

70585-13

03-13-2012

1/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

March 13, 2012

Mr. Ross Gilbert  
Agent for Novartis Animal Health US, Inc.  
Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Subject: Miscellaneous Labeling Changes (Signal Word, Precautionary Statements, etc.)

Product Name: Parastar Plus™  
EPA Registration No.: 70585-13  
Date of Application: December 07, 2011

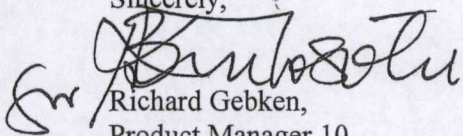
Dear Mr. Gilbert:

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

Please note that we have approved the amended labeling with the understanding that it is consistent with the Agency's previously stamped accepted label(s) for the subject product and the me-too product (Sergeant's EPA Reg. No. 2517-140). Also, other than the revisions indicated/highlighted on the submitted label and stated in your application (dated December 07, 2011), no other changes have been made to the labeling and/or the Confidential Statement of Formula (CSF).

See enclosed copy of the stamped label for your record. If you have any questions concerning this action please contact me or Dr. B.A. Akinlosotu at (Phone: 703-605-0653 or email: [Akinlosotu.bonaventure@epa.gov](mailto:Akinlosotu.bonaventure@epa.gov)).

Sincerely,

  
Richard Gebken,  
Product Manager 10  
Insecticide Branch  
Registration Division (7505P)

2  
14

[ ] - Denotes Optional Statements and/or Images that May be Used on Front, Back or Side Label Panels

**[FRONT CARTON LABEL - MASTER LABEL COPY STARTS]**

**Parastar Plus<sup>TM</sup>**

**ACCEPTED**  
**MAR 13 2012**  
**Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:**

[Apply to puppies over 12 weeks old]  
[Apply to puppies 12 weeks or older]

**EPA. Reg. No: 70585-13**

[Mosquitoes]

- [• [Kills mosquitoes] [within 24 hours for up to the first 7 days after application, and within 48 hours for up to 28 days]
- [• [Kills mosquitoes] [within 24 hours for up to 7 days] [and within 48 hours for up to 28 days]
- [Kills mosquitoes]

[Chewing Lice]

- [Kills chewing lice]
- [Rapidly eliminates infestations of chewing lice]

[Fleas]

- [•Kills adult fleas] [in as little as 1 hour] [!] [for up to three months]
- [•Kills newly emerged adult fleas (starts killing in as little as 1 hour) before they lay eggs]
- [•Kills fleas [in as little as 1 hour], which may be a source of flea allergy dermatitis] [or, flea bite anemia]
- [•Kills fleas [in as little as 1 hour]]
- [• Kills fleas [in as little as 1 hour] Up to [4 weeks] [1 month] [30 days]!]
- [•If dog is at high risk of flea reinfestation, apply once a month]

[Multiple Infestations]

- [•Kills chewing lice and controls mites that may cause sarcoptic mange]
- [• Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 12 weeks old and older] [more than 12 weeks of age]
- [•Kills Fleas (starts killing in as little as 1 hour), Ticks (starts killing in as little as 1 hour) [and] chewing lice [&] [and] [mosquitoes]
- [•Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [and kills Mosquitoes], [and kills chewing lice]]
- [•Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills chewing lice [&] [and] [mosquitoes]]
- [•Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], [mosquitoes,] and chewing lice]]
- [•Kills [and] Fleas, Ticks, [and kills chewing lice] [and] [mosquitoes]
- [•Monthly flea, tick, mosquito, and chewing lice application]
- [•Kills Fleas (starts killing in as little as 1 hour), Ticks (starts killing in as little as 1

hour), mosquitoes, and lice]]

[• [4 Week] [1 month] [30 day] [Flea and Tick Application]

[• [Four (4) Week] [1 month] [30 day] [Flea, Tick, Mosquito and Chewing Lice Application]

[• Kills Fleas (starts killing in as little as 1 hour) and Ticks (starts killing in as little as 1 hour) for up to [4 weeks] [1 month] [30 days]!] ]

[Once A Month Flea and Tick Application]

[•Use Parastar Plus™ monthly to control Ticks (starts killing in as little as 1 hour) and chewing lice]

[•Monthly flea, tick, mosquito, and chewing lice protection.]

