



mosquitoes



Mite

{End optional graphics}

{TUBE / VIAL LABEL}

{Option 1 Tube label related to CRP Option 1}

Front Label

Back Label

Brand Name {cat graphic with line through it}

Use only on dogs 8 weeks and older and [6.5/6½-22][23-44][45-88][89-132] lbs. Fipronil 9.8%, Novaluron 20.0% w/w [0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)

0.136 fl oz] [label code]

KEEP OUT OF REACH OF CHILDREN CAUTION: Read directions and precautions before using. Use scissors to open. EPA REG. No. 53883-GRE

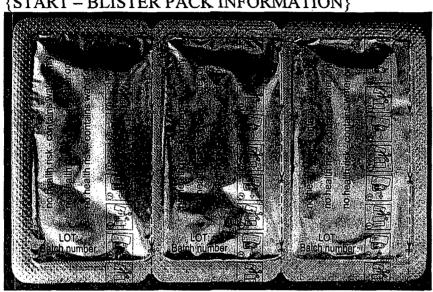
[label code]

{End Option 1}

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### {Option 2 Blister pack label related to CRP Option 2}

{START - BLISTER PACK INFORMATION}



{END - BLISTER PACK INFORMATION}

Front Label

Brand Name {cat graphic with line through

Use only on dogs 8 weeks and older and  $[6.5/6\frac{1}{2}-22][23-44][45-88][89-132]$  lbs.

Fipronil 9.8%, Novaluron 20.0% w/w [0.023 fl oz (or) 0.045 fl oz (or) 0.091 fl oz (or)

0.136 fl oz] [label code]

Back Label

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions

before using.

EPA REG. No. 53883-GRE

[label code]

{End Option 2}

June 27, 2013
Information in [ ] is optional.

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# **(OPTIONAL MARKETING LANGUAGE THAT MAY BE FOUND ON ANY PANEL OR INSERT OF THE LABEL OR PACKAGING)**

#### [Fleas]

- [• Research demonstrates that [brand name] kills adult fleas and flea eggs for up to one month]
- [• [Brand Name] prevents development of fleas for up to one month]
- [ Prevents adult fleas and flea eggs]
- [• If dog is a high risk for flea reinfestation, a once a month application is needed]
- [• Kills flea eggs for up to 1 month]
- [• With Novaluron Insect Growth Regulator which Breaks the Flea Life Cycle]
- [ With Novaluron to Break Flea Life Cycle]
- [ With Insect Growth Regulator to Break Flea Life Cycle]
- [• Dual Action [!]:Fipronil with Novaluron IGR Effectively Breaks the Flea Life Cycle]
- [• Dual Action [!]: Effectively Breaks the Flea Life Cycle[!]]
- [• Kills Fleas Up to [4 weeks][1 month][30 days]!]
- [ Prevents Flea Eggs From Developing Into Biting Adults]
- [ Breaks the flea life cycle]
- [ Effectively kills adult fleas and flea eggs]
- [• Kills adult fleas [for up to three months]]
- [• Kills newly emerged adult fleas before they lay eggs]
- [• Kills adult fleas, which may cause [flea allergy dermatitis] [and][or] [flea bite anemia]]
- [ Kills Fleas]
- [• Kills Flea Eggs]

#### [Ticks]

- [• Kills Ticks]
- [• 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 [(which may be a vector of Lyme disease)][(including those that may transmit Lyme disease)] for up to [4 weeks][1 month][30 days]]
- [• Kills all stages of deer ticks]
- [• Kills Ticks (including deer ticks) for up to [4 weeks][1 month][30 days]]
- [• Kills [brown [dog ticks],] [American [dog ticks],] [and] lone star [ticks]] [dog ticks] [and] [deer ticks] [(Rhipicephalus sanguineus)] [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 ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, and anaplasmosis]

#### [Mosquitoes]

[• Kills mosquitoes] [within 24 hours for up to 7 days] [and] [within 48 hours for up to 28 days]

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#### [Multiple Pests]

