2517-145

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

NOTIFICATION

JUN 2 1 2012

Kelly R Hoskins Director of Regulatory Affairs Sergeant s Pet Care Products Inc 10077 South 134<sup>th</sup> Street Omaha NE 68138 3710

Subject Application for Pesticide Notification EPA Registration Number 2517 145 Date of Submission June 7 2012

Dear Registrant

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration (PRN) 98 10 dated June 7 2012 for the abovementioned product The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98 10 and finds that the actions requested fall within the scope of PRN 98 10 The label submitted with the application has been stamped Notification and will be placed in our records

If you have any questions regarding this letter please contact Clayton Myers at (703) 347 8874 or via email at myers clayton@epa gov

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

Enclosures

Copy of Label Stamped Notification

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Please read instructions or	reverse before com	pleting forr	n	Form Approved	OMB No 2070	0060 A	opproval expires 05 31 98
EPA         Environmental Protection A           Washington DC 20460			ion Age		Registrati Amendme Other	on	OPP Identifier Number
		Applica	tion for	Pesticide Section I			
1 Company/Product Number 2517 145				2 EPA Product Manager Richard Gebken		3 Pro	pposëd Classifiçation
4 Company/Product (Name) Sergeant s Pet Care Products Inc / Sergeant s Fipronil + Etofenprox Methoprene Spot On for Cats			nprox +	5 PM# 10 None Restricted			
5 Name and Address of Appl	Icant (Include ZIP Cod	de)		6 Expedited Review In	accordance with	FIFRA S	Section 3(c)(3)(₺)⊁I, n y
Sergeant s Pet Care Products Inc				product is similar or identic	al in composition	and lab	sling te
2625 South 158 <sup>th</sup> Plaza Omaha NE 68130 1770				EPA Reg No			
				Product Name			
Check if this	is a new address						
			S	ection II			
Amendment Explain be	low			Final printed labels in response to Agency letter dated XX XX XX			
Resubmission in respons	e to Agency letter dat	ed XX XX X	X	Me Too Application			
Notification Explain below			Other Explain below				
Explanation Use additional page	age(s) if necessary (	For section i	and Secti	on II )			
Application for Pesticide No Number 2517 145)	tification (Label Rev	ision) for S	_	Fipronil + Etofenprox + Metho	prene Spot On f	for Cats	(EPA Registration
			Se	ection III			
1 Material This Product Will E							
Child Resistant Packaging	Unit Packaging			Water Soluble Packaging	2 Type of C		r
Yes				No res	Met Net		
	If Yes	No	per	If Yes No per			
Certification must	Unit Packaging wgt 0 017 fl oz (0 50		ntainer 456	Package wgt Container	Glass		
be submitted	0 0 17 11 02 (0 30	12 0	or 24	ļ			fy) Plastic Bag
2. Logation of Net Contents In	formation			ntoroor 5			
3 Location of Net Contents In	Container				Location of Lab	ei Direct	ions
			On Lab		On Labeling	eling accompanying product	
6 Manner in Which Label is Affixed to Product							
Section IV 1 Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application )							
	ems directly below for			ual to be contacted if necessary			
Name Tit Kelly R Hoskins					o (Include Area Code) 102 938 7079		
		s form and a		ents thereto are true accurate a e punishable by fine or imprison			6 Date Application Received (Stamped)
2 Signaturo			3 Title				
BY Kelly Mochens		Director of Regulatory Affairs					
4 Typed Name			5 Date	June 7 2012			
Kelly R	Hoskins		<u> </u>				

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Sergeant's Pet Care Products, Inc

10077 South 134th Street • Omaha NE 68138 3710 • Telephone 402 938 7000 • Fax 402 938 7091 • www.sergeants.com

June 7 2012

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Richard Gebken PM10 Office of Pesticide Programs (7504P) U S Environmental Protection Agency Document Processing Desk (NOTIF) Room S 4900 One Potomac Yard 2777 South Crystal Drive Arlington VA 22202 4501

Subject <u>Application for Pesticide Notification (Label Revision) for</u> Sergeant s Fipronil + Etofenprox + Methoprene Spot On for Cats (EPA Registration Number 2517 145)

Dear Mr Gebken

Sergeant s Pet Care Products Inc (EPA Company Number 2517) is submitting a notification of revision to the master label for the end use product Sergeant s Fipronil + Etofenprox + Methoprene Spot On for Cats (EPA Registration Number 2517 145) The following items are enclosed in support of this notification

- Application for Pesticide Amendment (EPA Form 8570 1) and
- Product master label v12 1 (2 copies one with changes highlighted)

