

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 24, 2012

Ms. Karen C. Cunningham, DVM, DABVP Head, Regulatory Affairs North America Merial Limited 3239 Satellite Boulevard, Building 500 Duluth, GA 30096-4640

Subject:

Amended Master Labeling; Removal of 2-Year Time-Limited Registration Restriction

FRONTLINE® Top Spot® For Cats, EPA Reg. No. 65331-2

Your Submission Dated April 13, 2012

Dear Ms. Cunningham:

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

In direct response to Merial Limited's submission (September 9, 2011) of enhanced reporting of adverse events for its FRONTLINE® products (EPA Reg. Nos. 65331-2, 65331-3, 65331-4, and 65331-5), the following changes are being made to the terms and conditions of the subject product registration as a result of EPA's recent review (copy enclosed) of this submission:

- 1. The 2-year time-limited registration restriction has been removed from the subject product registration.
- 2. Merial's reporting of enhanced incident data is now only required on an annual basis, rather than on a quarterly basis because 7 years of enhanced incident data reporting have been provided and these data did not demonstrate a concern.

Please note that this product is still subject to all other previously required conditions of registration, including the spot-on mitigation. A copy of your label stamped "Accepted" is enclosed for your records along with a hard copy of the HED review completed for the subject product. If you have any questions about this label review, 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"

HED Memo: "Fipronil Spot-On Products: Conditional Registration and Enhanced Reporting," dated February 27, 2012

065331-00002 D463901



How to Apply

### **FRONTLINE®** TOP Spot CATS

aten 1.

**OPEN Applicator** 

Hold upright with foil side toward you and snap applicator tip.

#### **APPLY FRONTLINE TOP SPOT**

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cat's skin. Do not apply on tcp of the hair coat. Avoid contact with treated area until dry.

**Questions or Comments?** Call: 1-800-660-1842, Monday-Friday, 8am-8pm EST or visit us at www.FRONTLINE.com



BACK

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## RONTLINE Top Spot FOR CATS

KEEP OUT OF REACH OF CHILDREN

CAUTION

Kills fleas, ticks, chewing lice & mosquitoes

Fast-acting Long-lasting intains 1-0.017 fl oz (0.50 mL) applicator

MADE IN FRANCE

Waterproof Kills ticks, including those that may transmit Lyme disease

3 00000 00000 For use ONLY on CATS & KITTENS

8 weeks and Older

> See inside panels for FIRST AID and MERIAL PRECAUTIONARY statements.



FRONT

### FRONTLINE Top Spot FOR CATS

Fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice and

ACTIVE INGREDIENT

Technical area:

No print except prod. barcode

.. 90.3%

#### KEEP OUT OF REACH OF CHILDREN CAUTION

#### FRON'LINE® TOP SPOT® for Cats: Fleas • Kills feas

- · Kills newly emerged adult fleas before they lay
- Stops existing infestations and prevents estati ishment of new infestations
- · Kills fleas which may cause flea allergy derm atitis

#### Ticks

- · Kills all life stages of ticks (larva, nymph and (Rhip'cephalus sanguineus), American dog ticks (Dermacentor variabilis), lone stor ticks (Amilyomma americanum) and deer ticks
- (Ixocles scapularis)
  Kills ticks that may transmit Lyme disease, haer obartonellosis, ehrlichiosis, babeilosis, anaplasmosis and other tick-borne diseases

- Rapidly eliminates chewing lice infestations Mosquitoes
- Kills inosquitoes
- FRONTLINE TOP SPOT is approved for use an all cats, including:

  Breeding, pregnant, and lactating queens
  Kitters as young as 8 weeks

One spot application is all that's needed: FRONTLINE TOP SPOT spreads from the single point of application, rapidly covering the entire cat and localizing in the hair, on the surface of the skin and in the sebaceous glands. These g ands act as a reservoir, continuously replenishing FRONTLINE TOP SPOT onto the skin and hair coat, so it keeps working even if the cat gets wet.

Fleas, ticks and chewing lice are killed quickly after coming into contact with a treated cct. Fleas and ticks do not need to bite the cat in order to die.

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labe ing. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH
USE. FOLLOW ALL DIRECTIONS AND
PRECAUTIONARY STATEMENTS CAREFULLY.
USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHEP ANIMALS. To kill fleas, ticks, chewing lice and mosquitoes apply FRONTLINE TOP SPOT for Cats as

 OPEN Applicator
Hold upright with foil side toward you and snap applicator t.p.

• APPLY FRONTLINE TOP SPOT

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the

cat's skin. Do not apply on top of the hair coat.
Avoid contact with treated area until dy.
FRONTLINE TOP SPOT for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8

FRONTLINE TOP SPOT remains effective even after bathing, water immersion, or exposure to sunlight.