[• Flea & Tick Control for Dogs & Puppies 12 weeks old and older] [more than 12 weeks of age]

[• Kills Fleas [(starts killing in as little as 1 hour)], Ticks [(starts killing in as little as 1 hour)], and kills chewing lice & mosquitoes]

[• Starts killing fleas and ticks in as little as 1 hour] [and continues to kill for a month]

[Ticks]

[•Kills Ticks (starts killing in as little as 1 hour) including those that may transmit Lyme disease]

[• Kills Ticks (starts killing in as little as 1 hour) 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 Ticks (starts killing in as little as 1 hour)]

[•Kills Deer Ticks for up to [4 weeks] [1 month] [30 days]]

[• Kills [Brown Dog Ticks], [American Dog Ticks,] [and Lone Star Ticks] (in as little as 1 hour) [(*Rhipicephalus sanguineus*)] for up to [4 weeks] [1 month] [30 days]]

[• Kills [Brown Dog Ticks], [(*Rhipicephalus sanguineus*)] for up to [4 weeks] [1 month] [30 days]]

[• Kills American Dog Ticks [and] [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!] ]

[•Prevents and control reinfestation of listed pests for [30 days] [1month]]

[• Kills ticks that may transmit Lyme disease, Rocky Mountain Spotted fever, ehrlichiosis, babesiosis, bartonellosis, anaplasmosis and hepatolozoonosis]

[All Others]

[•For Dogs and Puppies [12 weeks of age or older] [more than 12 weeks of age]]

[•For Dogs [up to 22 lbs], [23[-][to]44 lbs], [45[-][to]88 lbs], [89[-][to]132 lbs]

[•Fast Acting]

[•Dogs can be bathed 24 hours after application]

[•Long Lasting]

[•Remains effective, even after bathing, water immersion, or exposure to sunlight]

[•Convenient spot application]

[•Fast Action against chewing lice infestations]

[•Controls mites that may cause Sarcoptic Mange]

4  
14

- [• Three Applications] and/or [3 Month Supply] or [12 Week Supply]
- [• Best if used year round!]
- [• (ICON Showing 4 Week Protection)]
- [• 4 Week Dose!] [in Child Resistant Packaging]
- [• 1 Month Dose!] [in Child Resistant Packaging]
- [Fipronil (9.8%) + Cyphenothrin (5.2%)]
- [A fipronil and cyphenothrin product]
- [• 3 Easy-to-Use Applications!] [in Child Resistant Packaging]
- [• Easy to Use [Application]] [in Child Resistant Packaging]
- [• Specially Formulated for Dogs and Puppies 12 weeks of age or older]
- [• [Free] Calendar Stickers Inside!]
- [• [Free] Calendar Stickers Inside]
- [• Apply once every [4 weeks] [month] [30 days]!]
- [• Dogs can be bathed 24 hours after squeeze-on is applied]
- [• Waterproof]
- [•Can be used on puppies 12 weeks of age and older][more than 12 weeks of age]
- [•Monthly application reminder card inside]

[For use ONLY on Dogs & Puppies] [12 weeks or older] [and] [up to] 22 lbs.]  
 [For Dogs 23[-][to]44 lbs.]  
 [For Dogs 45[-][to]88 lbs.]  
 [For Dogs 89[-][to]132 lbs.]

**ACTIVE INGREDIENTS:**

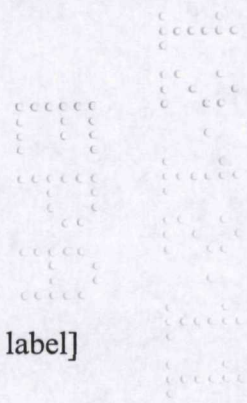
Fipronil.....	9.8%
Cyphenothrin.....	5.2%
<b>OTHER INGREDIENTS:</b> .....	<b>85.0%</b>
<b>TOTAL:</b> .....	<b>100.0%</b>

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See [Back][or][Side] [Label Panel[s] [or] [insert] for full Directions for Use, First Aid and Precautionary Statements

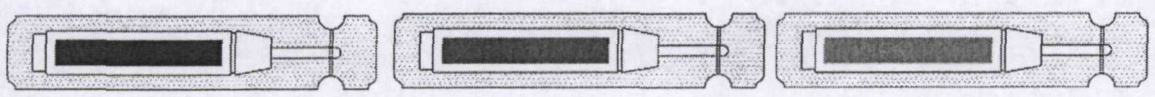
**NET CONTENTS:**

- Contains (3) 0.023 fl oz (0.67 ml) applicators
- Contains (3) 0.045 fl oz (1.34 ml) applicators
- Contains (3) 0.091 fl oz (2.68 ml) applicators
- Contains (3) 0.136 fl oz (4.02 ml) applicators