Sergeant s is submitting this notification to add optional marketing graphics and minor text additions to the labels Per Pesticide Registration Notice 96 6 the label now includes language related to pregnant or nursing animals in the Hazards to Domestic Animals section These minor label changes are being made via notification because they do not affect the dosage concentration, frequency or method of application or increase the amount of exposure All changes have been highlighted on one copy of the revised label (sections that include new optional graphics are denoted by the following [Optional diagram may or may not appear anywhere on the finished label])

This notification is consistent with the provisions of PR Notice 98 10 and EPA regulations at 40 CPR 152 46 and no other changes have been made to the labeling or the confidential statement of formula of this product I understand that it is a violation of 18 U S C Sec 1001 to willfully make any false statement to EPA I further understand that if this notification is not consistent with the terms of PR Notice 98 10 and 40 CPR 152 46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA

Richard Gebken June 7 2012 Page **2** of **2** 

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If you have any questions regarding this submission please contact me at 402 938 7079 or <u>khoskins@sergeants com</u>

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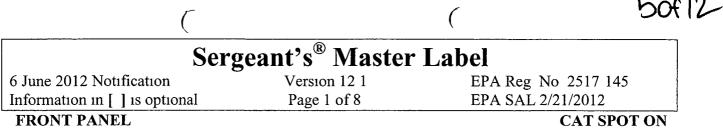
Sincerely

Kelly R. Hochens

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Kelly R Hoskins Director of Regulatory Affairs

Enclosures



FIPRONIL+ETOFENPROX + METHOPRENE

[Optional text appears in brackets the final label may include some or all of the optional text on the front back or side label panels ]

# **Sergeant's Fipronil + Etofenprox + Methoprene Spot On for Cats**

[ABNs ] [(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) FRONTIER GOLD (Spot On) for cats]
[(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) Ectoadvance<sup>™</sup> (Spot On) for cats]
[(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) Frontspot<sup>™</sup> (Spot On) for cats]
[(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) Firstline (Spot On) for cats]
[(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) Frontedge (Spot On) for cats]
[(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) Frontguard<sup>™</sup> (Spot On) for cats]
[(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) Frontguard<sup>™</sup> (Spot On) for cats]
[(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) FRONTPRONIL (Spot On) for cats]
[(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) FIPROLINE (Spot On) for cats]
[(Sergeant's<sup>®</sup>) (Sentry<sup>®</sup>) Advanspot (Spot On) for cats]

NOTIFICATION

JUN 2 1 2012

[Apply to kittens over 12 weeks old]

[Apply to kittens 12 weeks or older]

[For use ONLY on cats [[&][and] kittens 12 weeks or older]OF ALL WEIGHTS] [For use ONLY on cats][of ALL weights][over 12 weeks of age]

[Mosquitoes]

[Kills mosquitoes]

#### [Chewing Lice]

[Kills chewing lice] [Fast Action against chewing lice infestations]

#### [Adult Fleas]

[Stops and prevents reinfestations]
[Prevents and controls reinfestations]
[Controls flea reinfestations [for up to six weeks]]
[Kills Fleas [Up to [4] [6] weeks]']
[[Full or Partial Brand Name] kills adult fleas for up to six weeks]
[Kills Fleas that may cause flea allergy dermatitis flea bite anemia, and tapeworm infestation]
[If cat is a high risk for flea reinfestation a once month application may be needed]

#### [Flea Eggs and Larvae]

[Stops and prevents infestations] [Prevents and controls reinfestations] [Controls flea reinfestation [for up to six weeks]] [[Full or Partial Brand Name] prevents development of all flea stages for up to 6 weeks] [[Full or Partial Brand Name] kills adult fleas flea eggs [and] flea larvae [and prevents pupae] for up to six weeks] [Prevents all flea stages (adult fleas flea eggs flea pupae and flea larvae)] [Prevents Flea Eggs From Developing Into Biting Adults]

# Sergeant's<sup>®</sup> Master Label

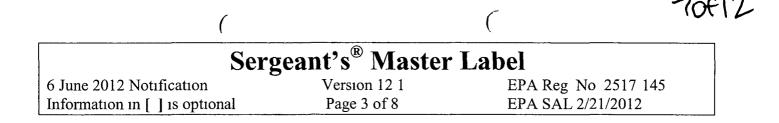
EPA Reg No 2517 145 6 June 2012 Notification Version 121 Information in [] is optional Page 2 of 8 EPA SAL 2/21/2012 [Kills Flea Eggs & Flea Larvae [for up to 4 months]'] [Kills flea eggs [and] [larvae] [and prevents pupae] for up to 4 months] [Kills all stages of the flea life cycle] [Triple Action [']] Effectively Breaks the Flea Life Cycle[']] [With (S) methoprene to Break Flea Life Cycle] [With Insect Growth Regulator to Break Flea Life Cycle] [With (S) methoprene Insect Growth Regulator which Breaks the Flea Life Cycle] [Triple Action [1] Fipronil and Etofenprox with (S) methoprene][IGR Effectively Breaks the Flea Life Cycle]] [If cat is a high risk for flea reinfestation a once month application may be needed]