#### FREQUENCY OF APPLICATION

When used monthly, FRONTLINE TOP SPOT completely controls flea, tick and chewing lice infestations. Do not reapply FRONTLINE TOP SPOT for 30 days

FRONTLINE TOP SPOT kills adult fleas for up to six weeks, however, if there is a high risk of reinfestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly

application may be needed. FRONTLINE TOP SPOT kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FRONTLINE TOP SPOT kills all life stages of icks (larva, nymph and adult). FRONTLINE TOP SPOT kills ficks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-barne diseases.

FRONTLINE TOP SPOT kills chewing lice for at least one month. A once monthly application is recommended where chewing lice control is

FRONTLINE TOP SPOT kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days with a monthly application.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage

and disposal.

STORAGE. Store unused product in original container only, out of reach of children and

PESTICIDE DISPOSAL If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if

Have the product container or label with you when calling a poison control center or doctor or going

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye 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 eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off

contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice

#### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using

#### HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets 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. Certain medications can interact with pesticides Consult a veterinarian before using an medicated, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST.

PHYSICAL OR CHEMICAL HAZARDS COMBUSTIBLE: Do not use or store near heat or open flame

#### WARRANTY

To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

Merial Limited 3239 Satellite Blvd

Duluth, GA 30096-4640, USA

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ACCEPTED April 24, 2012

INSIDE : PANELS

Under the Federal Insecticide, Fungicidi), and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No:\_\_\_

65331-2

# TOT #

8 Weeks
and Older



FRONTLINE®
Top Spot® FOR CATS



Kills fleas, ticks, chewing lice & mosquitoes

- · Fast-acting
- · Long-lasting
- Waterproof

Kills ticks, including those that may transmit Lyme disease

For use ONLY on CATS & KITTENS

8 Weeks and Older ACTIVE INGREDIENT:

| SEE | | SEE

SEE INSERT FOR FIRST AID AND PRECAUTIONARY STATEMENTS. KEEP OUT OF REACH OF CHILDREN

CAUTION



PROTOTYPE GRAPHICS

# FRONTLINE® Top Spot® FOR CATS

#### FRONTLINE® TOP SPOT® for Cats is:

- Fast-actingLong-lastingWaterproof

One spot application is all that's needed:
FRONTLINE TOP SPOT spreads from the single point of application, rapidly covering the entire cat and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing FRONTLINE TOP SPOT onto the skin and hair coar, so it keeps working even if the cat gets wet.

Fleas, ticks and chewing lice are dilled quickly after coming into contact with a treated cat. Fleas and ticks do not need to bite the cat in order to die.

#### FRONTLINE TOP SPOT for Cats:

#### Fleas

- · Kills fleas
- Kills newly emerged adult fleas before they lay eggs
   Stops existing infestations and prevents establishment of new infestations
   Kills fleas which may cause flea allergy dermatitis

#### Ticks

- Kills all life stages of ticks (larvu, nymph and adult), including deer ticks (Ixodes scapularis), brown dog ticks (Rhipicephalus sanguineus), American dog ticks (Dermacentor variabilis) and lone star ticks (Amblyomma americanum)
  Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis,
- babesiosis, anaplasmosis, haemobartonellosis and other tick-borne diseases

#### Lice

· Rapidly eliminates chewing lice infestations

#### Mosquitoes

Kills mosquitoes

#### FRONTLINE TOP SPOT is approved for use on all cats, including:

- Breeding, pregnant, and lactating queens
   Kittens as young as 8 weeks



Adult Fleas



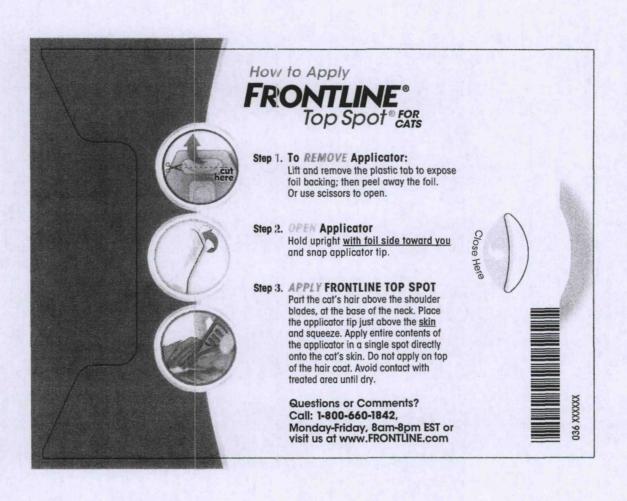
Ticks



Chewing Lice



Mosquitoes





### 8 Weeks and Older

For use ()NLY on CATS & KITTENS

# FROUTLINE® Top Spot Sals

# FRONTLINE® Top Spot® FOR CATS

FRONTLINE TOP SPOT for Cats provides fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice and mosquitoes for use ONLY on cats and kittens 8 weeks or older.