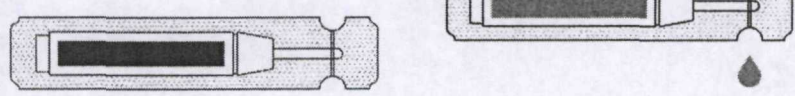


[Optional: Example pictograms that may or may not be found on the printed label]

5  
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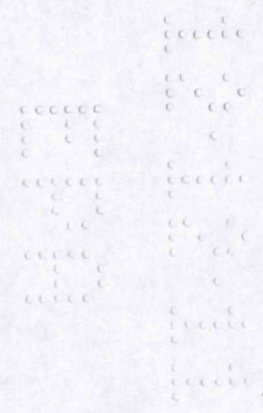


**3** EASY-TO-USE APPLICATIONS



**DO NOT  
USE ON  
CATS**

**[FRONT CARTON LABEL - MASTER LABEL COPY ENDS]**





7  
14

**Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS. DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats. FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age.

**How to open:** Remove product tubes [vial] from the package. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

**How to apply:** While holding the dog with one hand, use the other hand to apply the solution. Invert the [tube] [vial] and use the open end to part the dog's hair. Apply contents of one [tube] [vial] of Parastar Plus™ [as a spot to the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail]. Hold the dog for a few seconds to give the solution time to be absorbed into the dog's coat. When finished, wrap the [tube] [vial] in paper and put into the trash. Only one applicator per treatment is needed. Repeat application may be made if necessary, but do not apply more often than once every [4] [four] weeks.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by 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.  
**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container.  
If empty: Place in the 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.

Distributed by: [Manufactured for][Available exclusively from]:  
Novartis Animal Health US, Inc. [BAR CODE AREA]  
3200 Northline Avenue, Suite 300  
Greensboro NC 27408

EPA Reg. No. 70585-13  
EPA Est. No. XXXXX-XX-XXX

[Optional: Example pictogram that may or may not be found on the printed label]

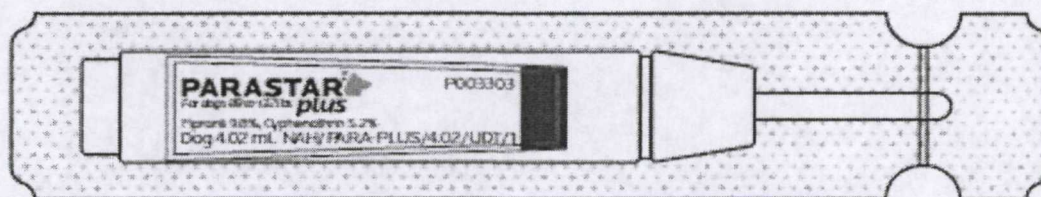
8  
14



**[BACK/SIDE CARTON LABEL - MASTER LABEL ENDS]**

**[VIAL LABEL – START]**

[Front Label]:



OR

{Front label may list 0.67 mL 1.34mL or 2.68 mL}

[Back Label]:

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read directions and precautions before using. Use scissors to open.

EPA REG. No. 70585-13 {label code}

**[VIAL LABEL – END]**



9  
14

## [OPTIONAL INSERT – START]

[IF INSERT IS NOT PROVIDED, DETAILS WILL BE ON THE CARTON, WITH A FLAP]

### KEEP OUT OF REACH OF CHILDREN CAUTION

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS. CAUTION** Causes moderate eye irritation. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

**HAZARDS TO DOMESTIC ANIMALS.** For external use only. Do not use on puppies under 12 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application. 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, pregnant, nursing, debilitated or aged dogs. Call 1-800-637-0281 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.  
READ ENTIRE LABEL BEFORE EACH USE.

**Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

**DO NOT USE ON CATS.** May be toxic and potentially fatal if applied to or ingested by cats. FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. [Do not split tubes 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. Over dosing your dog can result in serious illness and even death. **Best if used year round.** Certain medications can interact with pesticides. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. DO NOT USE ON CATS or animals other than dogs. Separate the treated dog from all other dogs and cats for 24 hours after product has been applied. Cats and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your

dog for the next 24 hours. If symptoms persist, contact a veterinarian. Cats exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

**Sensitivities may occur after using ANY pesticide product on dogs. Dogs may experience some temporary irritation at the site of product application. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.**

**[How to open:** Remove product tubes [vial] from the package. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

**How to apply:** Invert the [tube] [vial] and use the open end to part the 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 [30 days] [month].