#### [Ticks]

[Kılls Tıcks [for Up to 4 weeks]<sup>1</sup>]
[Kılls Amerıcan Dog Tıcks for up to 4 weeks]
[Kılls Tıcks (Including Deer Tıcks) for up to 4 weeks]
[Kılls Amerıcan Dog Tıcks [(*Dermacentor variabilis*)] for up to 4 weeks<sup>1</sup>]
[Kılls [Brown] [Amerıcan] [and Lone Star] dog ticks for up to 4 weeks]
[Kılls Deer Tıcks (which may transmit Lyme disease) for up to [4 weeks] [1 month] [30 days]]
[Kılls Tıcks including those that may transmit Lyme disease]

# [Multiple Infestations]

[Kills ticks in 1 hour] [Kills ticks][(Starts killing in as little as 1 hour)]] [Starts killing fleas and ticks in as little as 1 hour] [Kills [fleas] in 4 hours [and] [ticks] in one hour] [[Full or Partial Brand Name] kills fleas in 4 hours and Dermacentor ticks in one hour] [Kills fleas and ticks in [24 hours] [1 day]] [Starts to kill fleas and ticks in an hour continues to kill for a month] [Controls reinfestation for up to four weeks] [Kills Fleas and Ticks for up to 4 weeks'] [[4 Week] [Flea and Tick Treatment]] [Once A Month Flea and Tick Treatment] [[Four (4) Week] [Flea Tick [Mosquito] and Chewing Lice Control]] [Monthly flea tick [mosquito] and chewing lice protection] [Kills fleas ticks [mosquitoes] and chewing lice] [Kills fleas ticks [&] chewing lice [& mosquitoes]] [[Four][4][Three][3] Way Pest Protection] [Flea & Tick Control for Cats & Kittens 12 weeks old or older] [(Full or Partial Brand Name) provides convenient and effective flea tick [and] chewing lice [and mosquito] control for cats and kittens [12 weeks or older]] [When used monthly [Full or Partial Brand Name] completely breaks the flea life cycle and controls tick and chewing lice infestations ]



#### [All Others]

[For Cats and Kittens 12 weeks of age or older] [Specially Formulated for Cats and Kittens [12 weeks or Older]] [Fast Acting] [Long Lasting] [Waterproof] [Cats can be bathed 24 hours after treatment] [Stops and prevents infestations] [(ICON Showing 4 Week Protection)] [4 Week Dose<sup>1</sup>] [1 Month Dose<sup>1</sup>] [Apply once every [4 weeks] [month] [30 days]'] [Best if used year round'] [Easy to Use Application] [Convenient to use] [[1][2][3][4][5][6][12][24] Applications] [Dose(s)] [Treatment]] [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][20 Week Supply][24 Week Supply][48 Week Supply][52 Week Supply][104 Week Supply] [[Free] Brochure Inside'] [[Free] Calendar Stickers Inside<sup>†</sup>] [[Free] Brochure and Calendar Stickers Inside] [[Free with purchase] [Free inside] Monthly Application Reminder [Magnet] [clip] [insert]] [Patent Pending]

ACTIVE INGREDIENTS	
Fipronil	9 80%
Etofenprox	15 00%
(S) methoprene	11 80%
<b>OTHER INGREDIENT[**]</b>	<u>63 40 %</u>
TOTAL	100 00%

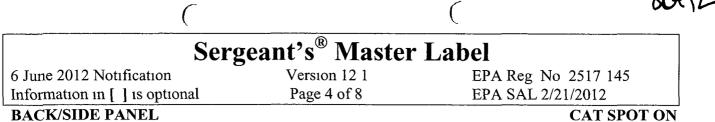
[\*\*diethylene glycol monoethyl ether]

#### KEEP OUT OF REACH OF CHILDREN CAUTION

See [Side] [or] [Back] Panel For Additional Precautionary Statements

#### **NET CONTENTS**

[1][One][2][Two][3][Three][4][Four][5][F1ve][6][S1x][12][Twelve][24][Twenty Four] 0 017 fl oz [0 50 ml] applicators