- [• Flea & Tick Control for Dogs & Puppies 8 weeks old and older]
- [• Kills fleas, flea eggs, ticks, chewing lice [& mosquitoes][for up to 4 weeks][30 days]1 month]]
- [• Controls flea reinfestation for up to [4 weeks][four weeks][one month]]
- [• Kills fleas, ticks, [mosquitoes,] chewing lice and flea eggs][for up to] [1 month][30 days][4 weeks]]
- [• Monthly flea, tick, [mosquito], chewing lice, and flea egg protection]
- [• Monthly flea, tick, [mosquito] and chewing lice protection]
- [• Kills fleas, ticks, [mosquitoes], flea eggs and chewing lice]
- [• [Six] [6] [5][Five] Way Protection [Kills fleas, ticks, [mosquitoes], [mites], chewing lice and flea eggs]]
- [• [5] [Five] [Four][4] Way Protection! Kills fleas, ticks, [mosquitoes], chewing lice, [and] [&] flea eggs]
- [• [4 Week] [1 month][30 day][Flea and Tick [Treatment][Application]]
- [• [Four (4) Week] [Flea, Tick, [Mosquito,] [flea egg,] and chewing lice control]
- [ 4 week Flea and Tick Treatment!]
- [ Once A Month Flea and Tick [Treatment][Application]]
- [• Kills Fleas and Ticks for up to 4 weeks!]
- [• When used monthly [brand name] completely breaks the flea life cycle and controls tick and chewing lice infestations.]
- [• Use [Brand Name] monthly to control fleas, ticks, [mosquitoes], flea eggs [and chewing lice]]
- [• Kills Fleas, Ticks & Flea Eggs for up to 4 Weeks]

#### [Other]

- [• Only for Dogs and Puppies 8 weeks of age or older]
- [• Can only be used on puppies 8 weeks of age and older]
- [ Formulated for Dogs and Puppies 8 weeks of age or older]
- [• Only for Dogs [6.5/6½-22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]
- [ Fast Acting]
- [• Long Lasting]
- [ Once a month treatment]
- [• Convenient and simple spot treatment]
- [• Convenient spot treatment]
- [• A once monthly application is required for chewing lice]
- [• Rapidly eliminates infestations of chewing lice]
- [• Rapid elimination of chewing lice infestation[s]]
- [• Kills chewing lice] and aids in the control of mites that may cause sarcoptic mange]
- [• Aids in Control of Sarcoptic Mange]
- [• Controls mites that cause sarcoptic mange]
- [• [X] Applications {for cartons with [X] applicators}] and/or [[X] Month Supply] or [[X] Week Supply]
- [• Best if used year round!]

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- [• For year-round protection, apply [Brand Name] monthly]
- [• (ICON Showing 4 Week Protection)]
- [• 4 Week Dose!]
- [• 1 Month Dose!]
- [• 30 Day Dose!]
- [• Easy to Use [Application]]
- [• Formulated for Dogs and Puppies over 8 weeks of age]
- [ Patented Technology]
- [• Apply once every [4 weeks][month][30 days]!]
- [• Repeat application [may][can] be made every four weeks.]
- [• Apply monthly]
- [• Fipronil (9.8%) + Novaluron (20.0%)]
- [• Prevents and controls reinfestation[s] of listed pests [for 4 weeks] [for 1 month][for 30 days]]
- [• Stops existing infestations of listed pests]
- [• Prevents [establishment of additional infestation] [infestation of listed pests] [for] [1 month][4 weeks][30 days]]
- [• Lift here for more information]
- [• [One Application] [Two Applications] [Three Applications] [Four Applications] [Five Applications] [Six Applications] [Twelve Applications] [Twenty-Four Applications] and/or [1 Month Supply] [2 Month Supply] [3 Month Supply] [4 Month Supply] [5 Month Supply] [6 Month Supply] [12 Month Supply] [24 Month Supply] or [4 Week Supply] [8 Week Supply] [12 Week Supply] [16 Week Supply] [17 Week Supply] [24 Week Supply] [18 Week Supply] [19 Week Supply] [19 Week Supply] [19 Week Supply] [10 Week Suppl
- [• [1][2][3][4][5][6][12][24] Applications]
- [• Contains Fipronil[,] [-]the [same] active ingredient used in Frontline® brand products\*]
- [• Contains Fipronil[,] [-]the [same] active ingredient used in the leading competitive brand[s]]
- [• \*[Brand Name] is not manufactured by or distributed by Merial, Frontline® is a registered trademark of Merial.]
- [• [Brand Name] is a trademark of [Company Name]]