**FREQUENCY OF APPLICATION**

Use Parastar Plus™ monthly for complete control of flea, tick [and] chewing lice [and mosquito] [infestations]. [[Studies show that] Parastar Plus™ kills adult fleas (starts killing in as little as 1 hour) for up to three months]. If your dog is at high risk of flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control ticks, mosquitoes and chewing lice. Parastar Plus™ kills mosquitoes within 24 hours for up to the first 7 days after application, then within 48 hours for up to 28 days. Parastar Plus™ remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

**For Dogs Weighing up to 22 lbs.**

**{For cartons containing .67ml (0.023 fl. oz.) applicator tubes}**

Apply one tube (.67ml)(0.023 fl. oz.) [as a spot to the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

**For Dogs Weighing Between 23 and 44 lbs.**

**{For cartons containing 1.34 ml (0.045 fl. oz.) applicator tube}**

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

**For Dogs Weighing Between 45-88lbs.**

**For cartons containing 2.68 ml (0.091 fl. oz.) applicator tube}**

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

**For Dogs Weighing 89-132 lbs**

**For cartons containing 4.02ml (0.136 fl. oz.) applicator tube}**

Apply one tube (4.02 ml)(0.136 fl. oz.) [as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

11  
14

<b>FIRST AID</b>	
<b>If In Eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>
<b>If On Skin Or Clothing</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If Swallowed</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
<b>HOT LINE NUMBER</b>	
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 1-800-637-0281.	
<b>NOTE TO PHYSICIAN OR VETERINARIAN</b>	
Treat patient symptomatically	

**WARRANTY**

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of NOVARTIS ANIMAL HEALTH US, Inc. (NAHUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NAHUS and Seller harmless for any claims relating to such factors.

NAHUS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or NAHUS, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW NAHUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with State law, in no event shall NAHUS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NAHUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS

12  
14

BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF NAHUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

[If you have questions or comments about this product, please write: Novartis Animal Health US, Inc., (address).]

For Technical Information, call 1-800-637-0281 [For more information] [Hours of service]  
Non-Emergency call (number) [Made in USA]

Distributed by: [Manufactured for][Available exclusively from]:

Novartis Animal Health US, Inc.  
3200 Northline Avenue, Suite 300  
Greensboro NC 27408

[BAR CODE AREA]

EPA Reg. No. 70585-13  
EPA Est. No. XXXXX-XX-XXX

**[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.]**

**How to open**

1. Remove product tubes [vial] from the package.
2. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

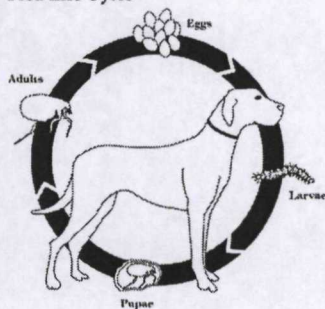
**How to apply:**

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 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.]

**[Example Flea life cycle diagram]**

13  
14

Flea Life Cycle



[Look at the Label (Look at the Label icon) 6 Step [Easy] [Parastar Plus™] [Spot On] [Squeeze-On] Checklist

- Read the label completely and follow directions
- Weigh your pet
- Do NOT use Dog products on Cats
- Do NOT treat with more than one pesticide product at a time
- Separate animals after application to avoid chance of ingestion
- Do NOT split tubes between pets]

Parastar Plus™

[Monthly reminder card] [Fill out this reminder card with your pet's name and the date each treatment should be given to your pet as a reminder to reapply Parastar Plus™ every 30 days.] [Apply Parastar Plus™ monthly for continuous protection against Fleas, Ticks, [and] chewing lice [and mosquitoes].]

[For year round protection apply Parastar Plus™ monthly.]

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

[First [dose] [Application] (Empty blank for owner to fill in date)]

[Second [dose] [Application] (Empty blank for owner to fill in date)]

[Third [dose] [Application] (Empty blank for owner to fill in date)]

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

[Visit [web-address] to download a free convenient application for your Smartphone for an electronic calendar reminder]

[calendar stickers with Parastar Plus™]

[3-month] [application tracker]

[Enclosed for your convenience are [three] [3] stickers.] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply Parastar Plus™ every 30 days.]

[Optional Example graphics for calendar stickers, reminder cards, and/or magnets.]



[Monthly Application Reminder Magnet (image of reminder magnet)]

14  
14

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply Parastar Plus™. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

[Optional: Example pictograms that may or may not be found on the printed label]



[INSERT – END]

[EPA APPROVAL DATE]