### FIPRONIL+ETOFENPROX+METHOPRENE

[Full or Partial Brand Name] contains Fipronil, Etofenprox and [the insect growth regulator]

**[IGR] (S)-Methoprene** to effectively kill fleas ticks [mosquitoes] and chewing lice The active ingredients in [Full or Partial Brand Name] features a sustained release formula developed for fast acting [and long lasting] control of fleas ticks [mosquitoes] and chewing lice [for 30 days] on cats [and kittens over 12 weeks old]

#### READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 12 WEEKS OF AGE

#### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS CAUTION** Causes moderate eye irritation Do not get in eyes or on clothing Wash thoroughly with soap and water after handling and before eating drinking chewing gum or using tobacco Remove and wash contaminated clothing before reuse Harmful if swallowed Harmful if absorbed through skin

**HAZARDS TO DOMESTIC ANIMALS** For external use only Do not use on kittens under 12 weeks of age Individual sensitivities while rare may occur after using any pesticide product [Some cats may experience temporary startle effects when any product is applied ] If signs persist or become more severe within a few days of application consult a veterinarian immediately If your pet 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 animals Call 1 800 224 PETS [7387] for 24 hour assistance

	FIRST AID
If In Eyes	<ul> <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>
If On Skin Or Clothing	<ul> <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>
If Swallowed	<ul> <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>
	HOT LINE NUMBER
treatment For m	t container or label with you when calling a poison control center or doctor or going for ore information on this pesticide product (including health concerns medical emergencies or its) you may call 1 800 781 4738

(		(	90f12	
Serg	eant's <sup>®</sup> Master	Label		
6 June 2012 Notification	Version 12 1	EPA Reg No 2517	145	
Information in [] is optional	Page 5 of 8	EPA SAL 2/21/2012		

#### **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

FOR EXTERNAL USE ON CATS ONLY Do not use on kittens under 12 weeks of age Use entire contents of tube [vial] on each cat [Do not split tubes between cats] [Do not use multiple tubes on one cat] Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death **Best if used year round** Consult a veterinarian before using this product on debilitated aged medicated cats. Consult a veterinarian before using on cats with known organ dysfunction. Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied. Cats and dogs that actively groom or engage in close physical contact with treated cat 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 cat and continue to monitor your pet for the next 24 hours.

Sensitivities may occur after using ANY pesticide product on cats If signs of sensitivity occur bathe your cat with a mild soap and rinse with large amounts of water If signs continue, consult a veterinarian immediately by calling 1-800-781-4738

[Optional diagram may or may not appear anywhere on the finished label]







[{Outer Packaging}]

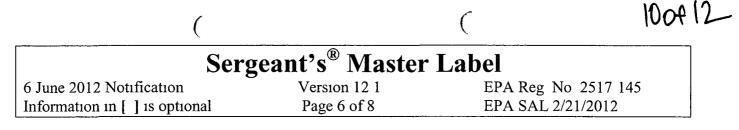
**How to open** Remove product tube(s) *[vial]* from the package [Separate one tube from the others ] Hold the tube *[vial]* with notched end pointing up and away from the face and body Use scissors to cut off the narrow end at the notches along the line

How to apply While holding the cat with one hand use the other hand to apply the solution Invert the tube *[vial]* and use the narrow end to part the cat s hair Apply contents of one tube *[vial]* of {Full or Partial Brand Name} [as a stripe starting high on the back of the cat s neck to in front of the shoulder blades] [as a spot between the shoulder blades] Hold the cat for a few seconds to give the solution time to be absorbed into the cat s coat When finished wrap the tube *[vial]* in paper and put into the trash Only one applicator per treatment is needed

#### **FREQUENCY OF APPLICATION**

Use [Full or Partial Brand Name] monthly for complete control of flea tick [and] chewing lice [and mosquito] infestations [Full or Partial Brand Name] kills fleas for up to six weeks and flea eggs [and] flea larvae [and prevents flea pupae] for up to 4 months

Apply monthly if your pet is at high risk for flea reinfestation[ or in a highly infested environment] Apply monthly to control ticks [mosquitoes] and chewing lice [[Full or Partial Brand Name] kills mosquitoes within 24 hours for up to 14 days and within 48 hours for up to 28 days] [Full or Partial Brand Name] remains effective even after bathing water immersion or exposure to sunlight Allow treated area to dry thoroughly Do not reapply for 30 days



#### STORAGE AND DISPOSAL

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

**CONTAINER DISPOSAL 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

#### [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 ] Sergeant s is committed to providing high quality products To the extent consistent with applicable law Sergeant s 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 Sergeant s 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 ]