#### 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 ENCLOSED DIRECTIONS BEFORE EACH USE. FOLLOW ALL, DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY, DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

To kill fleas, ticks, chewing lice and mosquitoes apply FRONTLINE TOP SPOT for Cats as follows:

- To REMOVE Applicator: Lift and remove the plastic tab to expose foil backing; then peel away the foil. Or use scissors to open.
- OPEN Applicator. Hold upright with foil side toward you and snap applicator tip.
- APPLYFRONTLINE TOP SPOT. Part the cat's hair above the shoulder blades, at the base of the neck. Place
  the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot
  directly onto the cat's skin. Do not apply on top of the hair coat. Avoid contact with treated area until dry.

FRONTLINE TOP SPOT for Cats is approved for use on all cats, including breeding, pregnant, and lactating queens and kittens as young as 8 weeks.

FRONTLINE TOP SPOT remains effective even after bothing, water immersion, or exposure to sunlight.

#### Frequency of Application

When used monthly, FRONTLINE TOP SPOT completely controls flea, tick and chewing lice infestations. Do not reapply FRONTLINE TOP SPOT for 30 days.

FRONTLINE TOP SPOT kills adult fleas for up to six weeks, however, if there is a high risk of reinfestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly application may be needed.

FRONTLINE TOP SPOT kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FRONTLINE TOP SPOT kills all life stages of ticks (larva, nymph and adult). FRONTLINE TOP SPOT kills ticks that may transmit Lyrne disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis, haemobartonellosis and other tick-borne diseases.

FRONTLINE TOP SPOT kills chewing lice for at least one month.

A once monthly application is recommended where chevring lice control is needed.

FRONTLINE TOP SPOT kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days, with a monthly application.

STISFACTION MERIAL PLANTER

Please call our experts a 1-800-660-1842. Monday-Friday. 8am-8pm EST with any questions or comments about flee, tick, chewing lice, or mosquito control or FRONTLINE Top Spot.



Merial Limited 3239 Satellite Blvd. Duluth, GA 30096-4640, USA *MADE IN FRANCE* 

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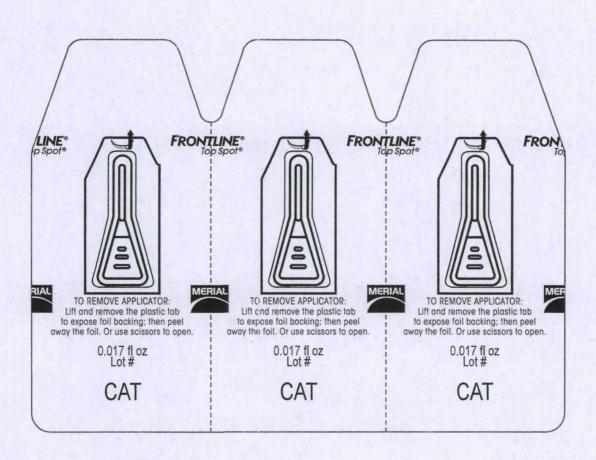
For cat use only

\* Toulouse EPA Es: . 65331-FR-2 Ivers Lee EPA Es: . 74528-CHE-1

TO

Reg. No.65331-2 Est. 00000-XX-0\*

EPA F





# FRONTLINE® Top Spot®for CATS

For use ONLY on CATS & KITTENS 8 weeks or older: Fast-acting, long-lasting, waterproof treatment and control of fleas, ticks, chewing lice and mosquitoes.

ACTIVE INGREDIENT

fipronil 9.7%
I/HERT INGREDIENTS 90.3% 

#### KEEP OUT OF REACH OF CHILDREN CAUTION

#### FRONTLINE® TOP SPOT® for Cats:

Fleas

(ills fleas

(ills newly emerged adult fleas before they lay eggs

Stops existing infestations and prevents establishment of new infestations

· (ills fleas which may cause flea allergy dermatitis

Ticks

· (ills all life stages of ticks (larva, nymph and adult), including brown dog ticks (Rhipicephalus sanguineus), American dog ticks (Dermacentor variabilis), lone star ticks (Amblyomma americanum) and deer ticks (Ixodes scapularis)

· (ills ticks that may fransmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases

Lice

Rapidly eliminates chewing lice infestations

Mosquitoes

FRONTLINE TOP SPOT is approved for use on all cats, including:

3reeding, pregnant, and lactating queens Cittens as young as 8 weeks

Cine spot application is all that's needed:
F?ONTLINE TOP SPOT spreads from the single point of application, rapidly covering the entire cat and localizing in the hair, on the surface of the skin and in the sebaceous glands. These glands act as a reservoir, continuously replenishing FRONTLINE glands act as a reservoir, commuously repletioning TOP SPOT onto the skin and hair coat, so it keeps working even if the cat gets wet.