[If you have questions or comments about this product please write Sergeant's Consumer Response PO Box 540399 Omaha NE 68154 0399 ]

In Case of Emergency call 1 800 781 4738 Non Emergency call 1 800 224 PETS (7387)

Distributed by Sergeant s Pet Care Products Inc P O Box 540399 Omaha NE 68154 0399 EPA Reg No 2517 145 EPA Est No XXXXX XX -XXX [Made in USA]

[BAR CODE AREA]

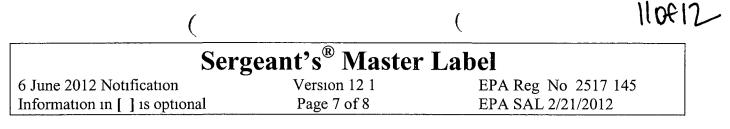
#### **{START - OPTIONAL INSERT OR PACKAGE COPY}**

[How to Apply May contain graphics illustrating product use eg cat with a drop falling onto its neck from a vial on front side or back carton label and/or applicator labeling]

[Application Instructions][Directions for Use]

#### [How to Open

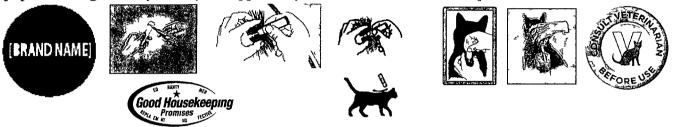
- 1 Remove product tubes *[vial]* from the package
- 2 [Separate one tube from the others ] Hold the tube [*vial*] with notched end pointing up and away from the face and body Use scissors to cut off the narrow end at the notches along the line



## How to Apply

- 1 Invert tube over cat and use open end to part cat s hair
- 2 Apply contents of one tube *[vial]* of {**Full or Partial Brand Name**} [as a stripe starting high on the back of the cat s neck to in front of the shoulder blades] [as a spot between the shoulder blades] Squeeze tube firmly to apply all of the solution to the cat s skin ]

[Optional diagram may or may not appear anywhere on the finished label]



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

[Look at the Label (Look at the Label 1con) [Easy] 6 Step [Easy][Spot On] [Squeeze On] [Top1cal] Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your pet
- [3] Do NOT use Dog products on Cats
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate animals after treatment to avoid chance of ingestion
- [6] Do NOT split tubes between pets][and use the entire tube contents]

# [Full or Partial Brand Name]

[Monthly reminder card]

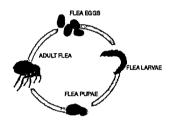
[Apply [Full or Partial Brand Name] monthly for continuous protection against fleas ticks flea eggs flea larvae [and] chewing lice [and mosquitoes]]

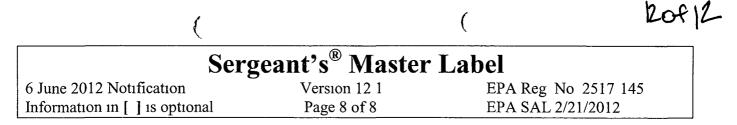
[Pet s Name (Empty blank for owner to fill in name)]

[Fırst] [1st] [Second] [2nd] [Thırd] [3rd][Fourth][4<sup>th</sup>][Fıfth] [5<sup>th</sup>][Sıxth][6<sup>th</sup>][Seventh] [7<sup>th</sup>][Eıght] [8<sup>th</sup>][Nınth][9<sup>th</sup>][Tenth][10<sup>th</sup>] [Eleventh][11<sup>th</sup>][Twelfth][12<sup>th</sup>][Dose] [Treatment] [Application] (Empty blank for owner to fill in date)(Date MM/DD/YY)]

[calendar stickers with Full or Partial Brand Name]

[Place stickers on your calendar as a reminder to reapply [Full or Partial Brand Name] in 30 days ] [Monthly Application Reminder Magnet (image of 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 [Full or Partial 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 ]





[Optional graphics which may or may not appear anywhere on the finished label]



### **{END - OPTIONAL INSERT OR PACKAGE COPY}** [TUBE] [VIAL] LABEL

Front Label	Back Label		
{Brand Name} [For use only on cats/kittens	KEEP OUT OF REACH OF CHILDREN		
12 weeks or older]	CAUTION Read directions and precautions		
F1pronil 9 8% w/w Etofenprox 15% w/w	before using Use scissors to open		
(S) methoprene 11 8% w/w	EPA REG No 2517 145 {label code}		
0 017 fl oz [0 50 mL] {label code}			