Fleas, ticks and chewing lice are killed quickly after coming into contact with a treated cat. Fleas and ticks do not need to bite the cat

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner in consistent with its labeling. Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON FABBITS. DO NOT USE ON OTHER ANIMALS.

To kill fleas, ticks, chewing lice and mosquitoes apply FRONTLINE TOP SPOT for Cats as follows:

• To REMOVE Applicator: Lift and remove the plastic tab to expose

fc I backing; then peel away the foil. Or use scissors to open.

**OPEN** Applicator

Hold upright with foil side toward you and snap applicator tip.

• APPLY FRONTLINE TOP SPOT

Part the cat's hair above the shoulder blades, at the base of the neck. Place the applicator tip just above the skin and squeeze. Apply entire contents of the applicator in a single spot directly onto the cct's skin. Do not apply on top of the hair coct. Avoid contact with traated area until dry.



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FRONTLINE TOP SPOT for Cats is approved for use on all cats. including breeding, pregnant, and lactating queens and kittens as

young as 8 weeks. FRONTLINE TOP SPOT remains effective even after bathing, water immersion, or exposure to sunlight.

FREQUENCY OF APPLICATION

When used monthly, FRONTLINE TOP SPOT completely controls flea, tick and chewing lice infestations. Do not reapply FRÓNTLINE

TOP SPOT for 30 days.
FRONTLINE TOP SPOT kills adult fleas for up to six weeks, however, if there is a high risk of reinfestation or if the cat has fleas which may cause flea allergy dermatitis, a once monthly

application may be needed.

FRONTLINE TOP SPOT kills ticks for at least one month. A once monthly application is recommended where tick control is needed. FRONTLINE TOP SPOT kills all life stages of ticks (larva, nymph and adult). FRONTLINE TOP SPOT kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases.

FRONTLINE TOP SPOT kills chewing lice for at least one month. A once monthly application is recommended where chewing lice

control is needed.

FRONTLINE TOP SPOT kills mosquitoes within 24 hours for up to 14 days, and within 48 hours for up to 28 days with a monthly application.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. STORAGE. Store unused product in original container only, out of reach of children and animals.

PESTICIDE DISPOSAL. If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

CONTAINER DISPOSAL. If empty: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for

recycling if available.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

unconscious person.

IF IN EYES: Hold eye 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 eye. Call a poison control center or

doctor for treatment advice

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS. CAUTION.

Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

HAZARDS TO DOMESTIC ANIMALS.

For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Pets 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. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged animals. Call 1-800-660-1842, Monday-Friday, 8am-8pm EST.

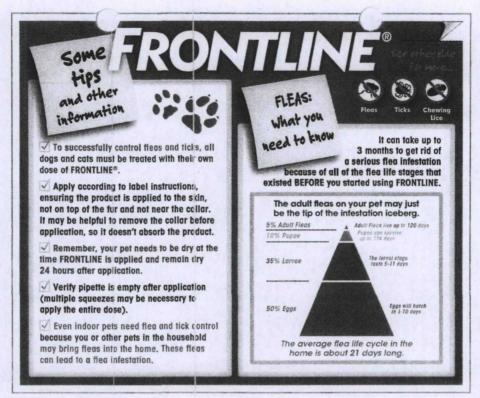
PHYSICAL OR CHEMICAL HAZARDS
COMBUSTIBLE: Do not use or store near heat or open flame. WARRANTY

To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.

EPA Reg. No. 65331-2

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To ensure continued protection of your Calendar Contact your veterinarian pets, use these stickers as a reminder or call our technical Reminder to apply and re-purchase FRONTLINE. 1-800-660-1842, stickers Monday-Friday, 8am-8pm. For more information, visit After treating your pet for the first time, peel off the sticker and place on your www.FRONTLINE.com calendar that day. MERIAL Place the remaining stickers on your @FRONTLINE is a Don't calendar as a reminder to apply registered trademark forget to FRONTLINE monthly. ©2011 Merial Limited, re-purchase! Duluth, GA. All rights reserved. 000000 6 Months use all 6 stickers 3 Months

Front